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Evaluating FNAC and TCB: A comparative study between in diagnosing Palpable breast lumps.

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INTRODUCTION

Background

In this study, the diagnostic accuracy of FNAC & Tru-Cut Biopsy (TCB) in differentiating benign and malignant lesions of palpable lump in breast is compared with its histopathological correlation

Methods

In order to obtain approval from the institutional ethics committee and written informed consent from the study participants, this was a single hospital-based prospective observational study that was carried out among 180 patients who underwent both FNAC and Tru-Cut Biopsy for a palpable breast lump in the Department of General Surgery, M.K.C.G. Medical College and Hospital, Berhampur, Odisha, over a 2-year period, from July 2022 to July 2024.

Results

In this study, TCB sensitivity 96.8%, specificity 100%, PPV 100%, NPV 93% and accuracy 97.7%. TCB has high sensitivity and specificity in detecting malignant lesion compared to FNAC. If the initial FNAC report is inadequate or inconclusive, TCB always provide definitive histopathological diagnosis and also about type, grade, receptor status of tumour that permits the eventual use of adjuvant therapy, which helps in planning the appropriate treatment for the patient and also avoids unnecessary excisional biopsy.

Conclusion

In order to diagnose a breast lump pre-operatively TCB is a straightforward, cost-effective, and highly dependable method compared to FNAC. As a result, proper neoadjuvant systemic therapy can be administered to shorten morbidity and mortality.

Keywords: Breast lump, FNAC, TCB, Histopathological Examination (HPE).

Introduction

A breast lump is a palpable swelling or thickening in the breast tissue, which can be a source of concern for women. It is essential to diagnose breast lumps accurately, as they can be benign, inflammatory, or malignant, and early detection and diagnosis are critical in managing breast cancer. Breast cancer is one of the leading causes of cancer-related deaths in women worldwide, accounting for approximately 523,000 deaths annually, according to the World Health Organization (WHO). In India, breast cancer is the most common cancer among women, accounting for nearly 27% of all cancer cases, highlighting the importance of diagnosis and early detection.[1]

Breast lumps can be caused by various factors, including hormonal changes, genetics, and environmental influences. The majority of breast lumps are benign, but a significant number can be malignant, making accurate diagnosis crucial. Fibroadenoma, fibrocystic changes, and

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duct papilloma are common benign breast lesions, while ductal carcinoma in situ (DCIS) and invasive ductal carcinoma (IDC) are malignant breast cancers that require prompt diagnosis and treatment.[2]

The diagnostic approach to breast lumps involves a combination of clinical evaluation, imaging studies, and tissue sampling. Clinical evaluation includes a thorough medical history, physical examination, and assessment of risk factors, providing valuable information for the diagnosis.[3] Imaging studies, such as mammography, ultrasound, and magnetic resonance imaging (MRI), ductography have been advocated and evaluated for additional insights into the size, location, and characteristics of the breast lump, helping healthcare providers determine the next steps in the diagnostic process

Tissue sampling is the gold standard for diagnosing breast cancer and due to advances in breast imaging & biopsy devices, the latter part of 20th century saw a paradigm shift of open surgical biopsy to percutaneous biopsy as the initial tissue acquisition procedure

Fine-needle aspiration cytology (FNAC) or core needle biopsy (CNB) are commonly used percutaneous tissue acquisition techniques[4]. FNAC involves aspirating cells from the breast lump using a fine needle, while CNB involves removing a small core of tissue from the lump using a larger needle[5]. True Cut Biopsy (TCB) is a type of CNB that involves removing a larger sample of tissue, providing more accurate results and better diagnostic yield.[6]

Therefore, the purpose of this study is to determine the diagnostic accuracy of FNAC & Tru-Cut Biopsy (TCB) in differentiating benign and malignant lesions of palpable lump in breast is compared. The study aimed to recruit a representative cohort of female patients with breast lumps who underwent FNAC and Tru-cut biopsy at the Department of General Surgery, MKCG Medical College and Hospital, Berhampur. The recruitment process involved a detailed screening of all patients presenting with breast lumps in the Breast Clinic and Surgical Wards, ensuring a comprehensive and representative sample for the study.

