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Comparison of Clinical, Radiological and Pathological 'T' & 'N' Staging and to Evaluate the Health Care Provider Delay in Cases of Malignant Breast Lump at a Tertiary Care Teaching Hospital

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1. Introduction

Breast cancer is the most common site-specific cancer and is the leading cause of death from cancer in women. (1)The upward trend in breast cancer globally and in India has become a matter of great concern. Breast lumps are mostly benign but certain benign proliferative disorders of breast can have a risk of progression to malignancy.(2-4).

Traditionally, the evaluation of any breast lump is done by triple assessment.(2)Triple assessment by clinical examination, imaging like mammography, pathological assessment by core biopsy has been a standard approach in the evaluation of breast lumps.(2) Sono-mammography is less expensive, easily available and doesn't cause any harmful radiation exposure. USG also gives information about tumour size, extent and number. Ultrasound (USG) is particularly useful in young women with dense breasts.

Fine needle aspiration cytology (FNAC) is an important first method of pathological assessment of breast disorders.(6). Open or core needle biopsy techniques are relatively more costly and traumatic. FNAC has been shown to be safe, rapid, reliable and cost-effective technique for diagnosis of breast lesions.Hence, ultrasound combined with FNAC showed excellent improved results in the diagnosis of breast lesions in a study done by Pagani et al.(7) FNAC when combined with clinical and imaging findings showed sensitivity up to 97%, specificity, positive and negative predictive values of 94%, 79%, 98% respectively.(8)

The clinical, radiographic, and pathologic findings should be in concordance. If the biopsy findings do not concur with the clinical and radiographic findings, the multi-disciplinary team (including clinician, radiologist, and pathologist) should review the findings and decide whether or not to recommend an image-guided or open biopsy to be certain that the target lesion has been adequately sampled for diagnosis. This study looks at comparison of clinical, radiological and pathological 'T' and 'N' staging in case of malignant lumps.

The delay in diagnosis and treatment of the disease is broadly classified into 'Patient' delay and 'Health care system'delay. Patients not considering the lump significant enough was the commonest reason for the delayed presentation as shown by previous studies by Thakur N, Humne A and Godale L in their study "Delay in presentation to the hospital and factors affecting it in breast cancer patients attending tertiary care centre in Central India"(9) , as well as in the study conducted by Gould J, Fitzgerald B, Fergus K, Clemons M and Baig F, " Why women delay seeking assistance for locally advanced breast cancer".(10)

The literature is biased towards studying the patient delay and the impact of healthcare system delay on patient is studied much less than the former. The approximate time from first visit of patient to first radiological investigation was approximately one week, between first visit and tissue biopsy report was around 03 weeks and between first visit to initiation of treatment was 01 month.

One of the objectives of this study is to assess the work-up time till completion of various investigations and definitive management in case of malignant lumps.

2. Materials and Method

It is an Observational prospective study from Oct 2016 to Sep 2018 in a tertiary care teaching hospital.All Female patients presenting with complaint of lump breast in the general surgery OPD were included in the study. Old case of Carcinoma Breast under Chemo/ radiotherapy/post-surgery under follow up and patients diagnosed with LABC (Locally advanced breast Carcinoma) during evaluation were excluded for evaluation of comparison of clinical, radiological and pathological 'T' & 'N' staging, however LABC patients were included in evaluation of ' Healthcare provider' delay.

Upfront surgery in cases of early breast cancer and referral to a medical oncologist for Neo- adjuvant chemotherapy were taken as end-points during evaluation of 'Healthcare provider' delay.

Institutional ethics committee clearance obtained prior to start of the study. A total of 200 patients were enrolled. The patients were evaluated by triple assessment, a clinical examination, FNAC or a core needle biopsy and imaging methods like ultrasonography, mammography was done. Once the diagnosis was established, the patients with malignant lumps were further evaluated for comparison of clinical, radiological and pathological 'T' & 'N' staging and in calculation of 'Healthcare provider' delay.

The data was obtained from patient's hospital documents and personal interview. Delay in the first visit to the hospital, reason for delay was evaluated. Data was statistically analyzed using Statistical Package for Social Sciences (SPSS ver 21.0, IBM Corporation, USA) for MS Windows.The p-values less than 0.05 are considered to be statistically significant.

