International Journal of Science and Research (IJSR)
ISSN: 2319-7064
SJIF (2022): 7.942

A Prospective Clinical Study to Evaluate the Accuracy of Axillary Lymph Node Staging Using Ultrasound Guided Fine Needle Aspiration Cytology in Breast Cancer Patients

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Abstract: ***Background: Breast cancer is one of the leading causes of malignant tumours in women. Axillary lymph node involvement has a significant role is staging, survival and management in patients with breast cancer. Axillary lymph node dissection was earlier regarded as a gold standard technique for axillary involvement in breast cancer patients for staging and prognosis. This technique was an invasive procedure with significant morbidity. Ultrasound guided fine needle aspiration is a technique which shows very little morbidity, is cheap and is readily available, which can help in assessment of axillary lymph nodes for its involvement and staging in breast cancer. This study is being undertaken to understand the role of ultrasound guided fine needle aspiration in breast cancer patients for assessment of axillary lymph nodes. Materials and Methods: This prospective study was conducted in the Department of Radiodiagnosis, Rama Medical College Hospital & Research Centre, Kanpur from August 2022 to February 2024. The study was conducted in 50 women with a confirmed diagnosis of breast cancer on HPE with clinical node status of N0 and N1. The collected data was analysed by using SPSS (Statistical Package for Social Sciences) Version 15.0. Result: The study of 50 women showed that the maximum number of breast cancer cases were diagnosed in the ages 52 - 59 with a clinically palpable lump of size 2 - 5cm. On HPE, invasive ductal carcinoma was the most common type of tumour which presented with calcifications of mammography. On ultrasound, level 1 nodes were most commonly affected with malignancy with cortical thickening >3mm. The comparison of accuracy in diagnosis of USG - FNAC and SLNB indicate that the SLNB method yielded total 23 true positive cases, 26 true negative cases, no false positive case, and 1 false negative case, therefore shows sensitivity of 95.83%, specificity of 100.0%, and accuracy of 98.0%. In comparison, the USG - guided FNAC method showed 18 true positive cases, 28 true negative cases, 2 false positive cases, and 2 false negative cases, with a sensitivity of 90%, specificity of 93.3%, and an accuracy of 92%. Conclusion: These results demonstrate that while SLNB has a higher sensitivity, USG - guided FNAC offers slightly better specificity and accuracy.***

Keywords: Axillary Lymph Nodes, Ultrasound, Fine Needle Aspiration Cytology, Breast Cancer

1. Introduction

In recent times, breast cancer has emerged to be one of the leading form of malignant tumors in women, which leads to approximately 31% of all cancer cases [1]. There is an emerging trend of breast cancer cases, even in India. There are reports of approximately 144, 946 registered cases which have resulted in approximately 70, 348 fatalities [2]

Axillary involvement of breast cancer has a significant role in survival, disease stage, and local management. To assess the status and prognosis of axillary lymph nodes (ALN) with patients of breast cancer, mammography usage with ultrasound doesn't hold any significant advantages [3].

Axillary dissection of lymph nodes (ALND) earlier was regarded gold standard, for identifying the involvement of lymph nodes [4]. Initially, the staging of axilla, was accomplished by undergoing dissection of axilla i. e. ALND [5].

Nevertheless, dissection of axilla yields favourable outcomes in 30% of tumours that can be felt and in 10% of tumours that cannot be felt in patients who do not show signs of axillary involvement. Between 70 and 90% of the remaining cases receive axillary dissection without a valid reason.

Utilization of sentinel lymph node biopsy (SLNB) have increased since it has been discovered as a substitute technique for individuals diagnosed with breast cancer in early stages. Purushottam et al. stated dissection of the axilla (ALND) is gold standard for axillary lymph node involvement. However, in many medical centres, sentinel lymphadenectomy has now become the predominant staging procedure, and is relatively less complicated [6].

SLNB is a longer, time taking process that necessitates the use of methylene blue or Technetium - 99 radioisotope. Each of these agents can also be used separately with an exactness rate of approximately 91 - 96%. However, when done together, the exactness increases to around 97 - 99%. However, both of these agents are not readily accessible at most higher healthcare institutions.