Targets and Goals

To evaluate diagnostic accuracy of FNAC & TCB with reference to their sensitivity, specificity, positive and negative predictive values and accuracy.

Methods

After receiving approval from the institutional ethics committee and written informed consent from the study participants, a single hospital-based prospective observational study was carried out among 180 patients who underwent both FNAC and TCB for diagnosis of palpable lump in breast at the Department of General Surgery, M.K.C.G. Medical College and Hospital, Berhampur, Odisha, over a 2-year period, from July 2022 to July 2024.

Inclusion Requirements

All female patients in excess of 18 years old and less than 75 years with a palpable lump in breast who underwent both FNAC and TCB at the MKCG MCH Berhampur, Odisha, during the research period.

Exclusion Standards

Patients with recurrent malignancy, currently undergoing chemotherapy.

Patients with acute and tender breast lumps, such as breast abscesses, or with frank malignant masses and breast ulceration

Patients deemed unsuitable for surgery or having significant

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co-morbidities and patients who decline to participate in the study.

Techniques for Collecting Data

Inclusion and exclusion criteria were applied to select cases, and clinical features were noted using a pre-structured case record form. Detailed medical histories, including demographics, medical history, and clinical examinations, were conducted, and findings were recorded. Pathological evaluations included FNAC and Tru-cut biopsy, and histopathological examinations were conducted to diagnose breast lump abnormalities. Follow-up assessments were conducted at admission, 1 month, 3 months, and 6 months post-surgery, during which clinical photographs and relevant radiographs were taken to monitor the progression and outcomes of breast lump treatment.

Statistical Procedures

Descriptive statistics were employed to summarize demographic and clinical characteristics of the patients, including measures of central tendency (mean, median) and variability (standard deviation). The primary analysis focused on comparing the diagnostic accuracy of FNAC and Tru-cut biopsy in breast lumps using cross-tabulation and chi-square tests. Data analysis for the study was conducted using IBMR, SPSSR 20.0, and WINDOWSR software, following systematic entry of all collected data into Microsoft Excel. Chi-square tests and ANOVA were used for comparison data, and significant variable comparisons were made using a p-value of <0.05.

RESULTS

Age Group (Years)	Number of Patients (n=180)	Percentage (%)
15-25	22	12.22
26-35	65	36.11
36-45	43	23.88
46-55	30	16.66
56-65	17	9.44
66-75	3	1.69
total	180	100

Table 1: Demographic Distribution

MENSTRUAL STSTUS	NUMBER OF PATIENTS (n=180)	PERCENTAGE
PREMENOPAUSAL	122	67.8
POST MENOPUASAL	58	32.2

Table 2: Menstrual status

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SIDE	NUMBER OF PATIENTS (n=180)	PERCENTAGE
LEFT	58	32.2
RIGHT	122	67.8
TOTAL	180	100

Table 3: Side wise distribution of breast lump

QUADRANT	NUMBER OF PATIENTS (n=180)	PERCENTAGE
CENTRAL	4	2.2
LOWER INNER	25	13.9
LOWER OUTER	20	11.1
UPPER INNER	22	12.2
UPPER OUTER	109	60.6
TOTAL	180	100

Table 4: Quadrant wise distribution of breast lump

LUMP SIZE (CM)	FREQUENCY (n=180)	PERCENTAGE
<2CM	55	30.6
2-4CM	117	65.0
>4CM	8	4.4
TOTAL	180	100

Table 5: Size of breast lump

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FNAC Diagnosis	Number of Patients (n=180)	Percentage (%)
IDC	73	40.6
FIBROADENOMA	50	27.7
ATYPICAL EPITHELIAL HYPERPLASIA	21	11.7
NON-SPECIFIC MASTITIS	11	6.1
F/S/O CARCINOMA BREAST	7	3.9
CYSTIC DEGENERATION	4	2.2
INFLAMMATORY BREAST ABSCESS	4	2.2
MEDULLARY CARCINOMA	4	2.2
FATTY DEGENERATION	3	1.7
LOBULAR CARCINOMA	3	1.7

