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# A COMPARATIVE STUDY BETWEEN PREOPERATIVE AXILLARY LYMPH NODE STATUS WITH POSTOPERATIVE HISTOPATHOLOGICAL DIAGNOSIS IN OPERABLE CASES OF BREAST CANCER

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## ABSTRACT :

**Background** : This study includes Early Breast cancer patients undergoing Modified Radical mastectomy and aims to compare the preoperative clinico-radiological axillary staging with pathological staging in operated specimens postoperatively and thus to study the precsion and accuracy of these preoperative staging modalities. Axillary nodal status has long been recognised as one of the strongest predictors of breast cancer recurrence and mortality. But this is now being challenged in the wake of new clinical trials dismissing the role of axillary nodal status in determining the overall survival.
**Methods**: This study was conducted with the approval of institutional ethical committee. This study was conducted at sree mookambikai Medical College.Inclusion criteria are Patients undergoing Modified Radical Mastectomy for Early breast cancerStages Ia,Ib,IIa,IIb. exclusion criteria are patients undergoing- breast conservation surgery ,neoadjuvant chemotherapy ,recurrent breast cancer,male patients with breast cancer. Patients undergoing Modified Radical Mastectomy for Carcinoma Breast in our Department from January 2023 to September 2024 are included in this study.
**Results**: Sensitivity and Specificity of Sonomammogram was 100% and 79% respectively and the Positive predictive value was 76.1%- means if a node is identified on Sonomammogram , the probability that it is a metastatic node is 76.1%. Negative predictive value was 100% - that is if nodesare not seen on Sonomammogram, there is 100% chance that it is an N0 disease.A subset of 23 patients from the total 40 patients studied had N0 disease. Based on observation certain tumor characteristics of this subgroup were:Majority of N0 tumors were in T1 stage ( 1.1-2cm) – 39.1%Most of them were of Grade I ( 13 out of 23) – 56.5%Majority fell in the 5 th decade ( 41-50 years) – 39.1%69.5% of N0 tumors were ER positive and 73.9% were her2neu negative
**Conclusion**: The aim of this study was to try and define few characteristics in N0 subset of patients in Early Breastcancer in whom a conservative approach to axilla could be adopted. On concluding this study, the following significant characteristics of N0 subgroup of patients could be utilized in selecting patients for conservative management of axilla with non-radical surgical method.
**Keywords:** Breast cancer, Modified Radical mastectomy.

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## INTRODUCTION:

Female Breast cancer was probably the first tumor to be reported in history, as early as Egyptian civilisation. Early physicians like Hippocrates and Galen described Breast cancer and suggested „black bile" as the cause of these tumors, which came to be known as Humoral theory. In late 17th century, Henry Le Dran , a French physician and Claude Nicolas argued that surgical removal was the treatment for breast cancer. The importance of axillary nodal metatasis was identified since Wilhelm Fabry described axillary nodal excision along with primary surgery.

By mid nineteenth century, Sir William Halsted popularised Radical Mastectomy as the gold standard treatment for Breast cancers which included radical nodal surgery. He popularised that addressing the nodes in a radical manner would prevent recurrence and save lives. He said that breast cancer patients do not do poorly because they have regional lymph node metastasis, rather they have thesemetastasis when they do poorly.." Axillary lymph node dissection as an integral part of Mastectomy was unquestioned until the landmark NSABP B-04 trial reported in 1977 that addition of axillary dissection to Mastectomy does not improve disease free or overall survival. Bernard Fischer in 1980 asserted that "… breast cancer is a systemic disease, likely at its inception.." and that "…The positive lymph node is the reflection of an interrelationship that permits the development of metastasis rather than the instigator of distant disese…"

Axillary nodal status has long been recognised as one of the strongest predictors of breast cancer recurrence and mortality. But this is now being challenged in the wake of new clinical trials dismissing the role of axillary nodal status in determining the overall survival. Added to these are the adverse effects of Axillary dissection like Lymphedema, nerve injuries and postoperative seroma formation.

For the same reasons, there has been a paradigm shift in treatment from a radical approach in the axilla to a conservative or minimally invasive approach. Advances in Systemic chemotherapy drugs and Radiotherapy techniques have complimented this shift in approach.

Recent trends for treatment of axilla in Breast cancer have evolved from radical dissection to Sentinel Lymph node biopsy and Sentinel Lymph node Dissection. Future of Breast cancer treatment lies in personalised treatment for axilla for each individual patient based on the tumor characteristics and risk factors.