Performing USG of the axilla might decrease the occurrence of false positive results during clinical examination. This can aid in preventing needless axillary dissection and improve selection of individuals who have done SNLB [7]. The SLNB procedure necessitates three specific requirements: (1) pre - operative procedure of lymphoscintigraphy, (2) the requirement of physician during the surgery, and (3) an intra - operative visualization of the sentinel node. The latter examination can be delayed for a final evaluation, and if node

is found to be positive, patient need to return for a delayed type of ALND, based on the surgeon's discretion.

Research including 232 women found that this operation had a complication rate of 4 - 14%, which includes paresthesia, immobility, pain, and lymphedema. [8]. So underscores necessity of identifying minimally invasive and diagnostic techniques for telling the involvement of breast cancer. A different approach was illustrated by imaging modes, including as PET - CT, MRI, and USG. Nevertheless, there was significant variation in precision of MRI and PET - CT, as indicated by a specificity and sensitivity of 96% and 57% for PET - CT, and 66% and 94% in MRI in detecting metastatic lymph nodes [9].

USG have potential to identify abnormal LN in axilla that show no clinical signs. This allows targeted selection of patients who need to go for needle biopsy, hence minimizing the necessity for unnecessary sentinel node biopsies.

Under ultrasound guidance fine - needle aspiration biopsy has potential to prevent unnecessary biopsy of the first draining lymph node, also called the sentinel node, in a considerable proportion of individuals [10]. Additionally, it can decrease the occurrence of the incorrect negative results by identifying LN that have significant spread of cancer and are obstructed in their drainage paths, meaning they would not be labelled by dye and/or radiopharmaceuticals. The pre - operative axillary USG is a commonly conducted method in individuals which have a diagnosis of breast cancer in early stages. [11].

FNAC under USG guidance is rapid and less invasive technique used to assess involvement in axilla. USG - FNAC result which is positive, eliminates the need for sentinel lymphadenectomy, enabling operative surgeon to move to dissection of the axilla (ALND) or neoadjuvant treatment.

Ultrasound - guided aspiration using fine needle (USG - FNAC) is less invasive, straightforward also dependable method for first assessing the level of involvement of lymph nodes of axilla in patients breast cancer. This technique is particularly useful for non - palpable lymph nodes that are uncertain or suspicious [12].

It is to be noted that ultrasound - guided FNAC is not at par or with similar sensitivity as biopsy of sentinel lymph node, as it has a higher rate of false negative to completely replace biopsy of sentinel lymph node. Consequently, individuals who have a negative result at ultrasound guided FNAC, to correctly evaluate axilla has to still take the biopsy of sentinel lymph node.

Axillary ultrasonography (US) done preoperatively, is a commonly conducted procedure in individuals with diagnosis of breast cancer. USG - FNAC enables the identification of a specific subgroup that is suitable for single - stage axillary operation [13]. Showing high levels of specificity and sensitivity, this method, especially when used alongside aspirational biopsy using fine - needle (FNAB), is used to accurately diagnosing nodal metastases in breast cancer before surgery. The US - FNAC demonstrated a specificity of 100% in nodes that were clinically or radiologically worrisome, and a NPV of 33.1% [14]. Which is then used to determine individuals who can skip biopsy of sentinel lymph node and move directly to dissection of axillary lymph nodes. The sensitivity of physical examination for identifying ALN metastases during preoperative evaluation is rather low, ranging from 34% to 76%. Combining ultrasonography lymph nodes of axilla (ALN) with USG - needle aspiration cytology of questionable lymph nodes has been found to have excellent diagnostic accuracy in numerous investigations. Research indicates that there is a 15% decrease in the likelihood of getting a false negative in detection of the nodes which are sentinel when ultrasonography is combined with USG - FNAC [15]. The USG examination's sensitivity and specificity in assessing ALN metastases have been documented to range from 36% to 92% and from 69% to 100%, respectively. Incorporating USG - FNAC into axillary US may enhance specificity to a range of 93 - 100% [16] Under ultrasound guidance aspirational fine needle cytology is a method which is minimally invasive and is used to investigate lymph nodes of the axilla in patients of breast cancer. The US - FNAC technique has numerous benefits, such as being minimally invasive, cost - efficient, and capable of delivering quick findings. Consequently, it has the potential to alleviate patient anxiety and expedite treatment planning.

