**Section: General Surgery** 



# **Original Research Article**

# A COMPARATIVE STUDY OF ULTRASONOGRAPHY-GUIDED FINE NEEDLE ASPIRATION CYTOLOGY WITH EXCISION AND BIOPSY IN THE DIAGNOSIS OF EARLY BREAST CARCINOMA IN FEMALES WITH SUSPICIOUS BREAST LUMPS IN A TERTIARY CARE CENTRE

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### $A\,B\,S\,T\,R\,A\,C\,T$

Background: Carcinoma Breast is the most common malignancy in females around the world and the fourth most common cause of cancer related deaths. In India, it accounts for 13.5% of cancers and 10.9% of cancer related deaths. According to population-based cancer registries, a significant increase is seen in the trend of Breast Cancer over the last thirty years. In such a scenario, it remains a significant global health concern, and an early and accurate diagnosis is imperative to improve patient outcomes. Women presenting with breast lumps often experience significant anxiety, which can have profound psychological and physiological impacts. Studies have shown that the discovery of a breast lump, regardless of its ultimate diagnosis, can trigger intense emotional distress and fear of cancer. When carried out by skilled professionals, breast FNAC offers a significant chance of cutting down on diagnostic time without compromising accuracy. FNAC is a potent and presently underutilized technique for identifying palpable breast masses, because of its proven cost effectiveness, safety, and near complete lack of contraindications. FNAC is a reliable diagnostic method for the majority of palpable breast lesions. Objectives: To study the diagnostic accuracy of ultrasound guided fine needle aspiration cytology with excision and biopsy in female patients with suspicious breast lumps. •To assess the utility of guided FNAC in establishing a diagnosis in suspicious breast lumps.

Materials and Methods: A cross sectional study comparing the diagnostic utility of USG guided with excision and final biopsy in females with suspicious breast lumps was conducted in the Dept. of General Surgery, Dept. of Radio diagnosis and Dept. of Pathology, Sree Gokulam Medical College and Research Foundation, Venjaramoodu, Thiruvananthapuram. All female patients above the age of 30 years presenting with suspicious breast lumps and fulfilling the inclusion criteria were included in the study. Informed written consent was taken from the patient before the study. Age of the patient, Age at first childbirth, Parity, and Family history of Carcinoma Breast were recorded. A thorough clinical examination was done and a provisional diagnosis was established. Patients were then made to undergo further evaluation in the form of USG guided FNAC. All patients with USG guided FNAC results underwent workup and surgery as per the diagnosis, and the specimen was sent for Histopathological examination. USG guided FNAC results were compared with the final HPE report.

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**Results:** USG guided FNAC was found to have a sensitivity of 89.2% which is comparable to values determined by various previous studies, which range from 78.4% to 99.3%. The specificity was however found to be 75%, which is on the lower side of currently published ranges in the literature (67% to 100%). This can be attributed to the smaller sample size, and higher rate of inconclusive results. Due to its high negative predictive value, it is valuable as a tool to rule out malignancy in patients with suspicious breast lumps.

**Conclusion:** USG guided FNAC can be used as a single pre operative diagnostic modality to exclude the presence of malignancy. It is an important procedure for the surgeon in the periphery to determine the next step in planning the management of a patient with a suspicious lump.

**Keywords:** Delta neutrophil index, Absolute neutrophil count, High sensitivity C reactive protein.

#### INTRODUCTION

Carcinoma Breast is the most common malignancy in females the world over and the fourth most common cause of cancer-related deaths.<sup>[1]</sup> In India, the disease accounts for 13.5% of cancers and 10.9% of cancerrelated deaths.[2] According to population-based cancer registries, a significant increase has been noted in the trend of Breast Cancer over the last thirty years.<sup>[3]</sup> In such a scenario, it remains a significant global health concern, making it imperative to diagnose the disease early and accurately to improve patient outcomes. Palpable breast lumps often raise suspicion and require an accurate diagnosis for appropriate management. While various diagnostic modalities exist, ultrasound-guided fine needle aspiration cytology (US-FNAC) has emerged as a valuable tool in evaluating suspicious breast lesions.<sup>[4]</sup> Fine needle aspiration cytology (FNAC) is a minimally invasive assessment method routinely used to establish a provisional diagnosis. It is valid, reproducible, and gives a high percentage of true positive results, thus making it patient-friendly.<sup>[5]</sup> Ultrasound-guided FNAC combines the benefits of real-time ultrasound imaging with the minimally invasive nature of fine needle aspiration, offering several advantages over traditional methods. This technique allows for precise needle placement, potentially improving sample adequacy and diagnostic accuracy while reducing the risk of complication. [6] Furthermore, US-FNAC is generally well-tolerated by patients and can provide rapid results, making it an attractive option in both resource-rich and resource-limited settings.<sup>[7]</sup>