This study includes Early Breast cancer patients undergoing Modified Radical mastectomy and aims to compare the preoperative clinico-radiological axillary staging with pathological staging in operated specimens postoperatively and thus to study the precsion and accuracy of these preoperative staging modalities. This studyalso aims to define tumor characteristics like size, grade and histology in the patients studied and to relate these to incidence of axillary lymph node metastasis in these patients.Finally, by studying these, the feasibility of defining a subgroup in early breast cancer patients without any axillary metastasis and to study the tumor characteristics and biology in this subgroup will be attempted.

### AIM AND OBJECTIVES OF THE STUDY:

- To compare the preoperative clinico-radiological axillary lymph node staging with postoperative

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histopathological staging and determine the accuracy of various staging modalities

- To identify a specific subgroup in early breast cancer patients without axillary metastasis and to define the tumor characteristics and biology for this subgroup.

## MATERIALS AND METHODS:

This study was conducted with the approval of institutional ethical committee. This study was conducted at sree mookambikai Medical College.Inclusion criteria are Patients undergoing Modified Radical Mastectomy for Early breast cancerStages Ia,Ib,IIa,IIb. exclusion criteria are patients undergoing- breast conservation surgery ,neoadjuvant chemotherapy ,recurrent breast cancer,male patients with breast cancer. Patients undergoing Modified Radical Mastectomy for Carcinoma Breast in our Department from January 2023 to September 2024 are included in this study.All patients included in the study were examined after admission preoperatively. A detailed clinical history, physical examination and radiological investigations were done as per the clinical proforma and Evaluation form attached at the end.reoperative Clinical Staging of Breast and Axilla was done with TNM staging which was revised after Radiological investigations if necessary.

The Patient profile was discussed in the Institutional Tumor Board, consensus opinion arrived and those patients planned for MRM were posted for surgery.Preoperative informed consent was obtained, counselling was done to patient regarding the preoperative Diagnosis, Staging workup done, prognosis as per international standard for her Stage of the disease, treatment options available for her, why surgical management was needed and suggested, consequences of non surgical management if she chose it, course of treatment after surgery, possible intraoperative and postoperative anaesthetic and surgical complications and importance of postoperative physiotherapy.

The possibility of discordance of the preoperative staging and histology with postoperative histopathological report was also informed. The option of Breast reconstruction at a later date was also informed.To avoid bias in the surgical technique, uniform preformed and preset protocols were implemented as follows for all patients:All patients were put on overnight fasting for 10 hours as per Anaesthetist requirementsSingle dose of Proton Pump Inhibitor (Omeprazole) and prokinetic drug (Domperidone) was prescribed for the night prior to surgery. No sedative was used.
Early morning preloading with 2 pints of Normal saline and 100 mL of 25% Dextrose at 6am on the day of surgery. This was to reduce intraoperative insensible fluid loss due to tissue exposure.
Preloading was not done for Diabetic patients, patients at high cardiac risk , patients with known End Stage Renal Disease.

Short acting Insulin continued till the previous night of surgery and Long acting Insulin continued till prior evening of surgery for diabetic patientsLong acting anti hypertensives discontinued 24 hours prior to surgery. Short acting anti hypertensives continued till day of surgery for hypertensive patients.Antiplatelet drugs discontinued 7 days prior to surgery and other cardiac drugs continued till day of surgery for cardiac patients.Inj.Lignocaine and Inj.Tetanus toxoid prescribed prior to surgery along with antibiotic test dose.Skin preparation with preparation of axilla on the side of surgery.Preoperative single dose of antibiotic half an hour prior to surgery for non diabetics – Inj.Ampicillin 2g iv stat for diabetics – Inj.Cefotaxime 1.5 g iv statAll patients were operated under General Anaesthesia with endotracheal Tube.Patient position – supine posture with sand bag under the

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scapula on the site of surgery with arms hyper abducted to $100^{o.}$. Skin prepared with 7.5% Povidone Iodine and draped.

Standard incision extending medially upto sternal edge, laterally upto anterior axillary line, and superior and inferiorly including skin upto 2.5cm from margin of the palpable tumor was made.Flaps were raised in the areolar plane preserving the subdermal plexus of vessels superiorly upto the clavicle, inferiorly upto submammary fold with Monopolar cautery.Dissection was done from medial to lateral aspect removing the breast tissue along with the Pectoral fascia.