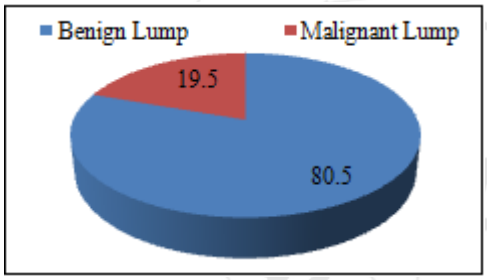
3. Results

Breast lump was the commonest complaint in breast related issues with which a lady presented to general surgery OPD. Breast lumps was the presenting complaint in 85 % cases, out of which 29 % had associated complaints like breast pain and nipple discharge or both pain and nipple discharge along with lump.

Prevalence of benign and malignant lump: Of 200 cases studied with breast lump, 161 (80.5%) had benign lump and 39 (19.5%) had malignant lump (Table 1 & figure 1)

Table (1) and Figure (1): Prevalence of benign and malignant lump in the study group

Breast lump	No. of cases	% of cases
Benign Lump	161	80.5
Malignant Lump	39	19.5
Total	**200**	**100.0**



Distribution of concordance and non-concordance for 'T' and 'N' staging :

Clinical Staging with Radiological Staging:

Clinical T staging and radiological T staging showed 69.2% concordance with relatively high degree of statistical agreement (Kappa value = 0.543, P-value<0.001).

Clinical N staging and radiological N staging showed 74.4% concordance with relatively high degree of statistical agreement (Kappa value = 0.593, P-value<0.001).

Clinical Staging with Pathological Staging:

Clinical T staging and pathological T staging showed 59.3% concordance with relatively high degree of statistical agreement (Kappa value = 0.388, P-value<0.01).

Clinical N staging and pathological N staging showed 55.6% concordance with relatively low degree of statistical agreement (Kappa value = 0.214, P-value>0.05).

Radiological Staging With Pathological Staging:

Radiological T staging and pathological T staging showed 85.2% concordance with relatively high degree of statistical agreement (Kappa value = 0.765, P-value<0.001).

Radiological N staging and pathological N staging showed 81.5% concordance with relatively high degree of statistical agreement (Kappa value = 0.516, P-value<0.01).

Table 2: Concordance and non-concordance for 'T' and 'N' staging

Staging	Status	Clinical With Radiological		Clinical With Pathological		Radiological With Pathological	
		n	**%**	**n**	**%**	**n**	**%**
T	Concordance	27	69.2	16	59.3	23	85.2
	Non-Concordance	12	30.8	11	40.7	4	14.8
	Kappa value	0.543		0.388		0.765	
	P-value	0.001^{***}		0.002^{**}		0.001^{***}	
N	Concordance	29	74.4	15	55.6	22	81.5
	Non-Concordance	10	25.6	12	44.4	5	18.5
	Kappa value	0.593		0.214		0.516	
	P-value	0.001^{***}		0.072^{NS}		0.002^{**}	

Values are n (% of cases). P-value by Chi-Square test. P-value<0.05 is considered to be statistically significant. *P-value<0.05, **P-value<0.01, ***P-value<0.001, NS-Statistically non-significant. NA-Not applicable due to non-symmetric frequency distribution.

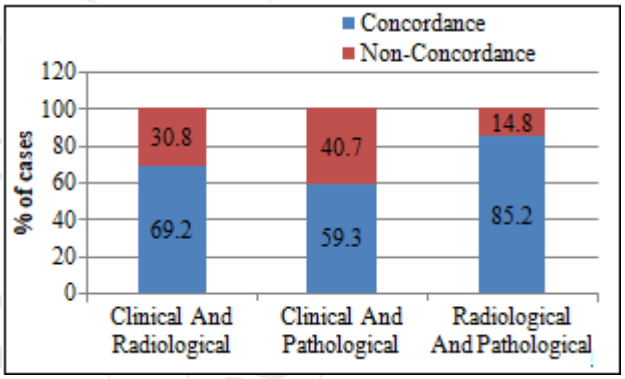


Figure 2.1: Concordance and Non-concordance for 'T' staging

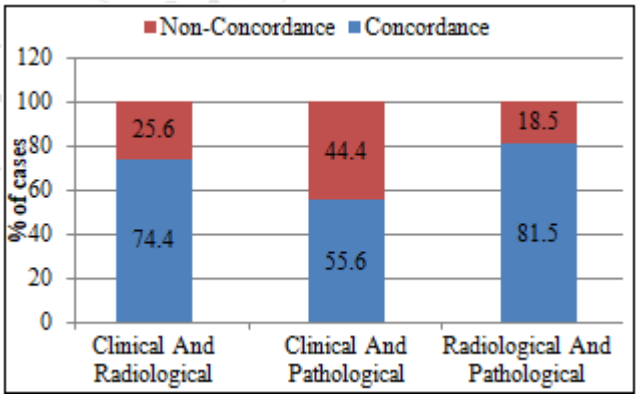


Figure 2.2: Concordance and Non-concordance for 'N' staging

Distribution of mean duration of intervention from first visit in patients with malignant breast lumps:

The mean ± SD of duration of intervention from first visit to Radiological Investigation was 6.8 ± 3.1 days. The mean ± SD of duration of intervention from first visit to the OPD to issuing the printed report of tissue diagnosis was 21.8 ± 4.1 days.