Aim of this study is to comprehensively assess the level of precision in staging of lymph node of the axilla using ultrasound guidance aspirational fine needle cytology in patients of breast cancer. By examining the existing body of literature, conducting a systematic review, and potentially incorporating our institutional data, this research seeks to give a better perception of the diagnostic performance, reliability, and constraints of US - FNAC in this context.

2. Materials and Method

This prospective study was conducted between August 2022 and February 2024 at the Department of Radiodiagnosis at Rama Medical College Hospital and Research Centre in Mandhana, Kanpur, Uttar Pradesh

50 women with breast cancer confirmed by histopathological examination with clinical nodal status of N0 or N1 we included in the study. The patients were provided with a detailed information sheet in their local language and consent was taken for inclusion in the study.

Technique of ultrasonography and characterization of lymph nodes

Ultrasound of the axilla was done by an experienced radiologist using a linear transducer of high - frequency with advanced ultrasonography machines. The lymphatic drainage from the breast first drains to lymph nodes of the pectoral group, even though any draining lymph node of the breast can be sentinel. The lymph nodes were evaluated based on their imaging findings-

a) Presence or absence of hilum.
b) Cortical thickness more than 3 mm with an eccentric looking hilum.
c) Cortical thickness more than 3 mm with a central hilum.

Asymmetrical cortical thickness of lymph nodes more than 3 mm with a hilum that is eccentric, and lymph nodes which lack fatty hilum, were suspicious of malignant disease.

Thickness of cortex greater than 3 mm with a central hilum was an indeterminate finding. In such cases, the lymph node which was considered suspicious underwent fine - needle aspiration cytology (FNAC).

Axillary lymph nodes are categorized into three levels: Level I nodes, are further divided into 3 groups – lateral or deep, subscapular or posterolateral, and pectoral or anteromedial.

Evaluation of the level I node starts by locating the axillary artery's third segment along with axillary vein, which travels deeper to level I lymph nodes and is a crucial anatomical landmark. Lateral group lymph nodes are typically located in close proximity to the axillary vein which drains lymph from the upper limb.

In ultrasonography of the axilla, the subscapular artery is an important anatomical landmark. This branch of axillary artery is the largest with its single branch which originates inferior to the axillary artery. Locating this branch is instrumental in identification of its two branches— thoracodorsal and circumflex scapular Circumflex scapular artery penetrates the muscles namely - latissimus dorsi, subscapularis and teres major. The thoracodorsal artery then runs along the axillary chest wall in lateral chest wall. Subscapular lymph nodes are located along the subscapular artery. These nodes are important in drainage for region of the scapula with posterior wall of the chest. Lateral thoracic artery is a crucial anatomical landmark of the axilla, present in the anteromedial to the level I lymph nodes. It is present posteriorly to the pectoralis minor and is one of the two main arteries supplying the breast tissue. Pectoral group of lymph nodes is present in the axillary pad of fat along the lateral thoracic artery. The lymphatic drainage of the breast primarily drains to the pectoral group lymph nodes and has the maximum chances of housing the sentinel lymph nodes. Neurovascular and muscular structures surrounding the axilla served as critical landmarks for locating lymph nodes, with suspicious nodes along these structures are labelled as a, b, c, and d. This labelling system facilitated precise node localization while doing ultrasound and biopsy of LN. For example, if FNAC was performed on a node present along the pedicle of latissimus dorsi was labelled as "c" and yielded positive cytology results then axillary node dissection (ALND) was performed. During ALND, nodes identified along the pedicle of latissimus dorsi were harvested and labelled accordingly as "c. " USG and ultrasound - guided fine needle aspiration cytology (USGFNAC) findings were then compared with the histopathological report of the same node. This approach ensured consistency and accuracy in correlating imaging and cytological findings with histopathological results, thereby enhancing the study's diagnostic reliability.

