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

A DISSERTATION SUBMITTED TO

THE TAMILNADU DR.M.G.R MEDICAL UNIVERSITY

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STANLEY MEDICAL COLLEGE AND HOSPITAL

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CHENNAI

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CERTIFICATE

This is to certify that the dissertation titled ***"A COMPARATIVE STUDY BETWEEN PREOPERATIVE AXILLARY LYMPH NODE STATUS WITH POSTOPERATIVE HISTOPATHOLOGICAL DIAGNOSIS IN OPERABLE CASES OF BREAST CANCER"*** is the bonafide work done by ***Dr. ARAVIND MENON K,*** Post Graduate student (2013 – 2016) in the Department of General Surgery, Government Stanley Medical College and Hospital, Chennai under my direct guidance and supervision, in partial fulfillment of the regulations of The TamilNadu Dr. M.G.R Medical University, Chennai for the award of M.S., Degree (General Surgery) Branch - I, Examination to be held in April 2016.

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DECLARATION

I, **Dr.ARAVIND MENON K** solemnly declare that this dissertation titled ***"A COMPARATIVE STUDY BETWEEN PREOPERATIVE AXILLARY LYMPH NODE STATUS WITH POSTOPERATIVE HISTOPATHOLOGICAL DIAGNOSIS IN OPERABLE CASES OF BREAST CANCER"*** is a bonafide work done by me in the Department of General Surgery,Government Stanley Medical College and Hospital, Chennai under the guidance and supervision of my unit chief.

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Examination to be held in April 2016

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Dr.ARAVIND MENON .K

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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 17^{th} 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 these

metastasis 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 study

also 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.

AIMS & OBJECTIVES:

1.To compare the preoperative clinico-radiological axillary lymph node staging with postoperative histopathological staging and determine the accuracy of various staging modalities

2. 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

PLACE OF STUDY:

Department of General Surgery, Govt. Stanley Medical College & Hospital,Chennai

DURATION:

JAN 2014 TO SEP 2015

INCLUSION CRITERIA:

Patients undergoing Modified Radical Mastectomy for Early breast cancerStages Ia,Ib,IIa,IIb

EXCLUSION CRITERIA:

-Patients undergoing - Breast Conservation Surgery

-Neoadjuvant chemotherapy

- Recurrent breast cancer

-Male patients with Breast cancer

METHODOLOGY:

- Patients undergoing Modified Radical Mastectomy for Carcinoma Breast in our Department from January 2015 to September 2015 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.
- Preoperative 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:

  1) All patients were put on overnight fasting for 10 hours as per Anaesthetist requirements

2) Single dose of Proton Pump Inhibitor (Omeprazole) and prokinetic drug (Domperidone) was prescribed for the night prior to surgery. No sedative was used.

3) 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.

4) Preloading was not done for Diabetic patients, patients at high cardiac risk , patients with known End Stage Renal Disease.

5) Short acting Insulin continued till the previous night of surgery and Long acting Insulin continued till prior evening of surgery for diabetic patients

6) Long acting anti hypertensives discontinued 24 hours prior to surgery. Short acting anti hypertensives continued till day of surgery for hypertensive patients.

7) Antiplatelet drugs discontinued 7 days prior to surgery and other cardiac drugs continued till day of surgery for cardiac patients.

8)Inj.Lignocaine and Inj.Tetanus toxoid prescribed prior to surgery along with antibiotic test dose.

9) Skin preparation with preparation of axilla on the side of surgery.

10) 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 stat

11) All patients were operated under General Anaesthesia with endotracheal Tube.

12) Patient position – supine posture with sand bag under the scapula on the site of surgery with arms hyper abducted to $100^{o.}$

13) Skin prepared with 7.5% Povidone Iodine and draped.

14) 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.

15) Flaps were raised in the areolar plane preserving the subdermal plexus of vessels superiorly upto the clavicle, inferiorly upto submammary fold with Monopolar cautery.

16) Dissection was done from medial to lateral aspect removing the breast tissue along with the Pectoral fascia.

11) Axillary dissection was done to remove Level I and Level II lymph nodes keeping the following structures as limits:

superior- axillary vein

inferior- Angular vein

medial- costoclavicular ligament

lateral-Thoracodorsal pedicle

12) Following structures were preserved during Axillary dissection:

-Medial & Lateral Pectoral Nerves

-Nerve to Latissimus Dorsi

-Nerve to Serratus Anterior

-Intercostobrachial Nerves

-Pectoralis Major & mInor

13) Flap tacking was done to the chest wall to minimize seroma as per positive Institutional study results done previously.

14) 14 size double-suction DT was placed – one limb in the superior flap and other in inferior flap.

15) 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.

16) Tight Elastoplaster dressings were applied with axillary padding.

17) Oral diet was resumed starting with clear liquids after 3 hours continuing to semisolid and soft solid diet subsequently.

18) Antibiotics were continued only for Diabetic patients postoperatively for 5 days.

19) 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.

20) First dressing change was done at 48 hours post-op and daily dressing done every 24 hours till 5th postoperative day. No dressings were applied after 5th post-op day.

21)DT tubes were kept in situ until drain fluid was less than 30ml for 3 consecutive days.

22) Suture removal was done on 7th postoperative day.

23) Patient was discharged after removal of Drainage tubes with advice of regular follow up for review and physiotherapy

Review Protocols:

First Month – every 2 weeks

Next 5 months- every 4 weeks

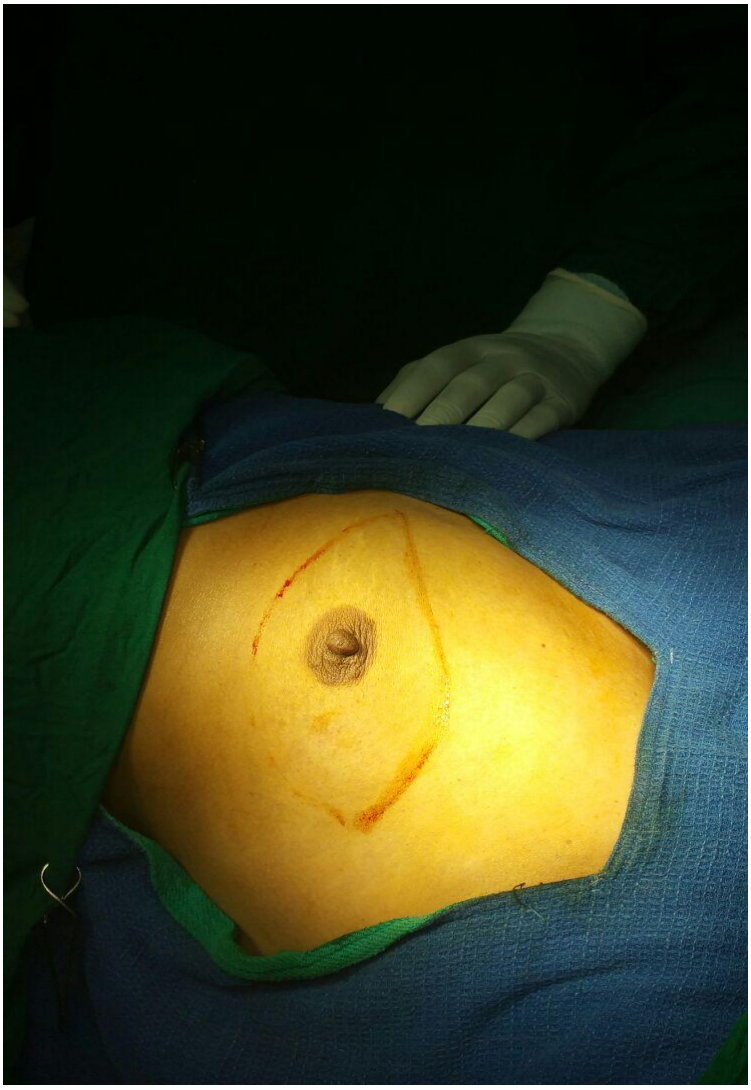
Next 1 year- every 3 months

Second year – every 6 months

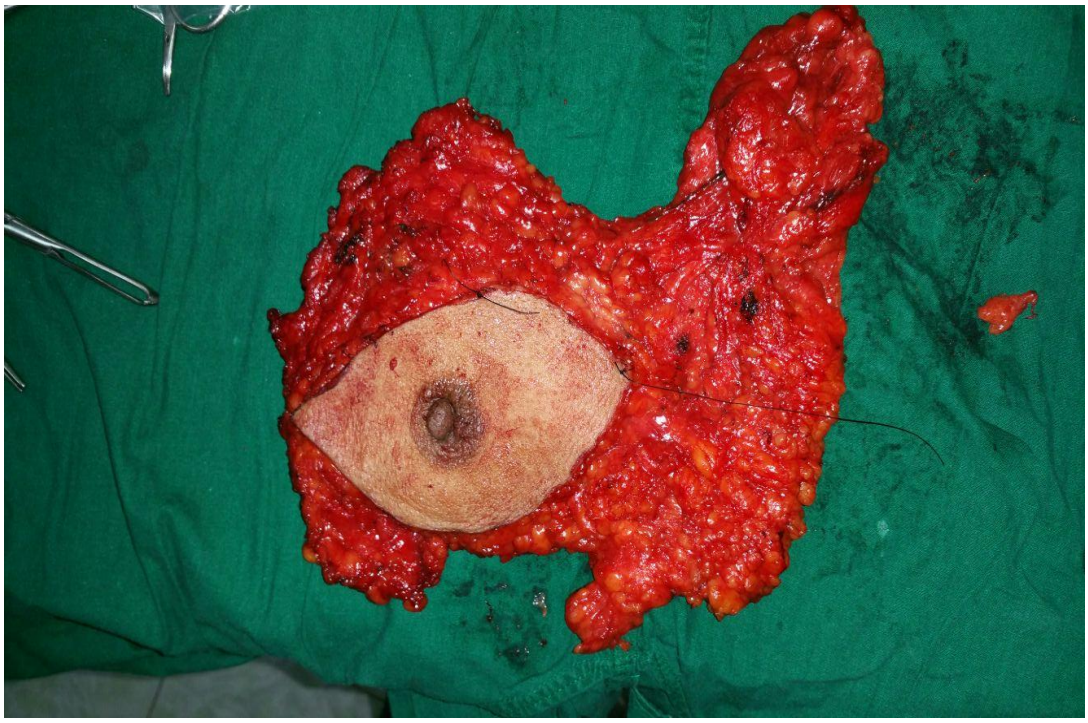
After second year - annually

23) 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.

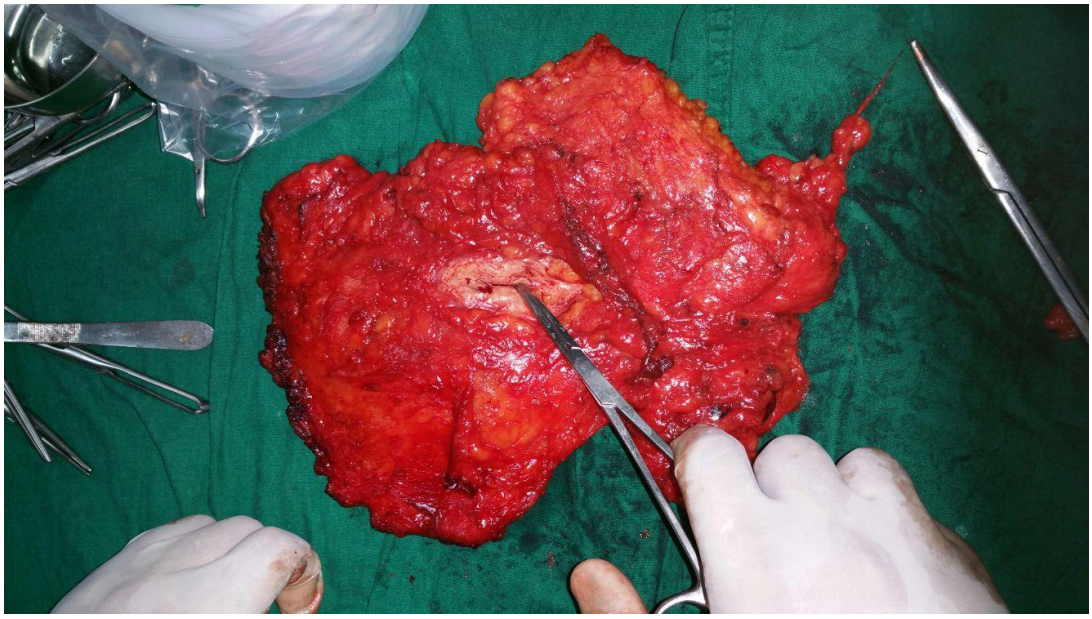
24) Histopathology of the tumor was reported by the Pathologist as per College of American Pathologists (CAP) Protocol. The same was studied and compared with the preoperative clinic-pathological staging and the Observations were made and Results arrived at.