Table 6: Results of FNAC

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BREAST LESION	NUMBER OF PATIENTS (n=180)	PERCENTAGE
INVASIVE DUCTAL CARCINOMA	106	58.8
MEDULLARY CANCER	23	12.8
FIBROCYSTIC DISEASE	13	7.2
FIBROADENOMA	7	3.9
GRANULOMATOUS MASTITIS	7	3.9
CHRONIC INFLAMMATORY ABSCESS	4	2.2
INVASIVE LOBULAR CANCER	4	2.2
NON-SPECIFIC MASTITIS	4	2.2
COMPLEX CYST WITH AEH	3	1.7
DCIS	3	1.7
GIANT FIBROADENOMA	3	1.7
LOBULAR CANCER	3	1.7
TOTAL	180	100

Table 7: Results of TCB

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BREAST LESION	NUMBER OF PATIENTS (n=180)	PERCENTAGE
INVASIVE DUCTAL CARCINOMA	106	58.9
MEDULLARY CANCER	26	14.4
FIBROCYSTIC DISEASE	10	5.6
FIBROADENOMA	7	3.9
GRANULOMATOUS MASTITIS	7	3.9
INVASIVE LOBULAR CARCINOMA	6	3.3
CHRONIC INFLAMMATORY BREAST ABSCESS	4	2.2
INVASIVE LOBULAR CARCINOMA WITH ALN METASTASIS	4	2.2
NON-SPECIFIC MASTITIS	4	2.2
DCIS	3	1.7
GIANT FIBROADENOMA	3	1.7
TOTAL	180	100

Table 8: Final HPE results of breast lesions

FNAC REPORT	OBSERVATION		COMPARISON

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VS HPE	TP	FP	FN	TN	TOTAL	Sn	Sp	PPV	NPV	ACCURACY	P-VALUE
IDC	59	7	43	71	180	57.8	91.0	89.4	62.3	72.2	<0.001*
MEDULLARY CARCINOMA	4	0	22	154	180	15.3	100	100	98.3	98.3	<0.001*
LOBULAR CARCINOMA	3	0	3	174	180	50	100	100	98.3	98.3	<0.001*
FIBROADENOMA	7	14	0	159	180	100	91.9	33.3	100	92.2	<0.001*
FIBROCYSTIC DISEASE	10	19	0	151	180	100	88.8	34.5	100	89.4	<0.001*

Table 9: Comparison of FNAC with final HPE report

Biopsy vs HPE	OBSEVATION					CORRELATION					
	TP	FP	FN	TN	TOTAL	Sn	Sp	PPV	NPV	ACCU	P value
INVASIVE DUCTAL	122	0	4	54	180	96.8	100	100	93.1	97.7	<0.001*
MEDULLARY CANCER	23	0	3	154	180	88.4	100	100	98.9	98.3	<0.001*
FIBROCYSTIC DISEASE	10	3	0	167	180	100	98.24	76.3	100	98.3	<0.001*
FIBROADENOMA	7	0	0	173	180	100	100	100	100	100	<0.001*
GRANULOMATOUS MASTITIS	7	0	0	173	180	100	100	100	100	100	<0.001*
LOBULAR CARCINOMA IN	3	0	3	174	180	50	100	100	98.3	98.3	<0.001*
INVASIVE LOBULAR	4	0	0	176	180	100	100	100	100	100	<0.001
DCIS	3	0	0	177	180	100	100	100	100	100	<0.001*
GIANT FIBROADENOM	3	0	0	177	180	100	100	100	100	100	<0.001*

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NON-SPECIFIC MASTITIS	4	0	0	176	180	100	100	100	100	100	<0.001*
CHRONIC INFLAMMATOR	4	0	0	176	180	100	100	100	100	100	<0.001*

Table 10: Comparison of TCB with final HPE report

TEST	SENSITIVITY	SPECIFICITY	PPV	NPV	ACCURACY
FNAC	64.62	94.34	71.44	91.78	90.08
TCB	94.10	99.84	97.84	99.11	99.32

Table 11: Comparison between FNAC vs TCB

Complication Type	FNAC (n=180)	TCB (n=180)
Hematoma	4	15
Infection	3	3
Pain	10	36

Table 12: Complication comparison FNAC vs TCB

Diagnostic Method	Average Time (Minutes)
FNAC	15
TCB	30

Table 13: Time taken for FNAC vs TCB

DISCUSSION

In this present study of 180 patient, FNAC sensitivity, specificity, positive predictive value, negative predictive value and accuracy for IDC is 57.8%, 91.0%, 89.4%, 62.3%, 72.2% respectively. For medullary carcinoma sensitivity is 15.3%, specificity is 100%, PPV is 100%, NPV is 87.5% accuracy is 87.9%, lobular carcinoma -sensitivity is 50%, specificity is 100%, positive predictive value is 100%, negative predictive value is 98.3% and accuracy is 98.3%.