The mean ± SD of duration of intervention from first visit to Definitive management was 31.4 ± 5.7 days (Table 3 and figure 3).

Table 3: Distribution of mean duration of intervention from first visit in malignant lump group.

	Duration of intervention (Days)	
	Mean ± SD	Median (Min – Max)
From first visit to Radiological Investigation	6.8 ± 3.1	6 (3 – 14)
From first visit to issuing printed report of tissue diagnosis	21.8 ± 4.1	21 (16 – 34)
From first visit to Definitive management	31.4 ± 5.7	32 (20 – 42)

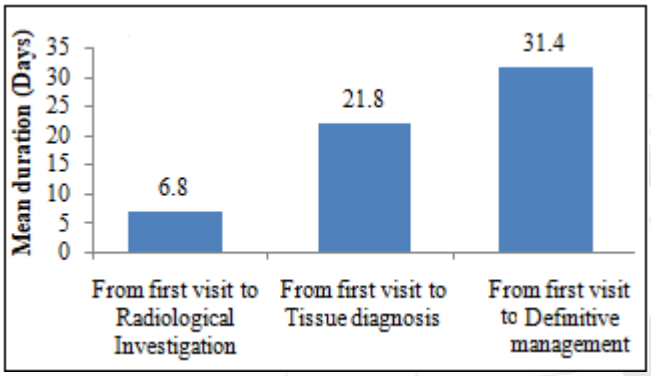


Figure 3: Distribution of mean duration of intervention from first visit in patients with malignant breast lump

4. Discussion

Breast lump is a very sensitive issue for the patient so a reliable, non-invasive and prompt diagnosis helps to lessen the associated anxiety and leads to early definitive treatment.(11)

The tools for clinical diagnosis i.e. history, clinical breast examination, FNAC, and diagnostic mammography provide valuable information and play important supplemental roles in ascertaining the presence of breast cancer.

Traditionally, the evaluation of any breast lump is done by triple assessment.(11, 12) Triple assessment by clinical examination, imaging like mammography, pathological assessment by core biopsy has been a standard approach in the evaluation of breast lumps. The clinical, radiographic, and pathologic findings should be in concordance. If the biopsy findings do not concur with the clinical and radiographic findings, the multi-disciplinary team (including clinician, radiologist, and pathologist) should review the findings and decide whether or not to recommend an image-guided or open biopsy to be certain that the target lesion has been adequately sampled for diagnosis.

In our study, the Clinical T staging and radiological T staging showed 69.2% concordance, clinical T staging and pathological T staging showed 59.3% concordance and radiological T staging and pathological T staging showed 85.2% concordance with relatively high degree of statistical agreement with maximum concordance seen between the radiological and pathological T staging.

Similar results were shown by study conducted by I V Gruber etal in their study "Measurement of tumour size with mammography, sonography and magnetic resonance imaging as compared to histological tumour size in primary breast cancer"(13) which showed there was no statistical significant difference between mammographic and histological sizing of the tumour.

There was no literature comparing the clinical, radiological and pathological 'N' staging in cases of carcinoma breast. However, in our study Clinical 'N' staging and radiological 'N' staging showed 74.4% concordance, clinical 'N' staging and pathological 'N' staging showed 55.6% concordance and radiological 'N' staging and pathological 'N' staging showed 81.5% concordance. The results showed that the radiological and pathological 'N'staging had higher concurrence as compared to comparing either of these to clinical N staging. This emphasizes the need of triple assessment in all cases of Carcinoma breast.

Delay in diagnosis and treatment:
Early diagnosis is a tenet in oncology and should enable early treatment with the expectation of improved outcome. Screening programs have been introduced for common cancer types such as breast or colorectal cancer in many countries. In general, delay in diagnosis and treatment of cancer is divided into patient and provider delay (Facione, 1993).*Patient delay* is defined as the period from first onset of symptoms to first medical consultation. *Provider delay* covers the period from first consultation to definite diagnosis and treatment.