Flap tacking was done to the chest wall to minimize seroma as per positive Institutional study results done previously.
14 size double-suction DT was placed – one limb in the superior flap and other in inferior flap.Postoperatively, the surgeon did a Grossing of the specimen – superior border marked with short silk ties, lateral border with Long silk ties. Tumor was palpated and identified and cut section was made to study the macroscopic features. Axillary nodes were dissected and minimum of 12 nodes were grossed. The Mastectomy specimen and the grossed axillary lymph nodes were sent to Pathologist in separate boxes with 40% Formaldehyde as preservative.Tight Elastoplaster dressings were applied with axillary padding.Oral diet was resumed starting with clear liquids after 3 hours continuing to semisolid and soft solid diet subsequently.Antibiotics were continued only for Diabetic patients postoperatively for 5 days.All patients were evaluated with DVT risk assessment form , categorized and Low Molecular weight Heparin was prescribed 0.4mg s.c single dose postop for medium and high risk patients.

First dressing change was done at 48 hours post-op and daily dressing done every 24 hours till $5^{th}$ postoperative day. No dressings were applied after $5^{th}$ post-op day.DT tubes were kept in situ until drain fluid was less than 30ml for 3 consecutive days.Suture removal was done on $7^{th}$ postoperative day.Patient was discharged after removal of Drainage tubes with advice of regular follow up for review and physiotherapyReview Protocols:First Month – every 2 weeks Next 5 months- every 4 weeksNext 1 year- every 3 months Second year – every 6 months After second year - annually
All patients were referred to Medical Oncology department after discharge for Adjuvant chemotherapy. All patients undergoing MRM received Adjuvant chemotherapy irrespective of the Stage as per Institutional Tumor Board Protocol.Histopathology of the tumor was reported by the Pathologist as per College of American Pathologists (CAP) Protocol. The same was studied and compared with the preoperative clinic-pathological staging and the Observations were made and Results arrived at.

Statistical analysis was done using the statistical package for social sciences (SPSS).Different statistical methods were used as appropriate. Mean ± SD was determined for quantitative data and frequency for categorical variables. The independent t- test was performed on all continuous variables. The normal distribution data was checked before any t-test. The Chi-Square test was used to analyze group difference for categorical variables. A p- value $< 0.05$ was considered significant

## RESULTS:

## ENROLLED PATIENTS AND THEIR MENOPAUSAL STATUS

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| Stage | | | Number of patients |
|---|---|---|---|
| Premenopausal | | | 16 |
| **Postmenopausal** | | | **24 (19+5)** |
| | Natural menopause | | 19 |
| | Surgical menopause | | 5 (3+2) |
| | | TAH alone | 3 |
| | | TAH with BSO | 2 |

## HISTOLOGY OF THE TUMOR UNDER STUDY

| Histology | No of patients |
|---|---|
| Infiltrating Ductal CA | 38 |
| Invasive Lobular CA | 1 |
| Ductal Carcinoma In situ | 1 |

## NODAL DISSECTION IN SPECIMEN

Maximum nodes dissected in a specimen : 22 Minimum nodes dissected in a specimen : 4

Average number of nodes dissected in a specimen: 13

## COMPARATIVE STATISTICS

N stage identified by clinical examination compared with N stage identified by Pathological Examination

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True Positives (N+ correctly diagnosed as N+) = 12 True negatives(N0 correctly diagnosed as N0) = 15 False positives (N0 incorrectly diagnosed as N+) = 9 False negatives ( N+ incorrectly diagnosed as N0) =4

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## TUMOR CHARACTERISTICS IN N0 DISEASE

Out of the 40 patients under study, 23 were found to have N0 disease in histopathology. The following tumor characteristics were observed in this subgroup of N0 disease.

### TUMOR SIZE:

| Size & Stage | No of patients |
|---|---|
| <1 cm | 0 |
| **1.1 – 2cm** | **9** |
| 2.1 – 3cm | 6 |
| 3.1 – 4cm | 5 |
| 4.1 – 5cm | 3 |
| TOTAL | 23 |

### GRADING OF N0 TUMORS

| Grade | No of patients |
|---|---|
| I | 13 |
| II | 9 |
| III | 1 |
| Total | 23 |

## RECEPTOR STATUS IN N0 TUMORS:

There was a high prevalence of ER positivity and Her2neu negativity among the 23 N0 tumors

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studied.16 out of 23 tumors showed an ER positivity whereas only 7 out of 23 tumors showed PR positivity. 17 out of 23 tumors showed Her2neu negativity.

| Status | ER | PR | Her2neu |
|---|---|---|---|
| Positive | 16 | 7 | 6 |
| Negative | 7 | 16 | 17 |

N stage identified by Sonomammogram compared with N stage identified by Pathological Examination.True Positives (N+ correctly diagnosed as N+) = 16 True negatives(N0 correctly diagnosed as N0) = 19 False positives (N0 incorrectly diagnosed as N+) = 5 False negatives ( N+ incorrectly diagnosed as N0) =0