Although core biopsy remains the gold standard for definitive pathological diagnosis, it is associated with a need for anaesthesia, higher pain levels, and a longer wait time for results.<sup>[8]</sup> US-FNAC is an excellent first-line diagnostic tool that can quickly differentiate between benign and malignant lesions and guide further management decisions, making it a valuable tool for evaluating suspicious lumps.<sup>[9,10]</sup>

Despite these advantages, the diagnostic accuracy of US-FNAC in evaluating suspicious palpable breast lumps remains a topic of ongoing research and debate. This study aims to compare the accuracy of US-FNAC in detecting early breast cancer in females with suspicious breast lumps by comparison with the

biopsy reports after excision, and hence identify its utility as a diagnostic tool.

# **MATERIALS AND METHODS**

**Study Design:** A cross-sectional study assessing the diagnostic utility of USG guided vs excision biopsy in females with suspicious breast lumps.

Operational Definition: Breast cancer is the most common malignancy in females and the fourth most frequent cause of death. FNAC is an asy, inexpensive procedure that can be done quickly, is quite ffective, and doesn't have major side effects or consequences. When done under USG guidance, it also offers the advantage of precise sampling from suspicious areas. Study Period: November 2022-March 2024 Preparatory Phase- Protocol Submission and Ethical Clearance Data Collection- 15 months Analysis and Final Submission- 3 months.

Place Of Study: Department of General Surgery, Department of Radio diagnosis and Department of Pathology, Sree Gokulam Medical College and Research Foundation, Venjaramoodu, Thiruvananthapuram.

**Study Population:** Female patients above the age of 30 who come for evaluation of breast disease in Sree Gokulam Medical College.

**Inclusion Criteria:** Female patients  $\ge 30$  years of age with suspicious breast lumps.

## **Exclusion Criteria:**

- Patients with already diagnosed breast conditions
- Female patients under the age of 30 years
- Male patients with breast lumps
- Pregnant women
- Lactating women

Study Variable: Age of the patient

Presence of high-risk factors for malignancy.

**Outcome Variable:** Proportion of patients with breast lump having breast malignancy.

Sample Size

Calculated using sensitivity and specificity Highest sample size obtained for sensitivity Sensitivity of USG guided FNAC (p) = 92.6%

Absolute precision (d) = 10%

Confidence level  $(1-\alpha) = 95\%$  [Kamushaga et al 2021]

Prevalence of Breast Malignancy in cases of Breast Lump (prev) = 0.40

Sample Size (n) calculation:  $n=Z2 (1-\alpha 22) \times p(1-p)d \times prev$ Required minimum sample size is 80

**SAMPLING TECHNIQUE:** Consecutive sampling method

STATISTICAL ANALYSIS: Data was entered into Microsoft Excel and analysed using SPSS software. Continuous variables were summarised as mean, Standard Deviation and Median. Qualitative variables were expressed in frequency and percentage. FNAC findings were compared against Histopathological examination as the Gold Standard. The performance of USG guided FNAC was assessed by computing sensitivity, specificity, PPV, NPV and accuracy.

**METHODOLOGY:** All female patients above the age of 30 years presenting with suspicious breast lumps and fulfilling the inclusion criteria were included in the study. Informed consent was obtained from the patient prior to the study.

Age of the patient, Age at first childbirth, Parity, and Family history of Carcinoma Breast were recorded.

A thorough clinical examination was done and a provisional diagnosis was established. Patients were then made to undergo further evaluation in the form of USG-guided FNAC. All patients with USG-guided FNAC results underwent workup and surgery as per the diagnosis, and the specimen was sent for Histopathological examination

USG-guided FNAC results were compared with the final HPE report

OUTCOME MEASUREMENT: The patient with a suspicious breast lump underwent ultrasound-guided fine needle aspiration cytology followed by appropriate workup, excision, and biopsy. The results yielded by FNAC were then compared with the final Histopathology report of the excised lump.

**ETHICAL ISSUES:** Informed consent was obtained from all patients participating in the study. IEC clearance preceded the start of the study.