In our study, we employed a mapping of pedicle–based nodal method during ultrasonography to find axillary lymph nodes. If LN are found to be indeterminate or negative on ultrasonography guided fine needle aspiration cytology (USG - FNAC), and there was no lymph nodes detected in the axilla on doing ultrasonography, these patients are sent for biopsy of sentinel lymph node. We utilized a dye (most commonly used methylene blue) technique for SLNB. Methylene of 2–3 ml blue dye was injected at the peri areolar site on the day when the surgery is performed. Towards the axilla Gentle milking was performed, that is followed by a 5–7 - minute wait after dye injection. An incision of size 2.5 - 3.9cm was done in axilla near the fold of pectoralis major. After dissection, up to 3 blue nodes were identified, defatted on the table, and sent for histopathology examination. If blue node was not found, the lymphatic streak of blue dye was followed to identify the receiving node, which was then removed.57 Nodes obtained from SLNB were subjected to frozen section analysis. Axillary lymph node dissection (ALND) was performed if sentinel nodes are found positive; if found negative, no further axillary dissection was done. Pathologist provided histopathology report which was considered as the gold standard against which comparison of both USG - FNAC and SLNB findings are done

The following metrics were calculated to evaluate diagnostic performance:
Sensitivity is defined as True Positive/True Positive + False Negative
Specificity is defined as True Negative/ True Negative + False Positive
Accuracy is defined as True Positive + True Negative/True Positive + True Negative + False Positive + False Negative
Positive Predictive Value (PPV) is defined as True Positive/ True Positive + False Positive
Negative Predictive Value (NPV) is defined as True Negative/ False Negative + True Negative

These metrics helped in clinical decision - making and therapeutic implications based on the reliance of axillary USG and FNAC findings. Evaluating the sensitivity, specificity, diagnostic accuracy, NPV, PPV, and false - negative rates provided valuable insights into the effectiveness of these diagnostic techniques. To facilitate the location of nodal structures during ultrasound, we developed a method to target suspicious nodes for fine needle aspiration cytology (FNAC) and subsequently isolate the same node during axillary surgery.

Statistical Analysis
The statistical analysis was done using SPSS (Statistical Package for Social Sciences) Version 15.0 statistical Analysis Software. The values were represented in Number (%) and Mean ± SD.

3. Results

The greatest number of breast cancer cases in this study occurred in aged 52 - 59 years, comprising 40% of the total cases. This age group has the highest prevalence among the studied population. This finding aligns with broader trends in breast cancer epidemiology, where incidence increases with age, particularly after menopause.

Table 1: Distribution of Age (total no. of cases- 50)

Age Group of Cases (in years)	No. of patients in each group	Percentage (%)
30- 39	5	10.0%
40- 49	15	30.0%
50- 59	20	40.0%
60- 69	7	14.0%
> 70	3	6.0%
Total Patients	50	100.0%

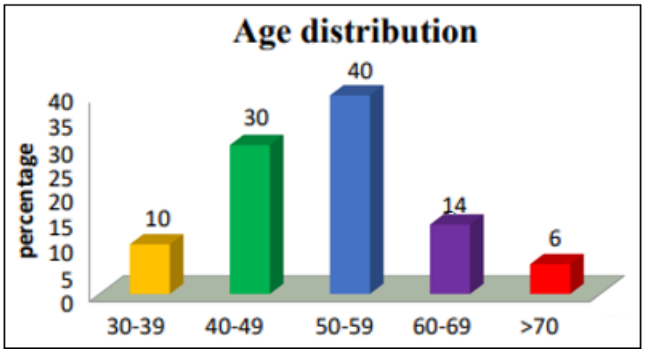

Figure 1: Distribution of Age

Presentation of clinically relevant size of the mass in the breast among the 50 patients was distributed as follows: 20% of patients have a mass of size < 2 cm, 60% have a size of lump between 2.1 - 5.2cm, and 20% had a lump size greater than 5.2 cm. This shows that the most of cases have a lump size in the 2 - 5 cm range.