Marking of Skin incision



Post MRM specimen with marking ties



Postoperative grossing of specimen

REVIEW OF LITERATURE

BREAST & AXILLA – RELATED ANATOMY

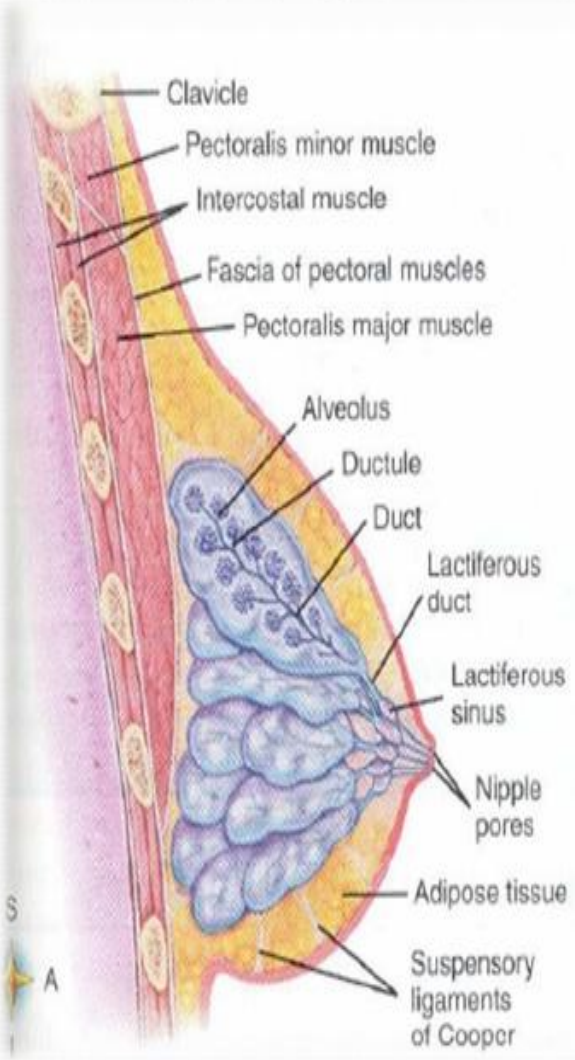
THE BREASTS

The breasts are placed in the subcutaneous layer of the thoracic wall superficial to Pectoralis Major muscle. They extend superiorly from the second rib to sixth rib inferiorly, medially from lateral margin of sternum to anterior axillary line laterally. Nulliparous women have a hemispherical breasts, while multiparous women have pendulant breasts. The mammary gland consists of fifteen to twenty lobes separated by septa of connective tissue and adipose tissue in the subcutaneous layer . The mammary tissue is abundant in the upper outer quadrant of the breast. The mammary tissue projects towards the axilla as an axillary process called tail of Spence .The duct of each lobe, the lactiferous duct ,opens separately into the mammary papilla. Each lobe is formed by lobules which in turn opens into the main duct.

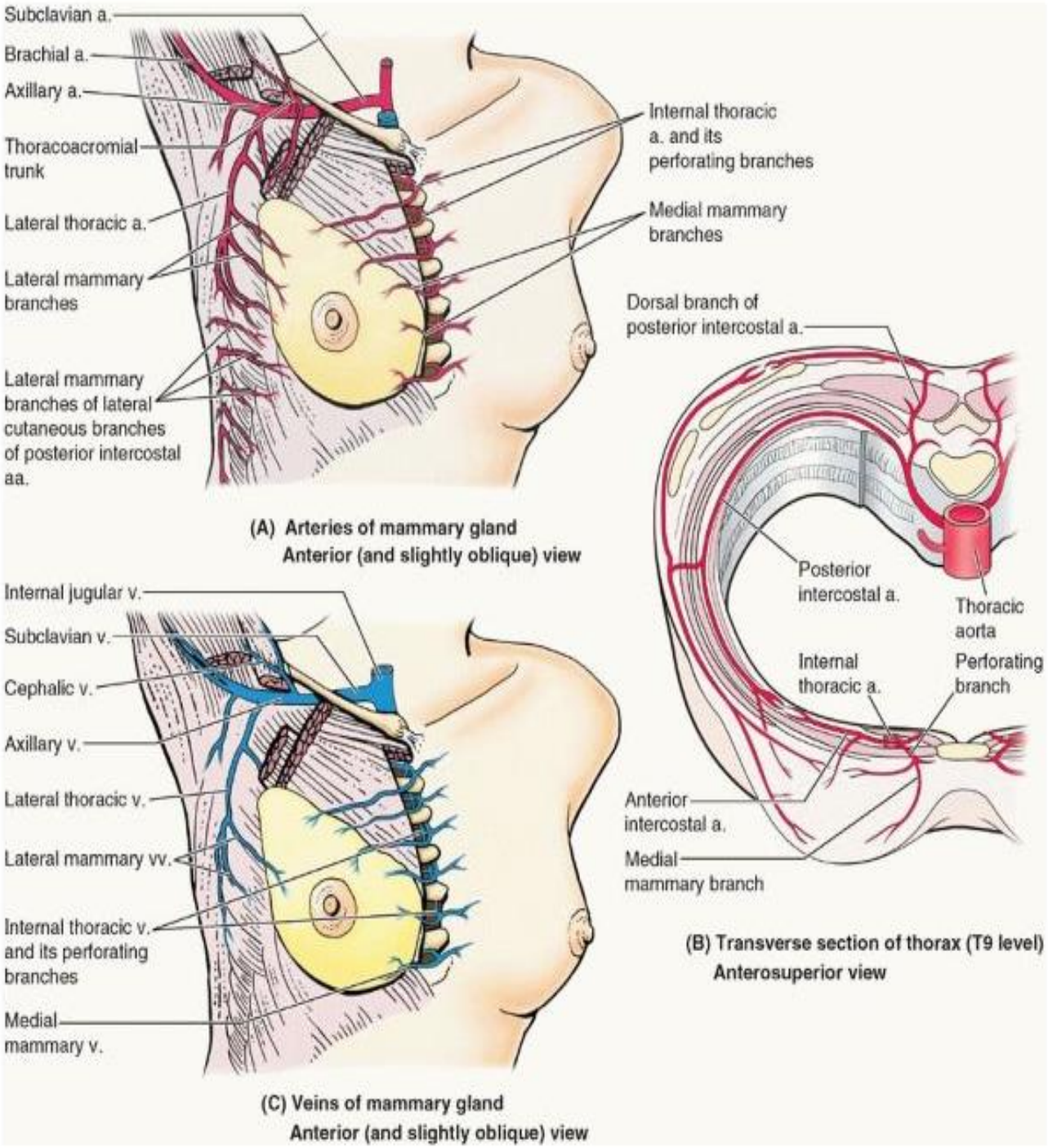
Strands of connective tissue extend from the dermis to the Pectoral fascia crossing the breast anteroposteriorly known as the Suspensory Ligaments of Cooper. The space between the subcutaneous layer and the fascia of the *pectoralis major* muscle is known as the retromammary bursa or also Chassaignac's bursa . This space is responsible for the mobility of the breast on the chest wall. On the surface of areola, it has granular and point like elevations known as areolar tubercles or Montgomery's tubercles .

ANATOMY OF BREAST

- Modified **apocrine sweat glands**.
- Breast parenchyma → 12 to 20 **lobes**.
- Within each lobe – Lactiferous duct - branches repeatedly → leads to no. of terminal ducts → each leads to a **lobule→ contains multiple acini/alveoli** → ***TDLU (TERMINAL DUCT + LOBULE)***
- Spaces around the lobules and ducts and between the lobes are filled with **fatty tissue, ligaments and connective tissue** → ***STROMA***



BLOOD SUPPLY OF THE BREAST



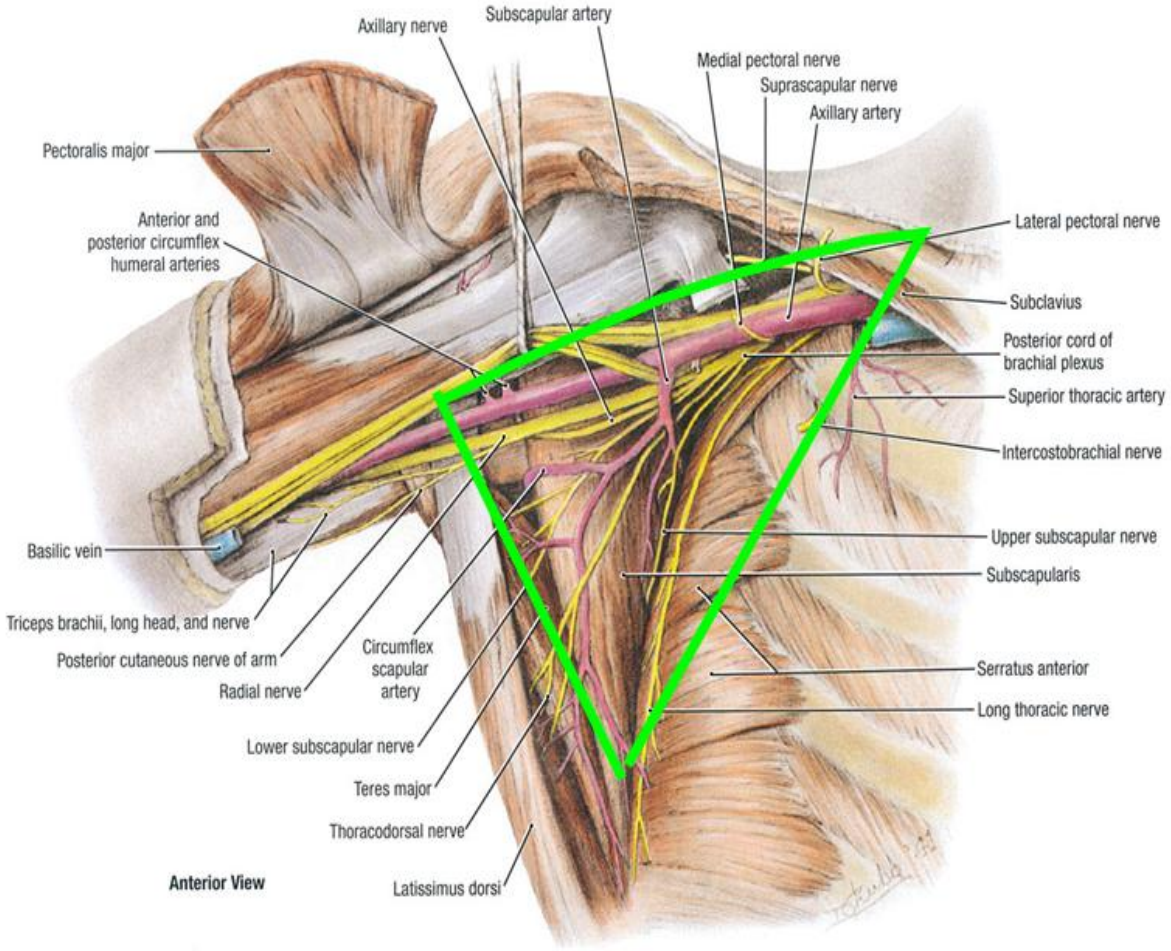
THE AXILLA

It is located between the upper part of the thoracic wall and the arm. It is a connecting passage for the vessels and nerves from the neck to the upper limb. Apex is formed by bones, namely the first rib, the upper margin of the scapula and medial part of the coracoid process of the scapula, and by the clavicle.