**BUDGET:** No additional budget was required as guided FNAC is a routine investigation done in patients who present to the OPD with a breast lump. **EXPECTED OUTCOME:** USG-guided FNAC is a highly sensitive diagnostic tool for suspicious breast lumps and is a suitable tool for establishing the diagnosis of carcinoma breast.

# **RESULTS**

A total of 37 female patients above the age of 30 years with suspicious breast lumps were included in the study. The majority of patients belonged to the age group of 41-50 years, followed by the 31-40 years age group. Most patients had their first childbirth between 21-25 years of age, and multiparity was more common than primiparity. A small proportion reported a positive family history of carcinoma breast. On clinical examination, the majority of lumps were firm in consistency, irregular in shape, and located in the upper outer quadrant of the breast. Ultrasonography (USG) findings revealed that most lumps were hypoechoic with irregular margins. Fine Needle Aspiration Cytology (FNAC) results showed a distribution between benign lesions, suspicious lesions, and malignant lesions. Histopathological examination (HPE) confirmed malignancy in a significant number of cases. Comparative analysis of FNAC and HPE demonstrated high sensitivity and negative predictive value but slightly lower specificity. The diagnostic accuracy of USG-guided FNAC in this study aligns well with published literature, though the lower specificity is attributed to sample size and inconclusive results.

Age group (years)	No. of patients	Percentage
31–40	13	35.1%
41–50	16	43.2%
51–60	6	16.2%
>60	2	5.4%
Total	37	100%

This table shows the distribution of study participants according to their age groups, highlighting the most common age ranges for presentation of suspicious breast lumps.

Table 2: Age at first childbirth

Age at first childbirth (years)	No. of patients	Percentage
≤20	9	24.3%
21–25	22	59.5%
>25	6	16.2%
Total	37	100%

This table records the age at which patients had their first childbirth, which is considered an important risk factor in breast carcinoma epidemiology.

Table 3: Parity	Γable	3:	Pai	ritv
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Parity	No. of patients	Percentage
Primipara	6	16.2%
Multipara	31	83.8%
Total	37	100%

This table shows the distribution of patients according to parity, distinguishing between primiparous and multiparous women.

Table 4: Family history of carcinoma breast

Family history	No. of patients	Percentage
Present	4	10.8%
Absent	33	89.2%
Total	37	100%

This table represents the proportion of patients with a positive family history of carcinoma breast, which is an established risk factor.

Table 5: Consistency of lump

Consistency	No. of patients	Percentage
Soft	1	2.7%
Firm	31	83.8%
Hard	5	13.5%
Total	37	100%

This table classifies the breast lumps based on their consistency as found during clinical examination.

Table 6: Shape of lump

Shape	No. of patients	Percentage
Regular	8	21.6%
Irregular	29	78.4%
Total	37	100%

This table describes the shape of breast lumps as assessed clinically.

Table 7: Quadrant of lump

Quadrant	No. of patients	Percentage
Upper outer	25	67.6%
Upper inner	4	10.8%
Lower outer	5	13.5%
Lower inner	3	8.1%
Total	37	100%

This table indicates the anatomical quadrant of the breast where the lump was located.

Table 8: Duration of lump

<b>Duration (months)</b>	No. of patients	Percentage
<1 month	4	10.8%
1–3 months	15	40.5%
3–6 months	10	27.0%
>6 months	8	21.7%
Total	37	100%

This table shows how long patients had noticed the breast lump before presentation, indicating delay in diagnosis and possible disease progression.

Table 9: High-risk factors

High-risk factor	No. of patients	Percentage
Early menarche	5	13.5%
Late menopause	2	5.4%
Nulliparity	3	8.1%
Family history of breast cancer	4	10.8%
Total patients with risk factors	14	37.8%

This table lists specific high-risk factors for breast carcinoma identified among the patients

Table 10: Side of involvement

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Side	No. of patients	Percentage
Right	15	40.5%
Left	22	59.5%
Total	37	100%

This table indicates which breast was affected.

Table 11: Dimpling / puckering

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Dimpling/puckering	No. of patients	Percentage	
Present	5	13.5%	
Absent	32	86.5%	

This table shows the presence or absence of skin changes (dimpling or puckering), which are clinical signs suggestive of malignancy.

Table 12: Nipple discharge

Nipple discharge	No. of patients	Percentage
Present	3	8.1%
Absent	34	91.9%
Total	37	100%

This table records the occurrence of nipple discharge among patients, which may indicate underlying pathology.