Table 2: Clinical Presentation: Lump Size in Breast

Lump Size (in cm)	No. of patients	Percentage (%)
<2	10	20%
2- 5	30	60%
>5	10	20%

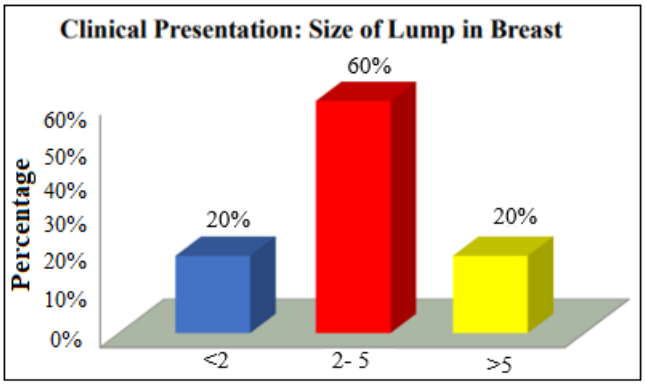

Figure 2: Clinical Presentation: Lump Size in Breast

The tumour characteristics among the 50 patients revealed that 70% were diagnosed with invasive ductal carcinoma, making it the most commonly found cancer of breast. Invasive lobular type of carcinoma was present in 20% of patients, while the remaining 10% had other types of tumours.

Table 3: Tumor Characteristics

Tumor Type	No. of patients	Percentage (%)
Invasive Ductal Carcinoma of breast	35	70%
Invasive Lobular Carcinoma of breast	10	20%
Other	5	10%

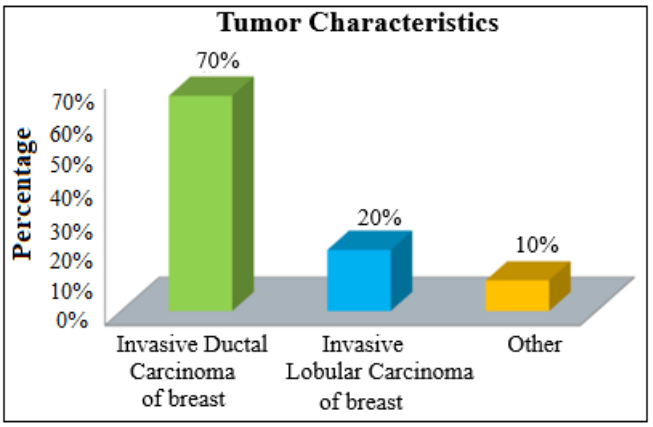

Figure 3: Tumor Characteristics

The mammogram findings among the 50 patients showed that 64% had a mass with calcification, 26% had a mass without calcification, and 10% exhibited architectural distortion.

Table 4: Mammogram Findings

Mammogram Findings	No. of patients	Percentage (%)
Mass with Calcification	32	64%
Mass without Calcification	13	26%
Architectural Distortion	5	10%

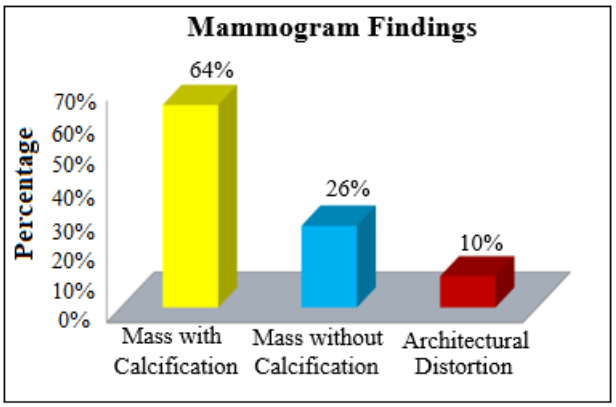

Figure 4: Mammogram Findings

Radiological characteristics of the nodes location of malignancy in axilla among the 50 patients were distributed as follows: 54% of the suspicious nodes were located mostly at - Level I, 34% are at Level II, and 10% are at Level III. This suggests that the majority of suspicious nodes were found at Level I.