Base is formed by the skin and thick layer of the *axillary fascia* between the *pectoralis major* muscle which forms the anterior axillary fold and the *latissimus dorsi* which forms the posterior axillary fold. The anterior wall is formed by the fibres of Pectoralis Major and intermediate portion of Pectoralis Minor. Posterior wall is formed by the *Subscapularis* muscle which forms the posterior wall in its upper part and the *teres major* and *latissimus dorsi* muscles, in its lower part .Medial wall is formed by the first four ribs and *intercostal* muscles and the *serratus anterior* muscle. The Lateral wall is formed by the tendon of the

long head of the *biceps brachii* muscle along with the *coracobrachialis* muscle medially.

2. Contents of the axilla. The contents of the axilla consist of the *Axillary* artery and its branches, the *Axillary* vein and its tributaries, branches from the *Brachial Plexus* and finally lymph vessels and *axillary* lymph nodes.



Anatomy of axilla

Axillary lymph nodes. The axilla contains several lymph node groups. Five axillary lymph node groups are described classically:

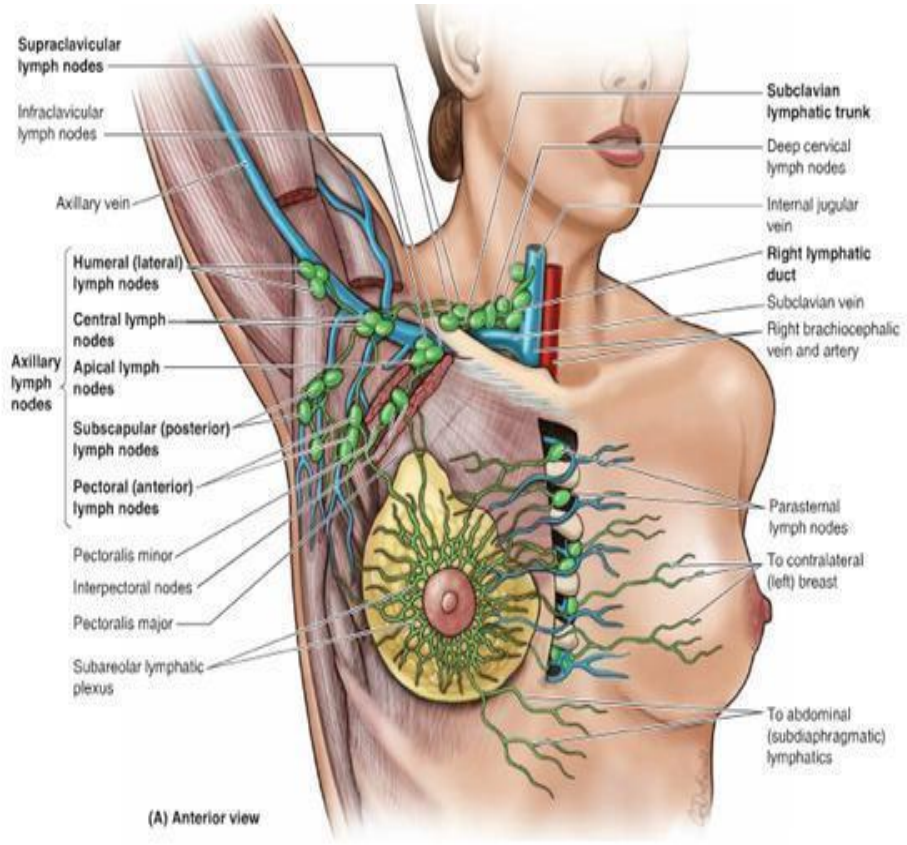
1.*Pectoral or Anterior*

2.Subscapular or Posterior

3.Central

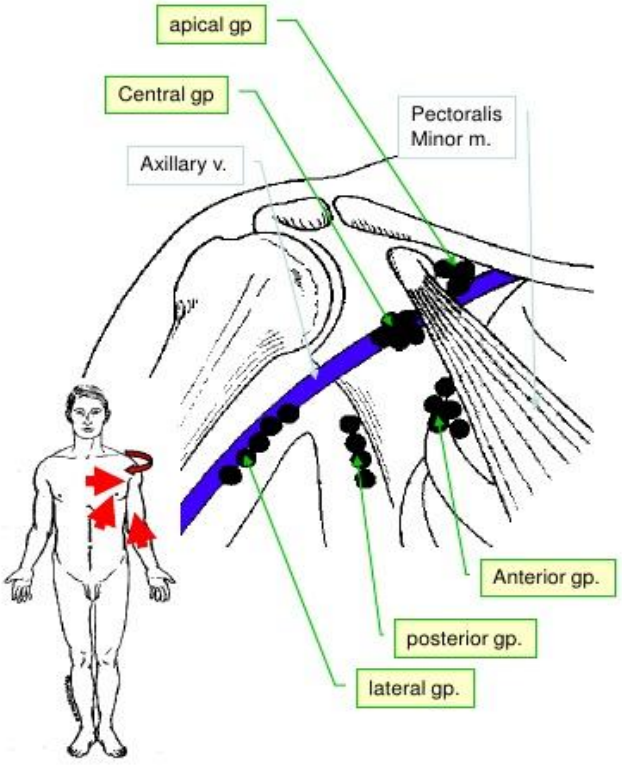
4. Lateral or humeral

5.*Apical.*



Axillary lymph nodes

- **Arrangement**:
- Anterior or pectoral group lying deep to pectoralis major along the inferior border of pectoralis minor muscle: drain most of the lymph of the breast.
- Posterior or subscapular group, lie in front of subscapularis on the posterior wall of the axilla.
- Lateral group lying along the axillary vein.
- Central group lying in the axillary fat.
- Apical group lying behind the clavicle at the apex of the axilla.
- **Drainage area**
  - Breast.
  - Pectoral region.
  - Upper part of the abdominal wall.
  - Upper part of the back.
  - Upper limb.



Dr. Akram Jaffar

The *axillary* lymph nodes are classified into three levels in relation with the *pectoralis minor* muscle. Lymph nodes located laterally or below the lower margin of the *pectoralis minor* muscle are classified as level I lymph nodes. The *pectoral*(*anterior*), *subscapular* (*posterior*) and *humeral*(*lateral*)

are Level I nodes. Lymph nodes located deep to the *pectoralis minor* muscle form the level II lymph nodes and are the *central* lymph nodes and *apical* nodes. Lymph nodes located medially or superiorly to the upper margin of the *pectoralis minor* muscle form the level III lymph nodes, and these are the *apical* lymph nodes .

Through knowledge of anatomy and physiology of the Breast is needed for understanding the Natural history and course of disease in Breast cancer. What was earlier considered a dreadful disease has now become an almost curable malignancy. Research into the natural course of the disease combined with advances in screening, diagnostic and treatment modalities have resulted in this achievement. There has been a drastic rise in the number of Breast cancer cases reported. Whether this is a true statistical increase or due to the newer screening modalities available is a matter of question. What as initially regarded a disease of the

socially forward class of the society has now changed its distribution to the lower class ,probably due to lack of awareness and education among the economically backward sections. Study of the disease requires detailed review of its epidemiology.

EPIDEMIOLOGY

WORLD SCENARIO

Breast cancer is a global disease. According to World Cancer Research fund Statistics 2012 , it is the most common cancer in women worldwide with 1.7 million new cases diagnosed in 2012. This represents 12% of all new cancer cases and 25 % of all cancers in women. Highest incidence of Breast cancer was in North America (92 per 100000 population) and Oceania and least in Asia and Africa.

INDIAN SCENARIO

Though incidence wise Asian countries are at the lower pole, there has been a steady increase in the incidence of Breast cancer

in Asian countries recently compared to prior reports. India too falls in this genre with an increasing incidence. Over 100000 new cases are estimated to be diagnosed annually in India (Nandakumar,1995; Agarwal et al. 2007). As per ICMR-PBCR data,Breast cancer is the commonest cancer among women in urban registries of Delhi, Mumbai, Ahmedabad, Kolkata and Trivandrum where it constitutes more than 30% of all cancers in females(National Cancer Registry Programme, 2001). The age standardized Incidence rates (AARs) range from 6.2-39.5 per 100000 Indian women.

Fig. 2.6: Ten Leading Sites of Cancer - Mumbai (2006-2008)

Age Adjusted Incidence Rates given in parentheses

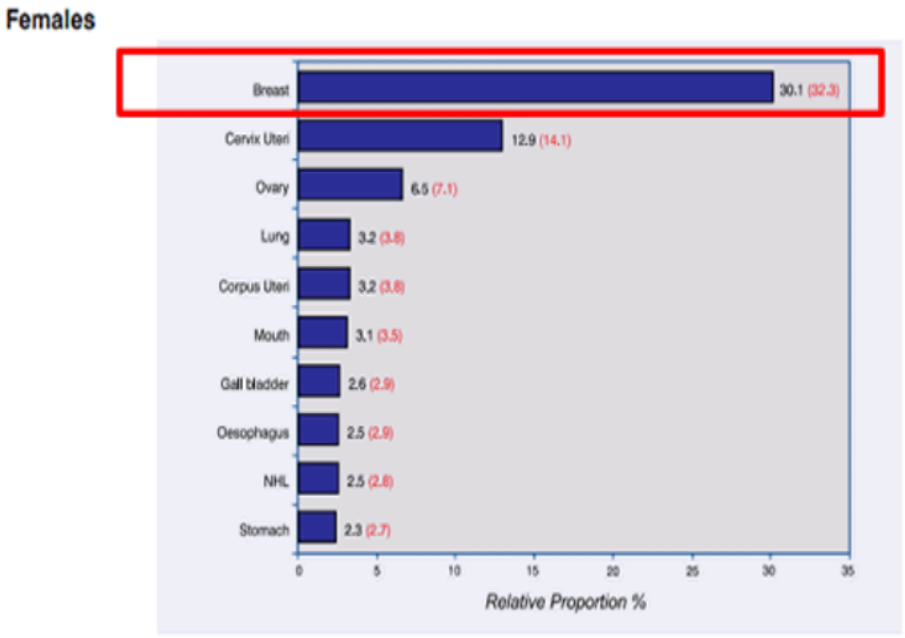
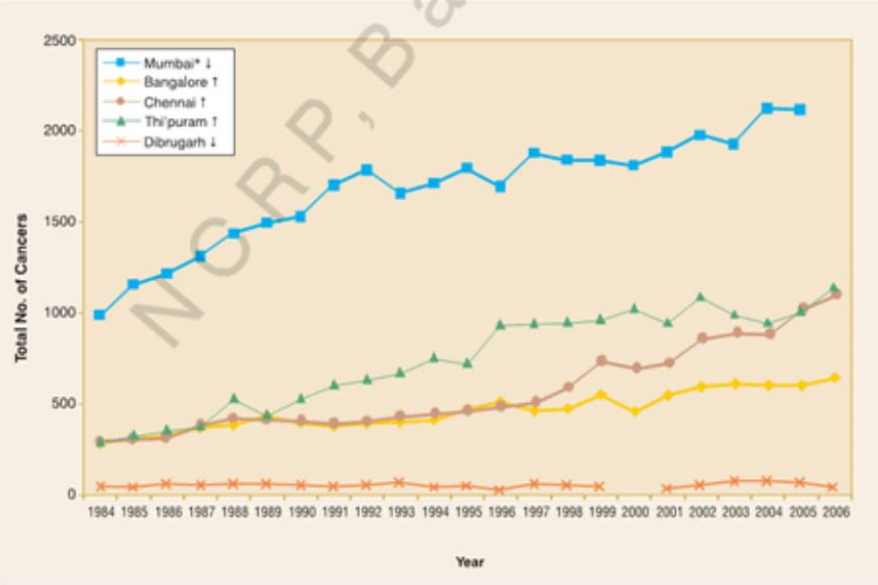
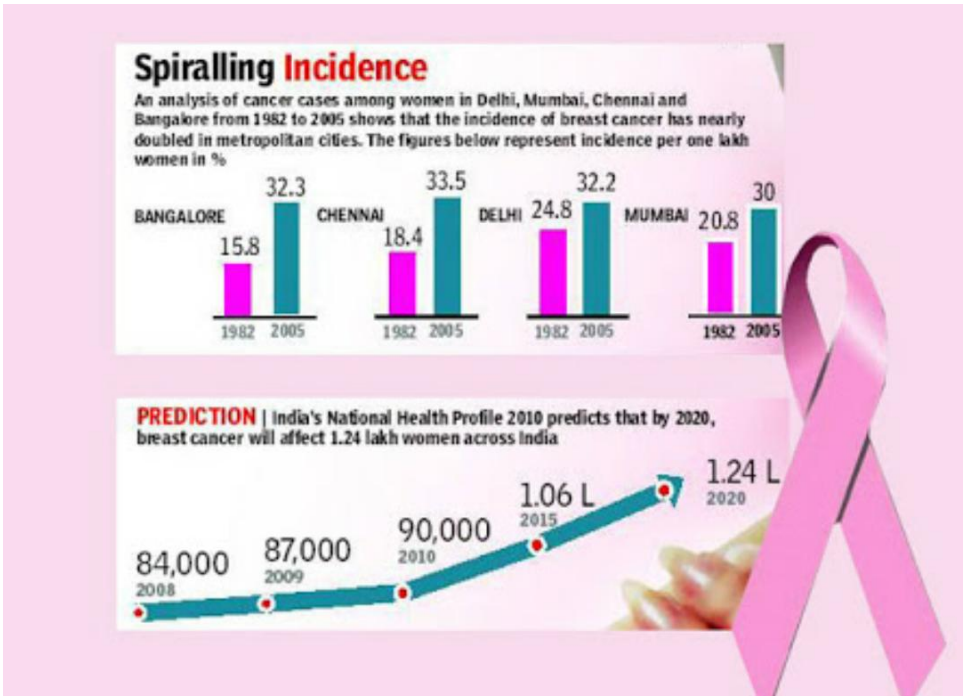