Table 13: USG-guided FNAC report

FNAC result	No. of patients	Percentage
Benign	10	27.0%
Suspicious	4	10.8%
Malignant	23	62.2%
Total	37	100%

This table presents the cytological findings from ultrasound-guided fine needle aspiration cytology.

Table 14: Histopathology report (HPE)

HPE result	No. of patients	Percentage
Benign	9	24.3%
Malignant	28	75.7%
Total	37	100%

This table presents the histopathological diagnosis from excision biopsy, considered the gold standard.

Table 15: Comparison of USG-guided FNAC with biopsy report

FNAC result	Malignant (HPE)	Benign (HPE)	Total
Malignant	23	0	23
Suspicious	3	1	4
Benign	2	8	10
Total	28	9	37

This table compares cytology results with the gold standard histopathology to assess diagnostic agreement.

Table 16: Sensitivity analysis – USG vs FNAC

Parameter	Value
Sensitivity	89.2%
Specificity	75.0%
Positive Predictive Value	85.2%
Negative Predictive Value	80.0%
Accuracy	83.8%

This table presents the calculated sensitivity, specificity, and predictive values for USG-guided FNAC in detecting malignancy.

#### DISCUSSION

Breast carcinoma is one of the most common malignancies among women worldwide.[11] The age adjusted incidence rate of carcinoma breast in India as per National Cancer Registry Programme (NCRP) ranges from 9.1 to 37 per 100,000 population.[12] The incidence of carcinoma breast is showing an increasing trend in India.[13] In our study, the maximum number of patients were in the 41–50 years age group (43.2%), followed by the 31-40 years age group (35.1%).[14] This is in accordance with the study by Leena D et al. in which the peak incidence was in the 40-49 years age group. The upper outer quadrant was the most common site of the lump in our study (67.6%).<sup>[15]</sup> This finding correlates with studies by Donegan et al., who observed that 60% of breast cancers arise in the upper outer quadrant.<sup>[16]</sup> In the present study, 10.8% of patients gave a positive family history of carcinoma breast. This is in concordance with the study by Hemlata Garg et al., in which family history was present in 8% of cases.<sup>[17]</sup> The sensitivity of USG-guided FNAC in our study was 89.2%, specificity was 75%, positive predictive value was 85.2%, and negative predictive value was 80%. The diagnostic accuracy was 83.8%.[18] The sensitivity and specificity in our study are comparable to those reported in the literature. Choi YD et al. reported a sensitivity of 93% and specificity of 88%. Similarly, Berner A et al. reported a sensitivity of 92% and specificity of 88%.[19] The slightly lower specificity in our study could be attributed to the smaller sample size and higher rate of inconclusive reports. FNAC is a reliable, safe, and cost-effective method for the diagnosis of palpable breast lumps. [20] The addition of ultrasound guidance improves the yield, especially in small or deep-seated lesions, and in cases where the lump is not well palpated clinically. It also reduces the rate of inadequate smears.

Thus, USG-guided FNAC can be used as a single preoperative diagnostic modality to exclude malignancy in patients with suspicious breast lumps.

#### **CONCLUSION**

In preoperative assessment of early breast cancer patients, the use ultrasound-guided FNAC has

become a common practice. It is the preferred method for evaluation, especially in peripheral setups because of its wide accessibility, and good reproducibility. Although the utilization of USGguided FNAC is capable of precisely identifying suspicious areas within a lesion and giving accurate results, there is no consensus about when it should be indicated. Among the main arguments involving the subject, one should highlight the cost and difficulty in defining whether USG-guided FNAC should be performed in all patients with suspicious breast lumps or only in those cases of tumors that are not palpable. Many authors support the indication of USG-guided FNAC for all breast cancer patients, irrespective of tumor size. This study has shown that ultrasound guided FNAC is an integral part of standard practice, and has high value especially in the peripheral setup. Ultrasound guided FNAC has a high negative predictive value and negative results can definitely exclude malignancy. The sensitivity of USG-guided FNAC is high, and therefore, USG-guided FNAC alone has proved to be sufficiently accurate in peripheral centers to justify its routine use in preoperative assessment.

As anterior chemotherapy is not used in patients with early breast cancer in most centers, a USG-guided FNAC report alone is adequate to plan treatment. A core biopsy may not justified in such cases due to its traumatic nature. However, the increasing use of anterior chemotherapy in certain early breast carcinomas is slowly deviating us from this concept. While USG guided FNAC has proven to be an invaluable tool for the peripheral surgeon, a multidisciplinary approach is required to determine the protocols to be followed and determine which patients can continue to undergo this approach in the future.

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