Table 5: Radiological Characteristics: Nodes Location in Axilla

Location	No. of patients	Percentage (%)
Level I	28	54%
Level II	17	34%
Level III	5	10%

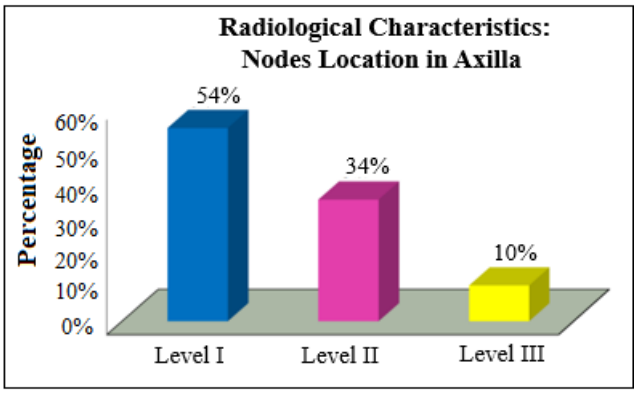

Figure 5: Radiological Characteristics: Nodes Location in Axilla

The features on radiology of LN predicts the likelihood of metastasis among the 50 patients indicated that 50% of the nodes had cortical thickness greater than 3 mm, 30% showed a loss of fatty hilum, and 20% exhibited irregular margins. This data suggests that cortical thickness >3 mm was common radiological feature associated with metastatic potential

Table 6: Lymph Nodes Radiological Features Predicting for possibility of Metastasis

SLNB Result	Number of Nodes	Percentage (%)
Cortical Thickening >3mm	25	50%
Loss of Fatty hilum	15	30%
Irregular Margins	10	20%

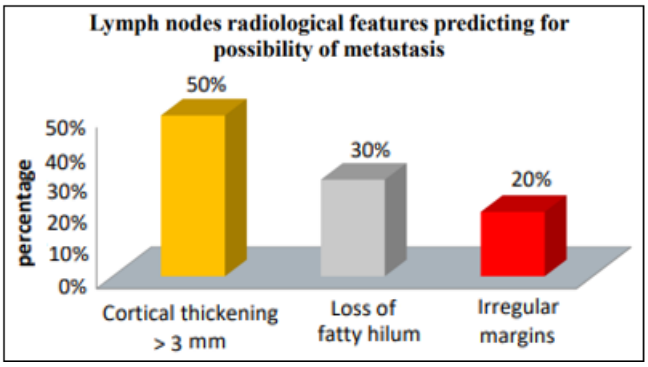

Figure 6: Lymph Nodes Radiological Features Predicting for possibility of Metastasis

The results of SLNB among the 50 individuals showed that 46% had a positive SLNB result, while 54% had a negative SLNB result.

Table 7: Sentinel Lymph Node Biopsy Result

SLNB Result	Total Number of Patients	Percentage (%)
Positive Cases	23	46%
Negative Cases	27	54%

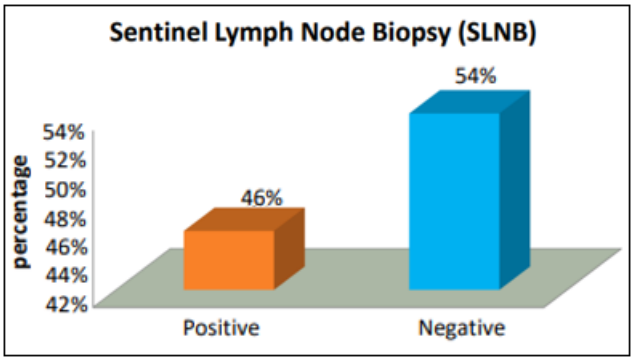

Figure 7: Biopsy of Sentinel LN

The comparison of accuracy in diagnosis of USG - FNAC and SLNB. Results indicate that the SLNB method yielded total 23 true positive cases, 26 true negative cases, no false positive case, and 1 false negative case, therefore shows sensitivity of 95.83%, specificity of 100.0%, and accuracy of 98.0%. In comparison, the USG - guided FNAC method showed 18 true positive cases, 28 true negative cases, 2 false positive cases, and 2 false negative cases, with a sensitivity of 90%, specificity of 93.3%, and an accuracy of 92%. These results demonstrate that while SLNB has a higher sensitivity, USG - guided FNAC offers slightly better specificity and accuracy.