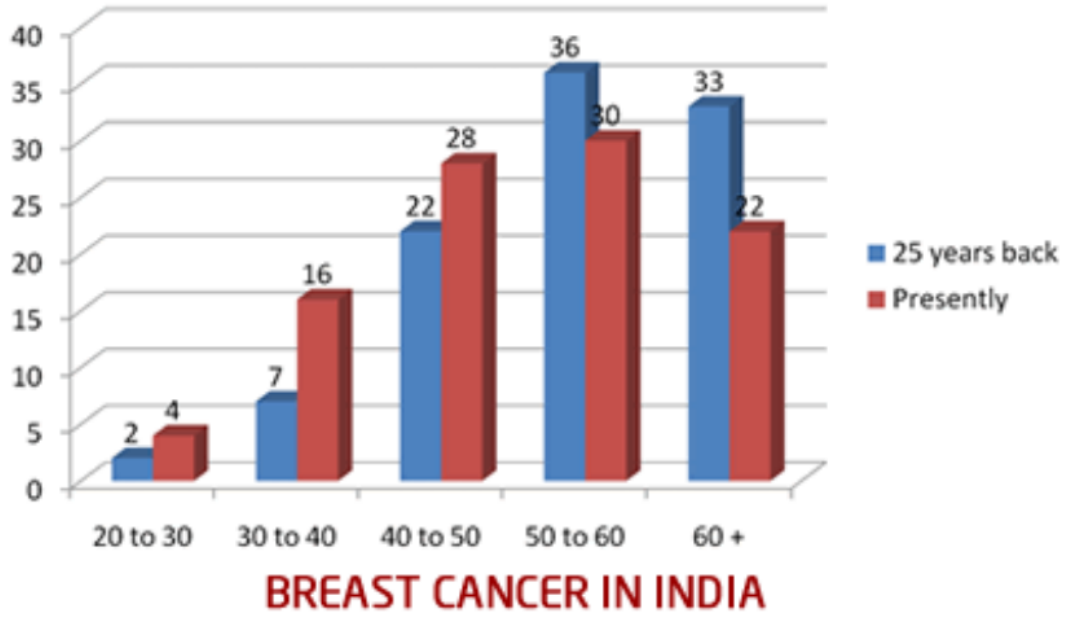
Fig. 14.1 Trends in actual numbers of cancers- Female Breast



The incidence of this disease has been consistently increasing and is estimated to have risen by 50% between 1965 and 1985 (Saxena et al. 2002) .



INCREASING INCIDENCE AMONG YOUNG AGE



The rise in incidence of 0.5-2% per annum has been seen across all regions of India and in all age groups but more so in the younger age groups (<45years) (Murthy et al. 2007). A significant proportion of Indian breast cancer patients are younger than 35 years of age. This varies from 11% at Tata Memorial Hospital, Mumbai (Dinshaw,2006) to 26% at SGPGIMS, Lucknow

(Agarwal et al., 2007) Alarming fact is that young age disease has been associated with larger tumor size, higher metastatic nodes, poorer grades of tumor, poorer overall survival rates.

RISK FACTORS FOR BREAST CANCER

NON MODIFIABLE RISK FACTORS:

1. GENETIC FACTORS

Genetic factors are known to be involved in increasing the risk of a number of cancers, including breast cancer. A woman's inherited genetic profile impacts her risk of developing breast cancer. Approximately 5-10% of breast cancers are attributable to genetic factors. The most common breast cancer susceptibility genes are BRCA1, BRCA2, PTEN (Cowden syndrome), and TP53 (Li-Fraumeni syndrome). Each child of a parent with a mutation has a 50% chance of inheriting the mutation. For persons with BRCA1 or BRCA2 mutations, the estimated risks of developing breast cancer by 70 years of age is about 55-65% (BRAC1) and 45-47% (BRAC2). BRCA1 and BRCA2 mutations can be inherited from either parent. Genetic testing requires both laboratory expertise and genetic counselling

services, which are often not available in low-resource settings.

2. FAMILY HISTORY OF BREAST CANCER: One's risk of developing breast cancer increases with the number of affected first-degree relatives. This is thought to be due to a combination of factors, both inherited (although not a specific gene) and environmental.

3. PERSONAL HISTORY OF BREAST CANCER: For women with a personal history of breast cancer (DCIS or invasive breast cancer) there is an increased risk of developing a second breast cancer in either the same breast or the opposite breast (estimates suggest a 4% increase over 7.5 years).

4. AGE: Patients above 50 years of age are at increased risk of developing Breast cancer especially post menopausal women. Cancer in the breast associated with BRCA mutations tend to occur at younger age.

5.SEX:

Breast cancer is a common cancer in females and female sex is a higher risk for developing Breast cancer. However , when a breast lump or malignant nodule develops in the male from mammary tissue, it tends to be more aggressive and metastasizes early due to lesser amount intervening tissue between the breast and chest wall.

MODIFIABLE RISK FACTORS:

1. IONISING RADIATION: Exposure to ionizing therapeutic radiation of the chest at a young age (highest risk if exposed at 10-14 years of age) increases one's risk; however, the risk of developing decreases dramatically if radiation is administered after age 40. For example, therapeutic radiation at a young age for treatment of Hodgkin lymphoma is associated with an increased risk of breast cancer. However, there are no data to suggest that current radiation therapy practices administered as part of breast cancer treatment, (i.e., radiation therapy after lumpectomy) increases the risk for developing a second breast cancer. Additionally, mammography and chest x-rays do not appear to increase breast cancer risk.

2. HORMONAL AND REPRODUCTIVE FACTORS: Endogenous hormones (hormones produced within the body's

cells), particularly estrogen exposure, play a role in breast cell growth and proliferation. Elevated or prolonged endogenous estrogen levels are associated with an increase risk of breast cancer in post-menopausal women. Known risk factors for breast cancer are associated with reproductive factors which extend natural exposure to hormones produced by the ovaries such as early onset of menstruation, late onset of menopause, later age of first pregnancy (i.e., over 30 years of age) and never having given birth. Laboratory evidence also suggests that higher levels of other endogenous hormones, (such as insulin and insulin-like growth factor (IGF), may play a role in breast cancer development.

3. ESTROGEN HORMONES:

The use of prolonged hormone replacement therapy (HRT) after menopause has been associated with an increased risk of breast

cancer. In a large randomized trial, women who took the combination of estrogen and progesterone for more than 5 years after menopause had an increased risk of being diagnosed with breast cancer. It is now recommended that HRT should be used only for specific indications (such as significant menopausal symptoms) and the duration of treatment should be limited.

4. WEIGHT (OBESITY):

An association between obesity and breast cancer risk

is thought to be at least partially related to the role of fat cells in

contributing to levels of circulating hormones and other factors.

Adiposity (fat cell volume) can affect circulating hormones as

estrogen precursors are converted to estrogen in fat cells.

Women's estrogen levels also vary based on their

menopausal status, so the effect of obesity on breast cancer risk

may depend on the menopausal status of the woman, with post-menopausal women being more affected than premenopausal women. Some experts suggest that up to 20% of breast cancer cases could be avoided by increasing physical activity and avoiding weight gain.

HISTOLOGICAL TYPES OF BREAST CANCER

The most common histological type is the Ductal carcinoma, followed by lobular carcinomas, and malignancies arising from other connective tissues. This list enlists the histological types of Breast cancer as per American Joint Committee on Cancer (AJCC) classification:

DUCTAL

- Intraductal (in situ)

- Invasive with predominant intraductal component
- Invasive, NOS
- Comedo
- Inflammatory
- Medullary with lymphocytic infiltrate
- Mucinous (colloid)
- Papillary
- Scirrhous
- Tubular
- Other

LOBULAR

- In situ
- Invasive with predominant in situ component
- Invasive

NIPPLE

- Paget's disease, NOS
- Paget's disease with intraductal carcinoma
- Paget's disease with invasive ductal carcinoma

OTHERS

- Undifferentiated carcinoma

Histological evaluation of a breast cancer is necessary to provide a diagnostic and prognostic picture as well to determine the future course of treatment

BREAST CANCER STAGING

The American Joint Committee on Cancer (AJCC) staging system divides patients into 4 stages according to the TNM system, which is based on tumor size (T), lymph node status (N), and distant metastasis (M).

TX		Primary tumor cannot be assessed
T0		No evidence of primary tumor
Tis		Carcinoma in situ
Tis (DCIS)		Ductal carcinoma in situ
Tis (LCIS)		Lobular carcinoma in situ
Tis (Paget's)		Paget's disease of the nipple NOT associated with invasive carcinoma and/or carcinoma in situ (DCIS and/or LCIS) in the underlying breast parenchyma. Carcinomas in the breast parenchyma associated with Paget's disease are categorized based on the size and characteristics of the parenchymal disease, although the presence of Paget's disease should still be noted
T1		Tumor ≤20 mm or less in greatest dimension
	T1mi	Tumor ≤1 mm in greatest dimension
	T1a	Tumor >1 mm but ≤5 mm in greatest dimension
	T1b	Tumor >5 mm but ≤10 mm in greatest dimension
	T1c	Tumor >10 mm but ≤20 mm in greatest dimension
T2		Tumor >20 mm but ≤50 mm in greatest dimension
T3		Tumor >50 mm in greatest dimension
T4		Tumor of any size with direct extension to the chest wall and/or to the skin (ulceration or skin nodules).