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Values entered:

| | Condition | | |
|---|---|---|---|
| | Absent | Present | Totals |
| Test Positive | 9 | 12 | 21 |
| Test Negative | 15 | 4 | 19 |
| Totals | 24 | 16 | 40 |

| | Estimated Value | 95% Confidence Interval | |
|---|---|---|---|
| | | Lower Limit | Upper Limit |
| Prevalence | 0.4 | 0.252811 | 0.566089 |
| Sensitivity | 0.75 | 0.474084 | 0.916672 |
| Specificity | 0.625 | 0.407576 | 0.804498 |
| For any particular test result, the probability that it will be: | | | |
| Positive | 0.525 | 0.363442 | 0.681838 |
| Negative | 0.475 | 0.318162 | 0.636558 |
| For any particular positive test result, the probability that it is: | | | |
| True Positive | 0.571429 | 0.34439 | 0.774092 |
| False Positive | 0.428571 | 0.225908 | 0.65561 |
| For any particular negative test result, the probability that it is: | | | |
| True Negative | 0.789474 | 0.539021 | 0.930293 |
| False Negative | 0.210526 | 0.069707 | 0.460979 |
| likelihood Ratios:<br>[C] = conventional<br>[W] = weighted by prevalence | | | |
| Positive [C] | 2 | 1.109881 | 3.603991 |
| Negative [C] | 0.4 | 0.163005 | 0.981568 |
| Positive [W] | 1.333333 | 0.719177 | 2.47196 |
| Negative [W] | 0.266667 | 0.108609 | 0.654743 |

**DISCUSSION:**

There was a higher prevalence of post menopausal subjects in the study group constituting 60% of the study group (24 out of 40 patients).Most of the patients were in the fifth decade of their life (41-50 years) constituting 42.5 % of the study group. This was the largest age group in the study population.In relation to the tumor size, maximum patients belonged to the T1 stage (1.1-2cm) – 15 out of 40 patients constituting 37.5% of the study group.The histology in 95% of tumors were Infiltrating Ductal Carcinoma, 2.5 % of the tumors had Invasive Lobular Carcinoma and another 2.5% Ductal carcinoma In situ

Most of the patients studied had N0 disease – 22 out of 40 patients (55%); 8 of them (20%) had N1 disease; 5 of them (12.5%) had N2 disease; 3 had N3 disease(7.5%), one tumor could not be staged due to insufficient nodal dissection.Average number of nodes dissected in a specimen was 13, which was in line with the NCCN prescribed guidelines of minimum 12 nodes in pathological dissection for accurate N staging.

On comparing the preoperative axillary lymph node staging done by clinical examination and

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sonomammogram with postoperative histopathological staging, Sonomammogram was found to be superior in detecting axillary lymph node metastasis compared to clinical examination.
Sensitivity and Specificity of Clinical examination was 75% and 62.5 % respectively and the Positive predictive value was 57.1 % - means if a node is palpated on clinical examination , the probability that it is a metastatic node is 57.1%. Negative predictive value was 78.9% - that is if a node is not palpable on clinical examination, there is 78.9% possibility that it is an N0 disease.

Sensitivity and Specificity of Sonomammogram was 100% and 79% respectively and the Positive predictive value was 76.1%- means if a node is identified on Sonomammogram , the probability that it is a metastatic node is 76.1%. Negative predictive value was 100% - that is if nodesare not seen on Sonomammogram, there is 100% chance that it is an N0 disease.A subset of 23 patients from the total 40 patients studied had N0 disease. Based on observation certain tumor characteristics of this subgroup were:Majority of N0 tumors were in T1 stage ( 1.1-2cm) – 39.1%Most of them were of Grade I ( 13 out of 23) – 56.5%Majority fell in the 5 th decade ( 41-50 years) – 39.1%69.5% of N0 tumors were ER positive and 73.9% were her2neu negative. This accounted for the good prognosis in this subset.65.2 & (15 out of 23) were postmenopausal patients.

**CONCLUSION:**

As discussed in the Literature review, the onus is now on the surgeon to adopt a more conservative approach to the axilla in Early Breast cancer patients. The aim of this study was to try and define few characteristics in N0 subset of patients in Early Breastcancer in whom a conservative approach to axilla could be adopted. On concluding this study, the following significant characteristics of N0 subgroup of patients could be utilized in selecting patients for conservative management of axilla with non-radical surgical method.

These are in concordance with this study alone, further large community based RCTs are required to confirm these results. The alternative non radical surgical method can be Sentinel node dissection, chemotherapy or Radiotherapy as per the treatment guidelines followed by the surgeon and the study results does notinclude the advantage or disadvantage of any of the described modalities.

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