Table 8: Sensitivity, Specificity and Accuracy of USG guided FNAC and SLNB

Method	True Positive Patients	True Negative Patients	False Positive Patients	False Negative Patients	Sensitivity in (%)	Specificity in (%)	Accuracy in (%)
SLNB Result	23	26	0	1	95.83%	100.0%	98.00%
USG Guided FNAC	18	28	2	2	90%	93.3%	92.0%

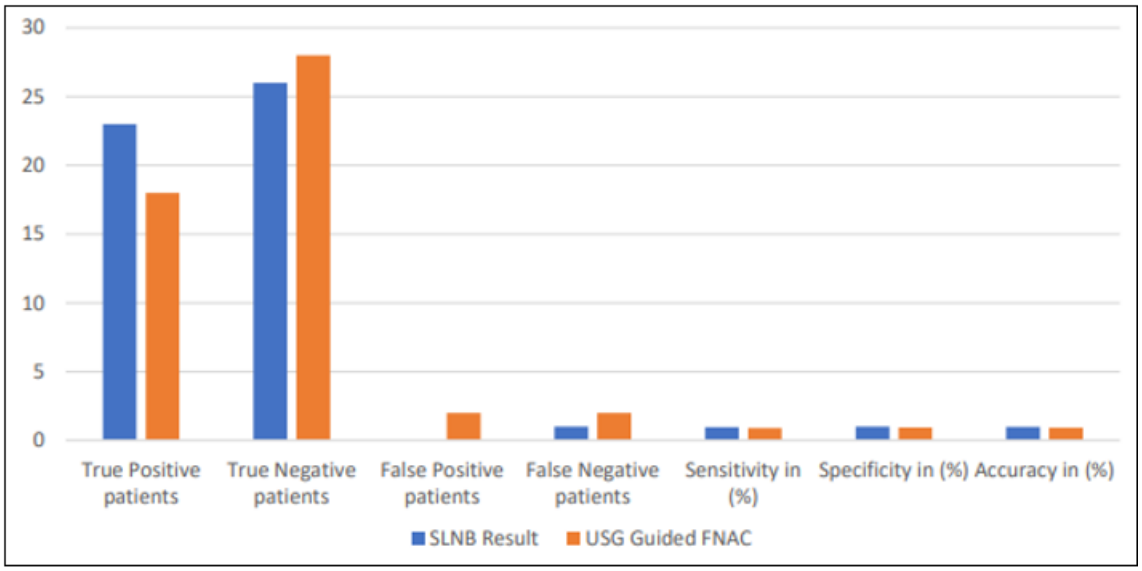

Figure 8: Sensitivity, Specificity and Accuracy of USG guided FNAC and SLNB

4. Discussion

The study was aimed in breast cancer patients to know the accuracy of axillary lymph node staging using ultrasound - guided fine needle aspiration cytology (USG - FNAC).50 patients were taken; to provide a comprehensive evaluation of diagnostic methods their findings were compared with established clinical trials.

Age Distribution and Clinical Presentation
The majority of patients (40%) fell within the 50 - 59 years age group, consistent with literature indicating increased breast cancer incidence with age. Clinical presentations showed that 60% cases have a range of 2.2 - 5.2 cm lump size, aligning with findings such as those by Fisher et al. (1997) [17], which correlated larger tumour sizes with higher rates of lymph node metastasis.

Tumour Characteristics and Mammogram Findings
Invasive type of ductal carcinoma (70%) was the most common tumor type, invasive lobular carcinoma (20%) is second common type after invasive carcinoma, consistent with observations by Bleiweiss (2012) [18], which identified invasive type of ductal carcinoma as the predominant form of cancer. Mammogram results indicated that 60% of patients presented with a mass containing calcifications, a common feature in malignant lesions as noted by Kopans (2007) [19]

Radiological Characteristics and Features Predicting Metastasis
Suspicious nodes were predominantly located at Level I (60%), consistent with studies by Veronesi et al. (1999) [20], which identified Level I nodes as the primary drainage site for breast cancer lymphatics. The most prevalent radiological feature predicting metastasis was cortical thickening greater than 3 mm (50%), aligning with findings by Yang et al. (2001) [21], highlighting its significance in predicting metastatic involvement.

Biopsy of Sentinel Lymph Node
SLNB results indicated positivity rate around 40%, falling within the range reported by the ACOSOG Z0011 trial (Giuliano et al., 2011) [22], which reported rates between 25% and 40%. This underscores SLNB's reliability in detecting sentinel lymph node metastasis.