Regional Lymph Nodes (N)

Clinical

NX		Regional lymph nodes cannot be assessed (e.g., previously removed)
N0		No regional lymph node metastasis
N1		Metastases to movable ipsilateral level I, II axillary lymph node
N2		Metastases in ipsilateral level I, II axillary lymph nodes that are clinically fixed or matted; or in clinically detected* ipsilateral internal mammary nodes in the *absence* of clinically evident axillary lymph node metastases
	N2a	Metastases in ipsilateral level I, II axillary lymph nodes fixed to one another (matted) or to other structures
	N2b	Metastases only in clinically detected* ipsilateral internal mammary nodes and in the *absence* of clinically evident level axillary lymph node metastases
N3		Metastases in ipsilateral infraclavicular (level III axillary) lymph node(s) with or without level I, II axillary lymph node involvement or in clinically detected* ipsilateral internal mammary lymph node(s) with clinically evident level I, II axillary lymph node metastases; or metastases in ipsilateral supraclavicular lymph node(s) with or without axillary or internal mammary lymph node involvement
	N3a	Metastasis in ipsilateral infraclavicular lymph node(s)
	N3b	Metastasis in ipsilateral internal mammary lymph node(s) and axillary lymph node(s)
	N3c	Metastasis in ipsilateral supraclavicular lymph node(s)

ANATOMIC STAGE/PROGNOSTIC GROUPS

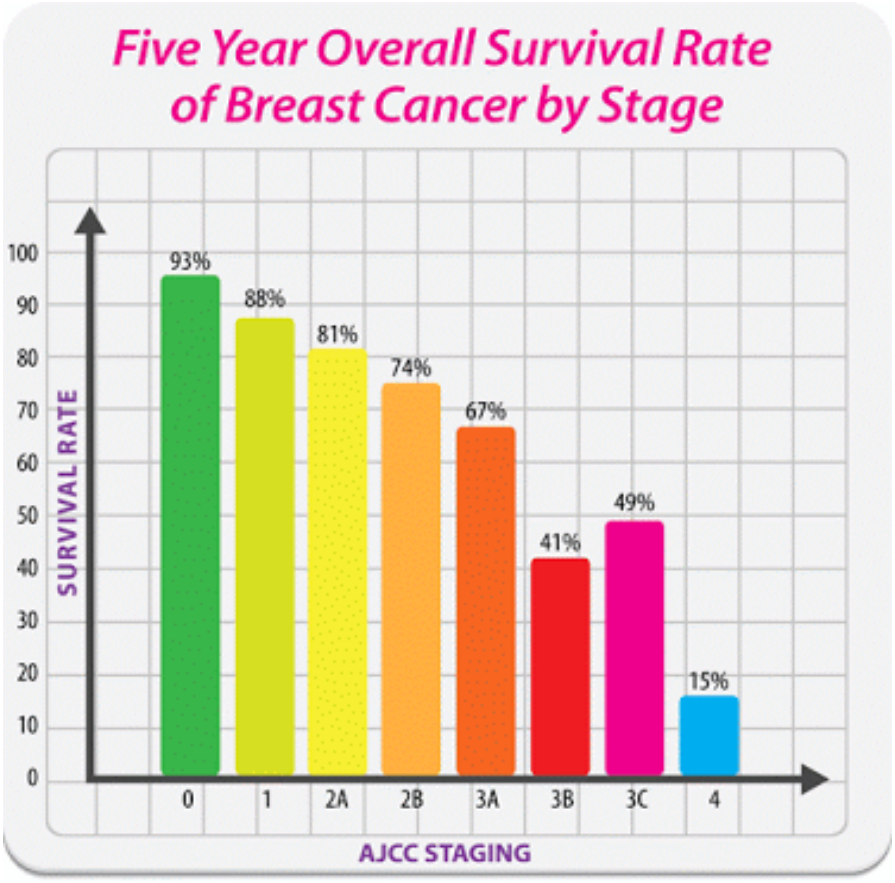
Stage 0	Tis	N0	M0	**Stage IIIA**	T0	N2	M0
Stage IA	T1*	N0	M0		T1*	N2	M0
Stage IB	T0	N1mi	M0		T2	N2	M0
	T1*	N1mi	M0		T3	N1	M0
Stage IIA	T0	N1**	M0		T3	N2	M0
	T1*	N1**	M0	**Stage IIIB**	T4	N0	M0
	T2	N0	M0		T4	N1	M0
Stage IIB	T2	N1	M0		T4	N2	M0
	T3	N0	M0	**Stage IIIC**	Any T	N3	M0
				Stage IV	Any T	Any N	M1

NOMENCLATURE

DESCRIPTION	STAGE
In Situ Breast Cancer	**Stage 0**
Early Invasive Breast Cancer	**Stage I,IIA,IIB**
Locoregional Breast Cancer	**Stage IIIA or IIIB**
Metastatic Breast Cancer	**Stage IV**

The 5-year survival rates are highly correlated with tumor stage. The AJCC staging system correlates well with the prognosis of staging groups though it does not take into account other associated factors like Tumor grading or histology or Receptor status.

Bases on observations, survival rates for each Staging group has been assigned as follows:



Adapted from American Cancer Society and National Cancer Data Base

PROGNOSTIC FACTORS

Several tumour characteristics that have important prognostic significance need to be considered when designing an optimal treatment strategy for the individual patient. These are:

- **Age of patient.**

- **Tumor size.**

- **Axillary lymph node status.** This is the most important predictor of disease recurrence and survival: 70%–80% of patients with node-negative status survive 10 years; prognosis worsens as the number of positive lymph nodes increases. About 40%–50% of patients with 1 to 3 positive nodes survive 10 years, whereas only 15% of those with more than 4 nodes survive with surgical treatment alone.

- **Histological grade.**

- **Estrogen receptor (ER) and progesterone receptor (PR)**

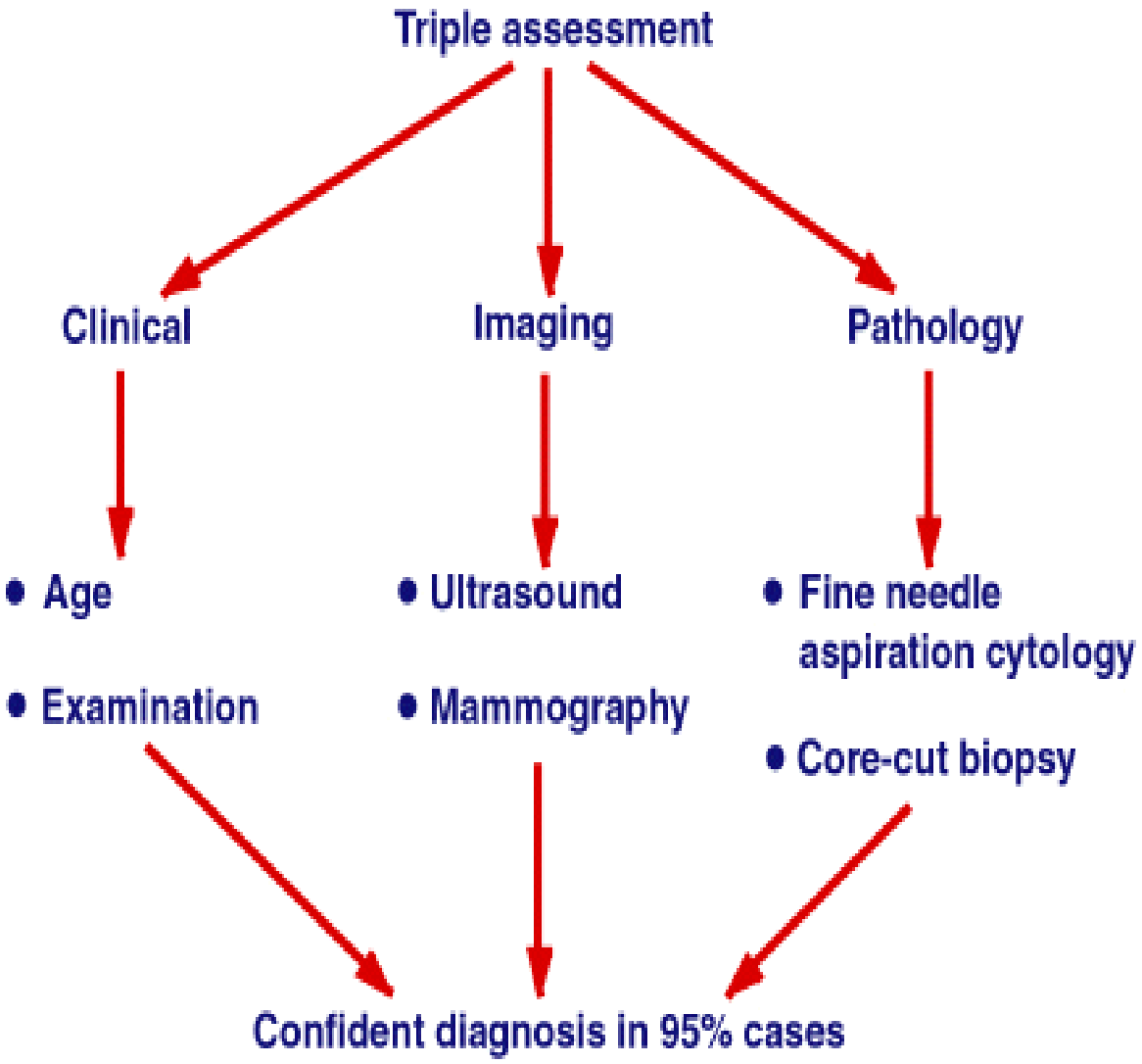
status. These are cellular proteins present in hormone-responsive target tissues. Patients with receptor-positive primary tumors have lower rates of recurrence and longer survival than those with receptor-negative tumors.

- **HER2-neu**(C-erbB2).

- **Tumor suppressor genes** p53 and bcl-2 are presently considered research tools.

MANAGEMENT OF BREAST CANCER

An integral part of the workup of any case of Breast cancer Is Triple assessment. It consists of Clinical Examination, Imaging and Tissue sampling as shown.



NCCN GUIDELINES FOR MANAGEMENT

The National Comprehensive Cancer Network is a not for profit alliance 26 of world's leading cancer centres dedicated improving quality, effectiveness and efficacy of cancer care so that patients can live better lives. The NCCN Guidelines are a comprehensive set of guidelines detailing the sequential management decisions and interventions that currently apply to 97% cancers affecting patients in United States. NCCN Guidelines provide recommendations based on best evidence available at the time they are derived. Because new data are published continuously, NCCN Guidelines are updated continuously and revised to reflect new data and clinical information that may add to or alter current clinical practice standards. Hence NCCN Guidelines is a set of scientific guidelines which can be followed as it is based on evidence based published data. The following are the guidelines for the workup and management :