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Similar results are found in Noor BA et al[8] series with sensitivity, specificity, PPV, NPV as 70.49%, 93.80%, 84.31% and 87.05% and also in M. Ahmed et[7] series where sensitivity, specificity, PPV, NPV and accuracy as 71.43%, 92.68%, 80.95%, 85.71% and81.82%.

Hence from above results it can be concluded that FNAC detect benign breast lesion correctly (100%) however the sensitivity, NPV and accuracy is low compare to final HPE in detecting malignant lesion.

Results of FNAC	**Present Study**	**Noor BA et al[8]**	**M. Ahmed et al[7]**	**Pravalika F et al[9]**
Sensitivity	64.62	70.49	71.43	76.92
Specificity	94.34	93.80	92.68	96.2
PPV	71.44	84.31	80.95	90.9
NPV	91.78	87.05	85.71	89.65
Accuracy	90.08	-	81.82	90

Table 14: Comparison of results FNAC with final histopathology

In this present study of 180 patient, the sensitivity of TCB found to be 95.8% in detecting malignant lesion, specificity is 100%, PPV is 100%, NPV is 93.1% and overall accuracy in detecting malignant lesions is 97.7%. Similar results were found in Noor BA et al[8], M. Ahmed et al[7] and Pravalika F et al[9] series, hence it can be concluded that TCB detects benign breast lesion correctly (100%). The sensitivity, specificity, and accuracy in detecting malignant lesion is higher and almost similar to final HPE.

So, on comparative analysis between FNAV and TCB (Core Needle Biopsy) in the diagnosis of breast carcinoma; sensitivity, positive predictive value, negative predictive value, diagnostic accuracy are higher in case of TCB compared to FNAC. Detection of false negative cases are also lower in TCB assessment. Regarding specificity and detection of true negative cases both the procedures are turned out to be similar. Both the procedures have statistically significant correlation with the confirmatory HPE of excision specimen (p-values<0.001).

Tru Cut Biopsy	**Present Study**	**Noor BA et al[8]**	**M.Ahmed et al[7]**	**Pravalika F et al[9]**

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Sensitivity	94.10	80.33	82.86	85.7
Specificity	99.84	96.12	95.24	100
PPV	97.84	90.74	88.57	100
NPV	99.11	91.18	92.31	92.85
Accuracy	99.32	91.05	89.09	100

Table 15: Comparison of results of TCB with final histopathology report

CONCLUSION

When there is suspicion of malignancy, breast lumps should be evaluated.

In this study, FNAC showed a sensitivity of 57.8%, specificity of 91.01%, PPV of 89.4%, NPV of 62.3%, and an accuracy of 72.2% for IDC. FNAC is a rapid, less complicated, economical, reliable, and relevant method for preoperative pathological diagnosis of breast carcinoma. However, due to its low sensitivity and high specificity compared to TCB, malignant breast lesions can be missed by FNAC, although it is 100% effective in detecting benign breast lesions.

In this study, TCB demonstrated a sensitivity of 96.8%, specificity of 100%, PPV of 100%, NPV of 93%, and an accuracy of 97.7%. TCB has higher sensitivity and specificity in detecting malignant lesions compared to FNAC. If the initial FNAC report is inadequate or inconclusive, TCB always provides a definitive histopathological diagnosis, including information about the type, grade, and receptor status of the tumor. This allows for the use of adjuvant therapy, helping to plan appropriate treatment for the patient and avoiding unnecessary excisional biopsies. TCB is cost-effective and has minimal complications compared to excisional biopsy.

Therefore, it is concluded that TCB is superior to FNAC in evaluating breast lumps.

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