Diagnostic Accuracy of FNAC and USG - FNAC
FNAC demonstrated a specificity around 93.3%, sensitivity around 90% and which is comparable to some studies such as Britton et al. (1999) [23], which reported similar accuracy in axillary staging. USG - guided FNAC showed specificity around 100.0%, sensitivity around 95.83% and consistent with Houssami et al. (2011) [24], demonstrating high sensitivity and moderate specificity in axillary staging

ACOSOG Z0011 Trial (Giuliano et al., 2011) [22]
This trial emphasized SLNB's role in axillary staging, showing comparable outcomes between SLNB alone and additional ALND. Our study's SLNB results support SLNB's reliability as a diagnostic tool.

ALMANAC Trial (Mansel et al., 2006) [25]
Highlighting reduced morbidity with SLNB compared to ALND, the ALMANAC trial's findings align with our study's high sensitivity of USG - FNAC, indicating effective identification of metastatic nodes through non - invasive techniques.

Sentinel Node vs. Observation After Axillary Ultrasound (SOUND) Trial (Gentilini et al., 2013) [26]
This trial compared Sentinel LN biopsy to observe in patients with axillary ultrasound which is negative. Our study's findings on the accuracy of USG - guided FNAC support the SOUND trial's approach, suggesting that a negative USG - guided FNAC result may be sufficient to avoid unnecessary SLNB.

5. Conclusion

Based on the findings of our study done on 50 individuals presented with early breast cancer, several key conclusions can be drawn:

- Age and Screening - The highest prevalence of breast cancer was observed among patients aged 50 - 59 years. This underscores the importance of targeted screening and

preventive measures for women in this age group to facilitate early detection and intervention.

- Tumour Size - A majority of patients presented with a breast lump size between 2 - 5 cm. This highlights the critical role of early detection programs in identifying breast masses promptly, which can significantly impact treatment outcomes.
- Tumour Type - The most common type of tumour is Invasive ductal carcinoma, diagnosed in 70% of the patients. This finding emphasizes the necessity for tailored treatment protocols focusing on the management of invasive ductal CA, which is the most common type of breast cancer.
- Mammogram Findings - The most frequent mammogram finding was a mass with calcification, observed in 60% of the patients. This underscores the importance of mammography in detecting calcified masses, which serve as primary diagnostic features in breast cancer patients.
- Lymph Node Involvement of Axilla - Most of suspicious nodes were present at Level I in the axilla. This suggests that initial screening for axillary LN involvement in breast cancer cases should prioritize assess the Level I nodes, as they are most frequently affected.
- Radiological Features - The most common radiological feature was cortical thickness >3 mm associated with metastatic potential, identified in 50% of the nodes. This highlights the critical role of detailed radiological assessment in assessing the metastatic spread in breast cancer patients.
- Sentinel LN Biopsy - Nearly positive result was present in half of the patients. This indicates that SLNB remains a crucial diagnostic tool for detecting early metastatic involvement in breast cancer patients, guiding subsequent treatment decisions. These conclusions collectively underscore the importance of age - specific screening, accurate diagnostic imaging, and targeted biopsy methods in the management of breast cancer cases. They provide valuable insights into optimizing diagnostic and therapeutic strategies to improve patient outcomes in clinical practice.
- USG - guided FNAC - offers a significant advantage in reducing the number of surgical SLNB procedures, thereby lowering surgical costs and minimizing associated morbidities, infections of wound, hematomas, lymphedema and seromas even in patients with SLNB - negative disease.

These potential complications can often be avoided with USG - guided FNAC. Moreover, USG - guided FNAC is a cost - effective and readily accessible evaluation method, particularly beneficial in centres where work load is more like those in developing countries. While we don't want to compare SLNB directly with USG - guided FNAC, it highlights that USG - guided FNAC can mitigate technical and logistical complications associated with SLNB. However, it's important to note that SLNB demonstrates higher sensitivity and overall accuracy compared to USG - guided FNAC. This suggests that while USG - guided FNAC offers advantages in reducing procedural complications, SLNB may still be preferred for accurately diagnosing LN metastasis in patients of breast cancer.

This study underscores importance of age - specific screening, early detection through detailed radiological assessment, and the judicious use of SLNB to enhance diagnostic accuracy and improve management outcomes for breast cancer patients.

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