A. Early Breast cancer

B. Locally Advanced Breast Cancer

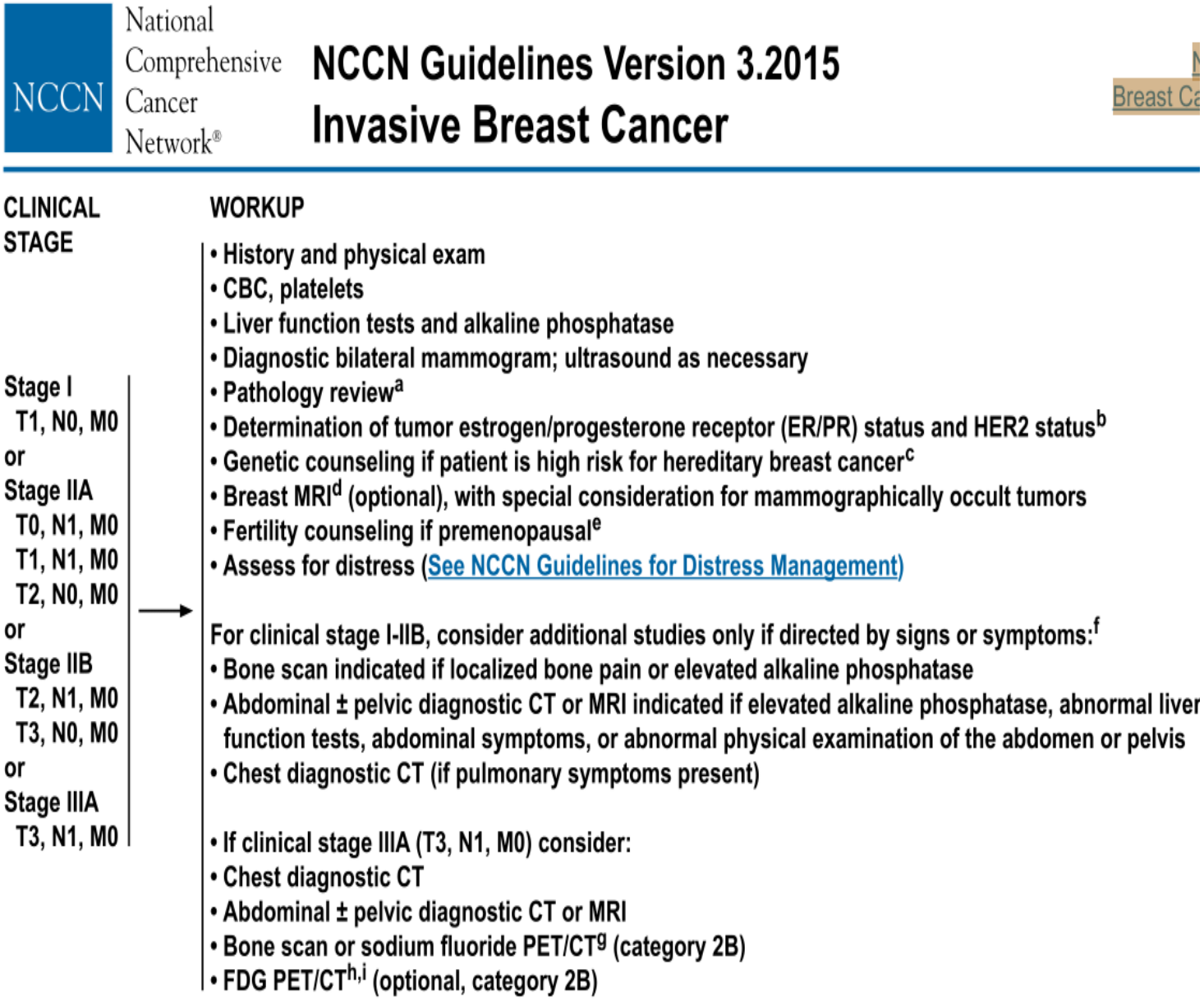
C. Metastatic Breast Cancer

D. Guidelines for Neo-adjuvant/Adjuvant chemotherapy

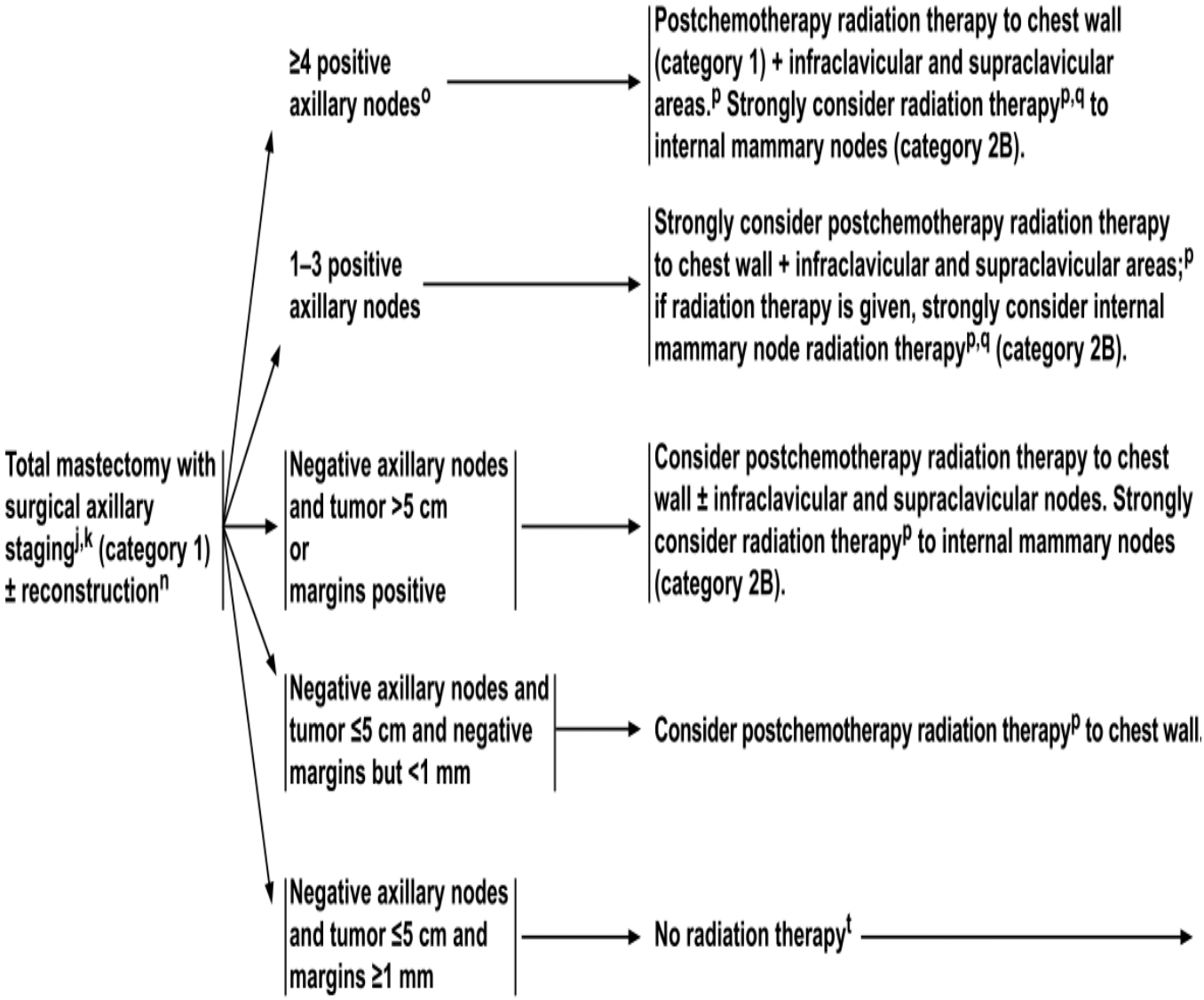
E. Guidelines for Adjuvant Hormone Therapy