The patient interval:Patient interval can be further subdivided two component intervals; Symptom appraisal (time period between experiencing a symptom for the first time and concluding that there is a need to visit a health care practitioner) and Help-seeking (time period from deciding a need to visit a health care practitioner to the actual first consultation)(14). The literature review also revealed studies which suggest that by using terms such as 'delay' and 'patient delay', there is an underlying attribution of blame to the to the patient. For the patient, such terms may seem to be judgemental and uncomplimentary.(15)

Healthcare / provider interval: The literature is biased towards studying the patient delay and the impact of healthcare system delay on patient is studied much less than the former. Although, it is universally accepted that any kind of delay will lead to upstaging of malignancy and hence, poor patient outcome, the contribution of healthcare delay towards the same has not been brought out very clearly in literature.(16, 17)This aspect of delay is grossly under-researched, however there is evidence to suggest that, even with improved diagnostic and treatment pathways in cancer, there are still problems with: waiting times for tests, waiting times for non-urgent referrals and administrative delays for follow up (leading to increased patient delays)

No other study in literature available has done an in-depth analysis of time taken in various investigations as a part of system delay. Thus there was no data available to compare our results in this regard with the similar environment. The

overburdened system coupled with shortage of facilities further compounds the total provider delay.

The mean ± SD of duration of intervention from first visit to Radiological Investigation was 6.8 ± 3.1 days. The minimum time taken was 03 days and maximum was of 14 days for sono-mammography. The mean ± SD of duration of intervention from first visit to issuing a printed report for tissue diagnosis was 21.8 ± 4.1 days. The minimum time taken was16 days maximum delay was of 34 days from the first visit to issuing the printing report of tissue diagnosis.

As the core-cut biopsy for the lesion was carried out only after the radiological investigation, hence, the time taken was more if we calculate from the first OPD visit. Secondly, as the OPD days for a general surgery unit at our Centre is not on daily basis, hence patient reported to OPD for core cut biopsy after radiological investigation on the next designated OPD day, this must have led to further delay. The maximum delay of 34 days was in a case where patient did not follow-up in OPD after radiological investigation due to personal commitments. Tissue investigations like Core-cut biopsy and histo-pathology usually take about 5-7 days at our centre owing to high volume. This was the case with maximum patients.

Additional time was taken for cases in which diagnosis was uncertain/ immune-histo chemistry tests were required and other special staining/ tests needed to be performed.

Patient undergoing up-front surgery in cases of Early breast cancer or giving a written referral to medical Oncologist for NACT in case of Locally advanced Carcinoma breast was taken as the end point calculating the time taken for definitive management from the first OPD visit. The mean ± SD of duration of intervention from first visit to Definitive management was 31.4 ± 5.7 days.

The duration between first visit to our centre and start of treatment varied between 20 to 42 days. The longest duration of 42 days was because the patient was lost to follow up and reported very late again. There were 3 more such cases which were lost to follow up, hence adding on to the total delay. All cited personal/ financial reasons for the delay.

In this study, the Locally advance breast carcinoma was included in the evaluation of total time taken from the first OPD visit for various investigations and definitive management, however it was not a part of evaluation while comparing the clinical, radiological and pathological 'T' and 'N' staging, as these patients were referred for neo-adjuvant chemotherapy and upfront surgery was not performed in these patients. This has already been mentioned in the exclusion criteria of the study.

5. Conclusion

Breast lump is one of the commonest complain with which a female patients present to a General surgery OPD in a tertiary care centre. Benign breast disease is far more common than malignant breast disease accounting for approximately 80 % of the breast lumps.

Early diagnosis of the breast lump alleviates patient anxiety and has significant survival benefits in case of malignant lumps. The evaluation of any breast lump is done by triple assessment. On comparing the clinical, radiological and pathological stage T and N staging in cases of malignant lumps, the radiological and pathological staging were more corroborative with each other as compared to clinical staging thus emphasising the need of triple assessment.

In our study the workup time for various investigations from first visit to definitive management was 31.4 ± 5.7 days.

Strategies to shorten delay by patients will probably be educational in nature. Similarly, interventions to shorten delay by providers may include professional educational programmes or organisational changes.

Capacity building of human resources in form of training at various levels, supplemented by regular CMEs will go a long way in achieving desired target. At the same time, the importance of supervision, monitoring and evaluation cannot be stressed upon anymore stronger. The various departments in a tertiary care centre should join together for better outcomes and aim towards minimising the 'Healthcare provider' delay. This will be in line with the inherent spirit of medical profession – 'Primum non nocere'.

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