F. Guidelines for Adjuvant Radiotherapy

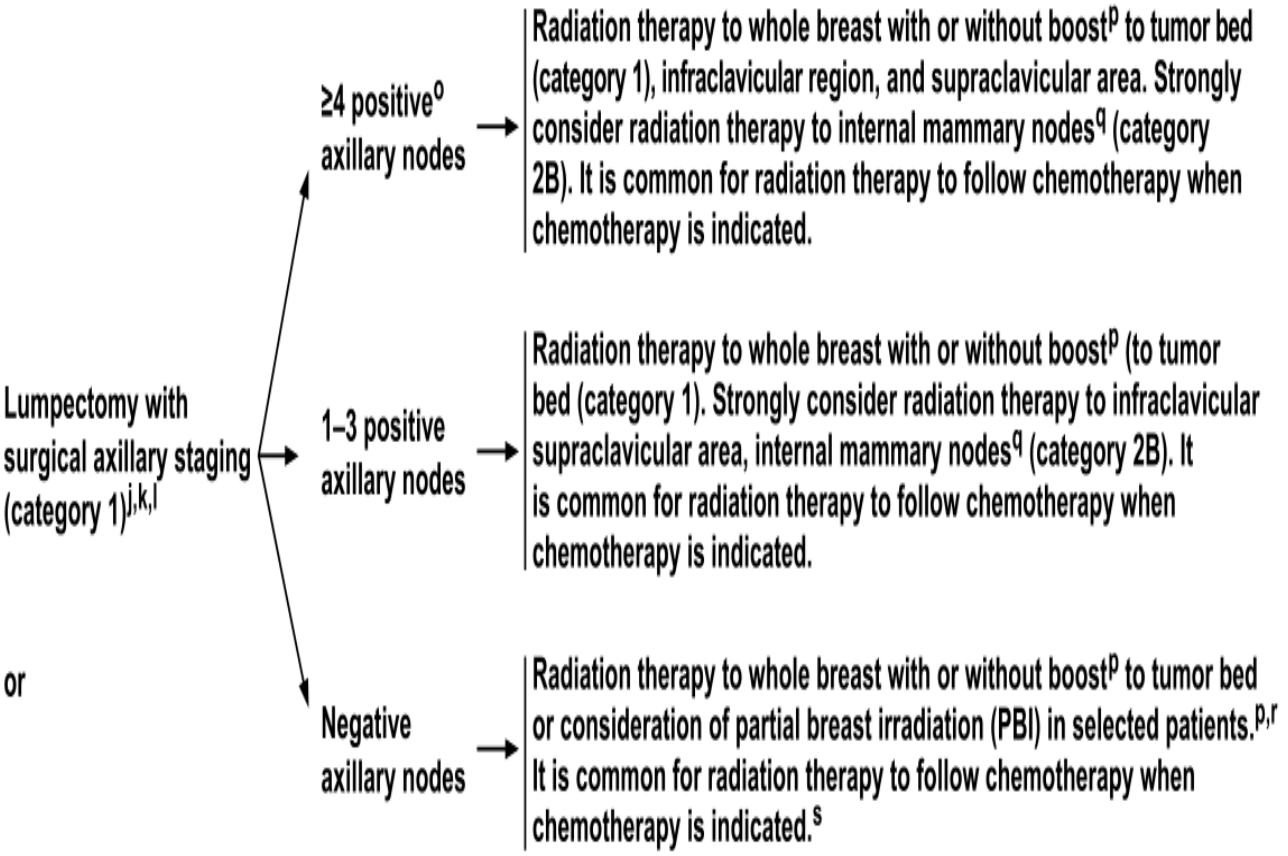
A.EARLY BREAST CANCER



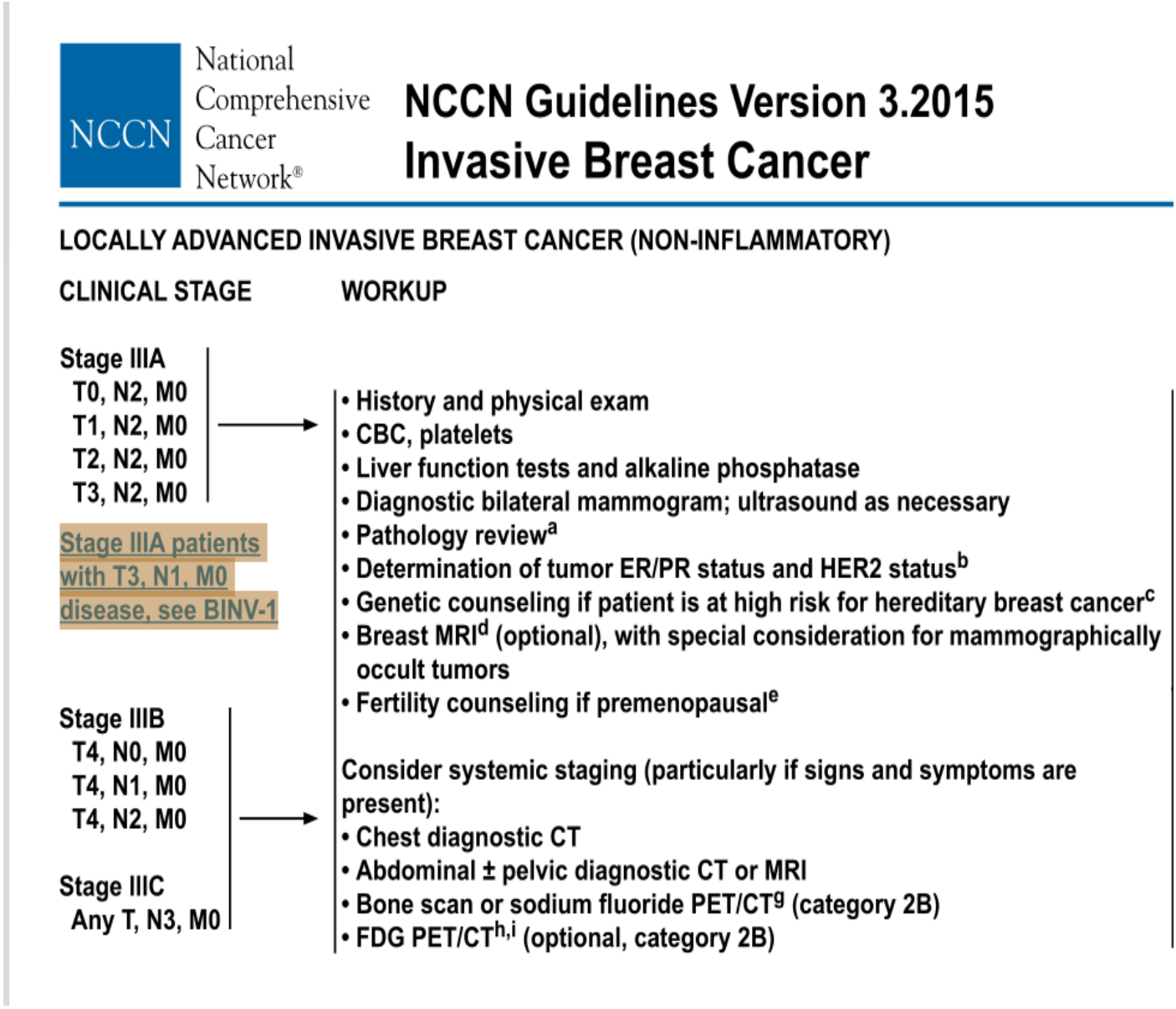
LOCOREGIONAL TREATMENT OF CLINICAL STAGE I, IIA, OR IIB DISEASE OR T3, N1, M0



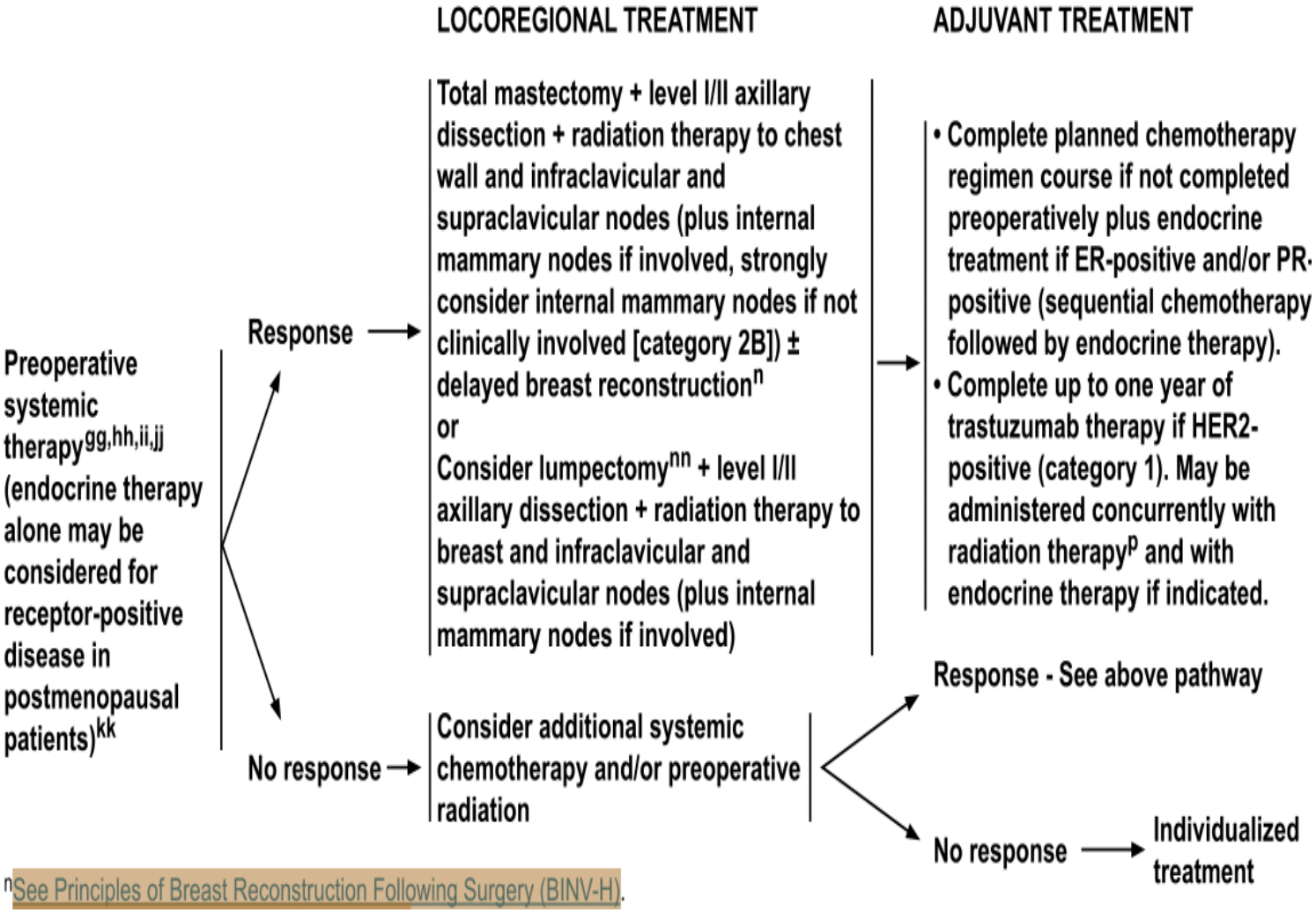
LOCOREGIONAL TREATMENT OF CLINICAL STAGE I, IIA, OR IIB DISEASE OR T3, N1, M0



B.LOCALLY ADVANCED BREAST CANCER

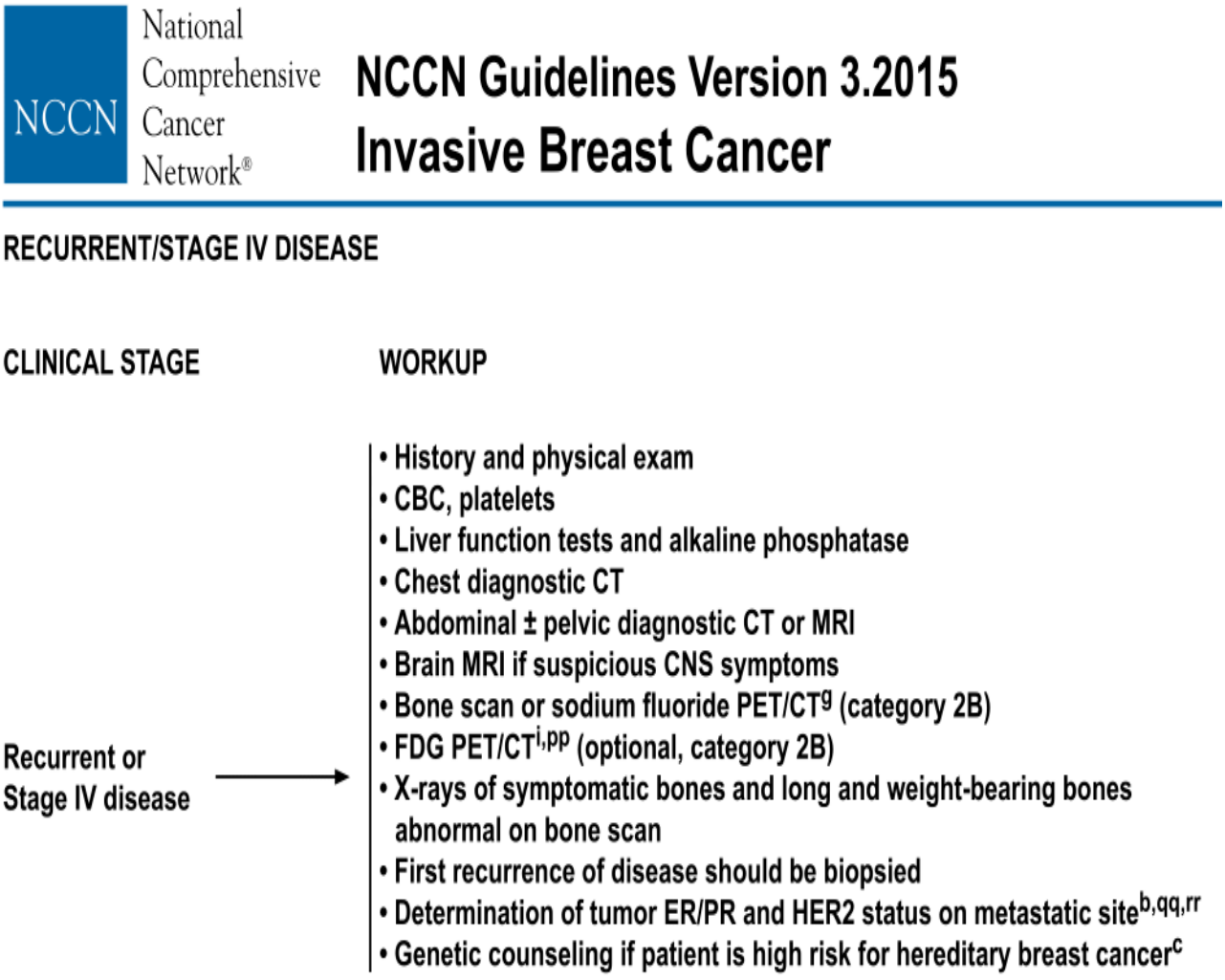


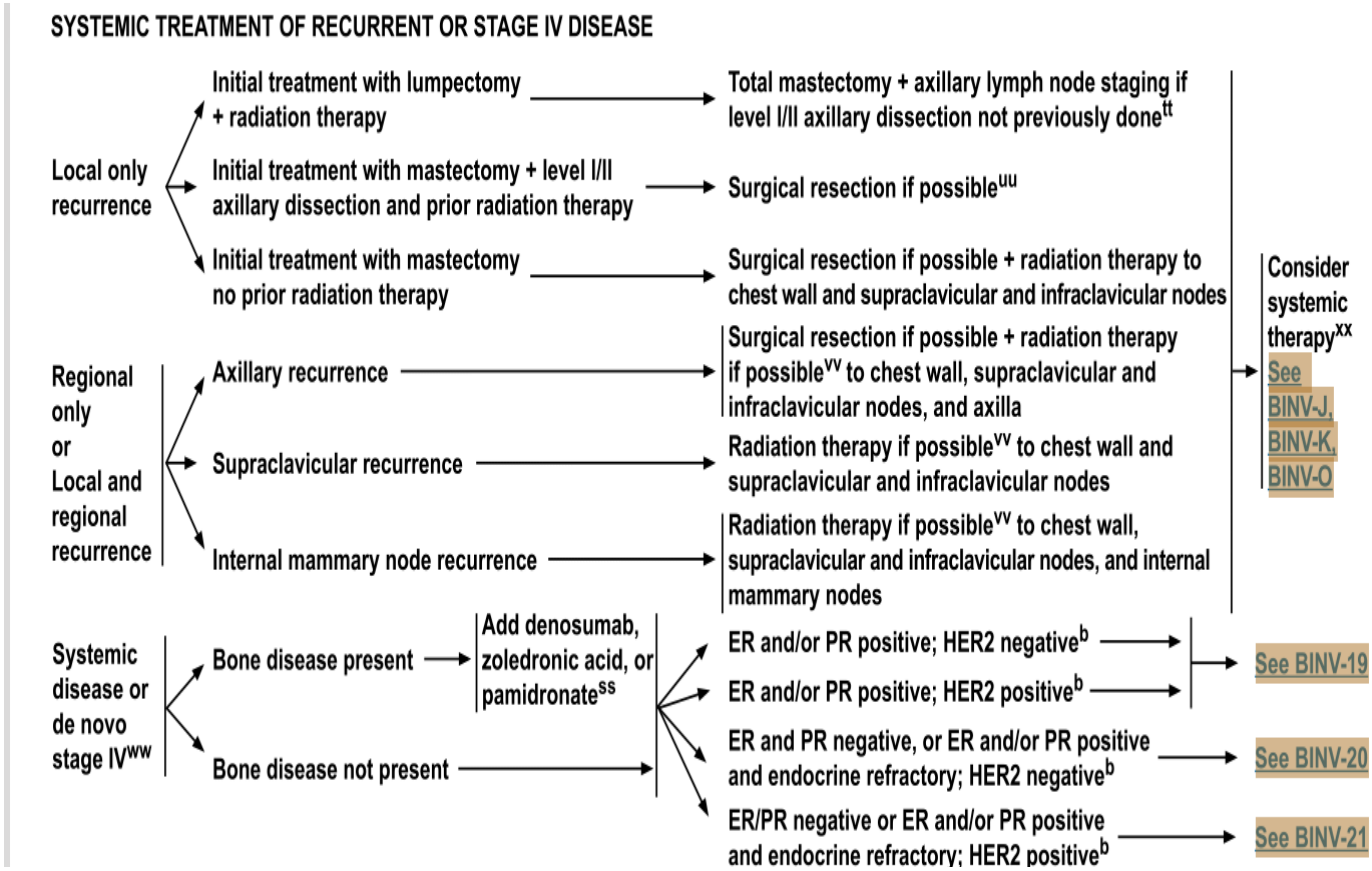
PREOPERATIVE SYSTEMIC THERAPY FOR LOCALLY ADVANCED INVASIVE BREAST CANCER (NON-INFLAMMATORY)

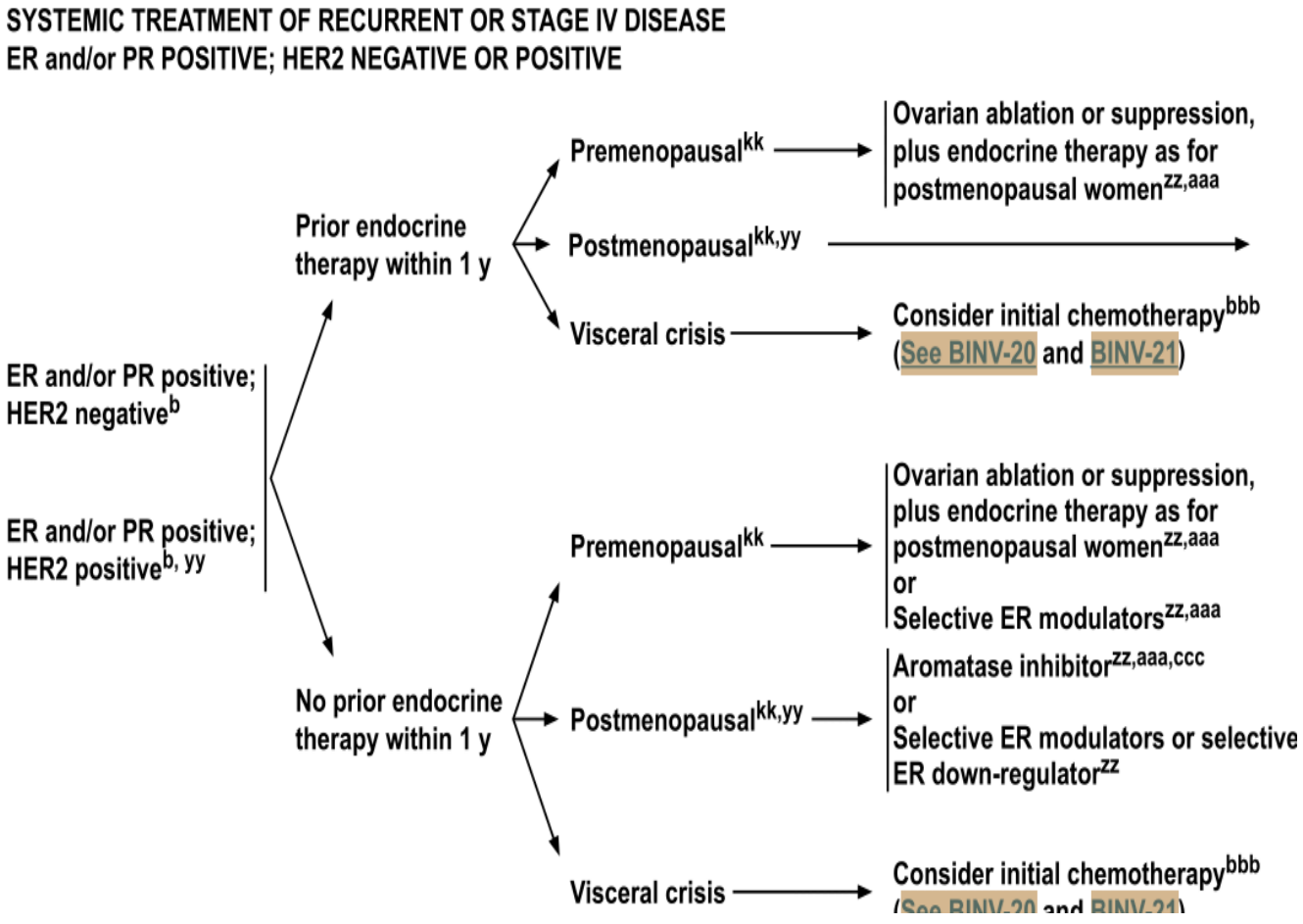


[n] See Principles of Breast Reconstruction Following Surgery (BINV-H).

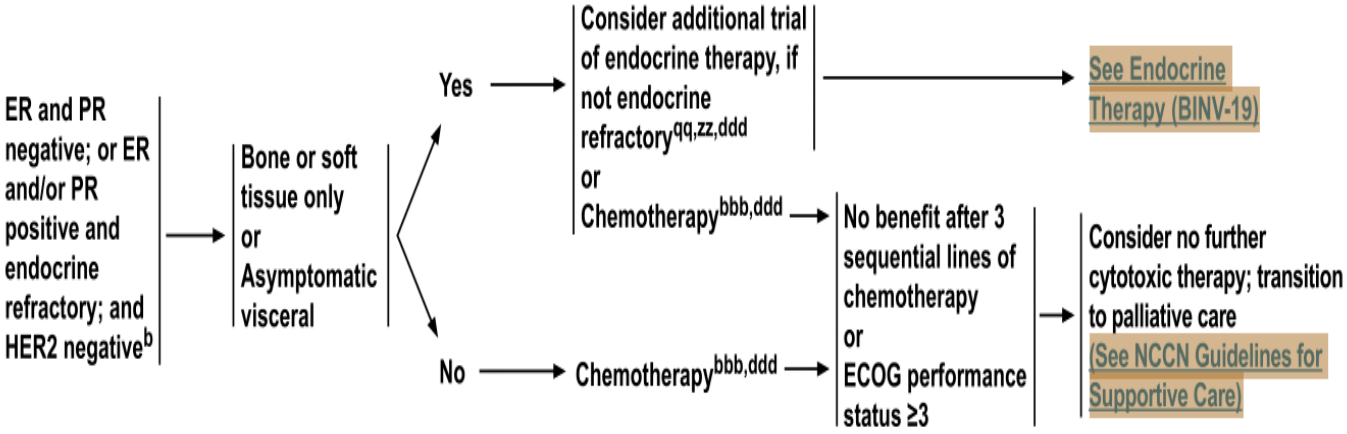
C.METASTATIC BREAST CANCER



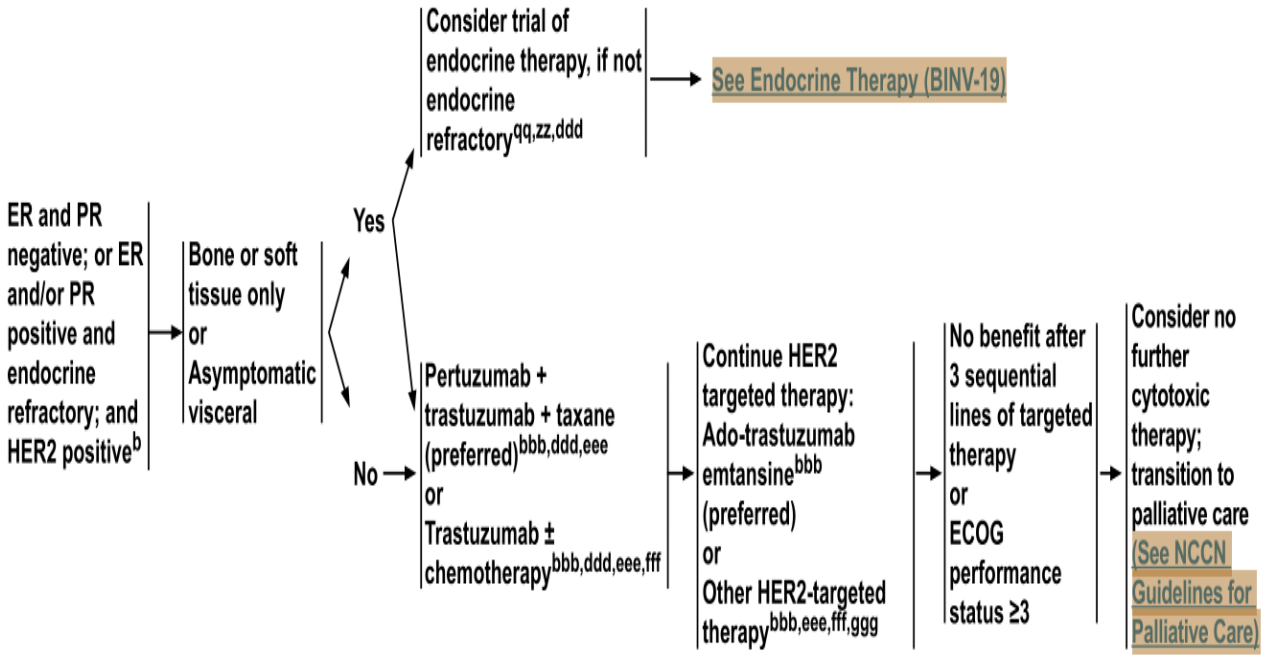

SYSTEMIC TREATMENT OF RECURRENT OR STAGE IV DISEASE
Local only recurrence
Initial treatment with lumpectomy + radiation therapy
Total mastectomy + axillary lymph node staging if level I/II axillary dissection not previously done[tt]
Initial treatment with mastectomy + level I/II axillary dissection and prior radiation therapy
Surgical resection if possible[uu]
Initial treatment with mastectomy no prior radiation therapy
Surgical resection if possible + radiation therapy to chest wall and supraclavicular and infraclavicular nodes
Regional only or Local and regional recurrence
Axillary recurrence
Surgical resection if possible + radiation therapy if possible[vv] to chest wall, supraclavicular and infraclavicular nodes, and axilla
Supraclavicular recurrence
Radiation therapy if possible[vv] to chest wall and supraclavicular and infraclavicular nodes
Internal mammary node recurrence
Radiation therapy if possible[vv] to chest wall, supraclavicular and infraclavicular nodes, and internal mammary nodes
Consider systemic therapy[xx]
See BINV-J, BINV-K, BINV-O
Systemic disease or de novo stage IV[ww]
Bone disease present
Add denosumab, zoledronic acid, or pamidronate[ss]
Bone disease not present
ER and/or PR positive; HER2 negative[b]
ER and/or PR positive; HER2 positive[b]
See BINV-19
ER and PR negative, or ER and/or PR positive and endocrine refractory; HER2 negative[b]
See BINV-20
ER/PR negative or ER and/or PR positive and endocrine refractory; HER2 positive[b]
See BINV-21


SYSTEMIC TREATMENT OF RECURRENT OR STAGE IV DISEASE
ER and/or PR POSITIVE; HER2 NEGATIVE OR POSITIVE
ER and/or PR positive; HER2 negative[b]
ER and/or PR positive; HER2 positive[b, yy]
Prior endocrine therapy within 1 y
Premenopausal[kk]
Ovarian ablation or suppression, plus endocrine therapy as for postmenopausal women[zz,aaa]
Postmenopausal[kk,yy]
Visceral crisis
Consider initial chemotherapy[bbb] (See BINV-20 and BINV-21)
No prior endocrine therapy within 1 y
Premenopausal[kk]
Ovarian ablation or suppression, plus endocrine therapy as for postmenopausal women[zz,aaa] or Selective ER modulators[zz,aaa]
Postmenopausal[kk,yy]
Aromatase inhibitor[zz,aaa,ccc] or Selective ER modulators or selective ER down-regulator[zz]
Visceral crisis
Consider initial chemotherapy[bbb]

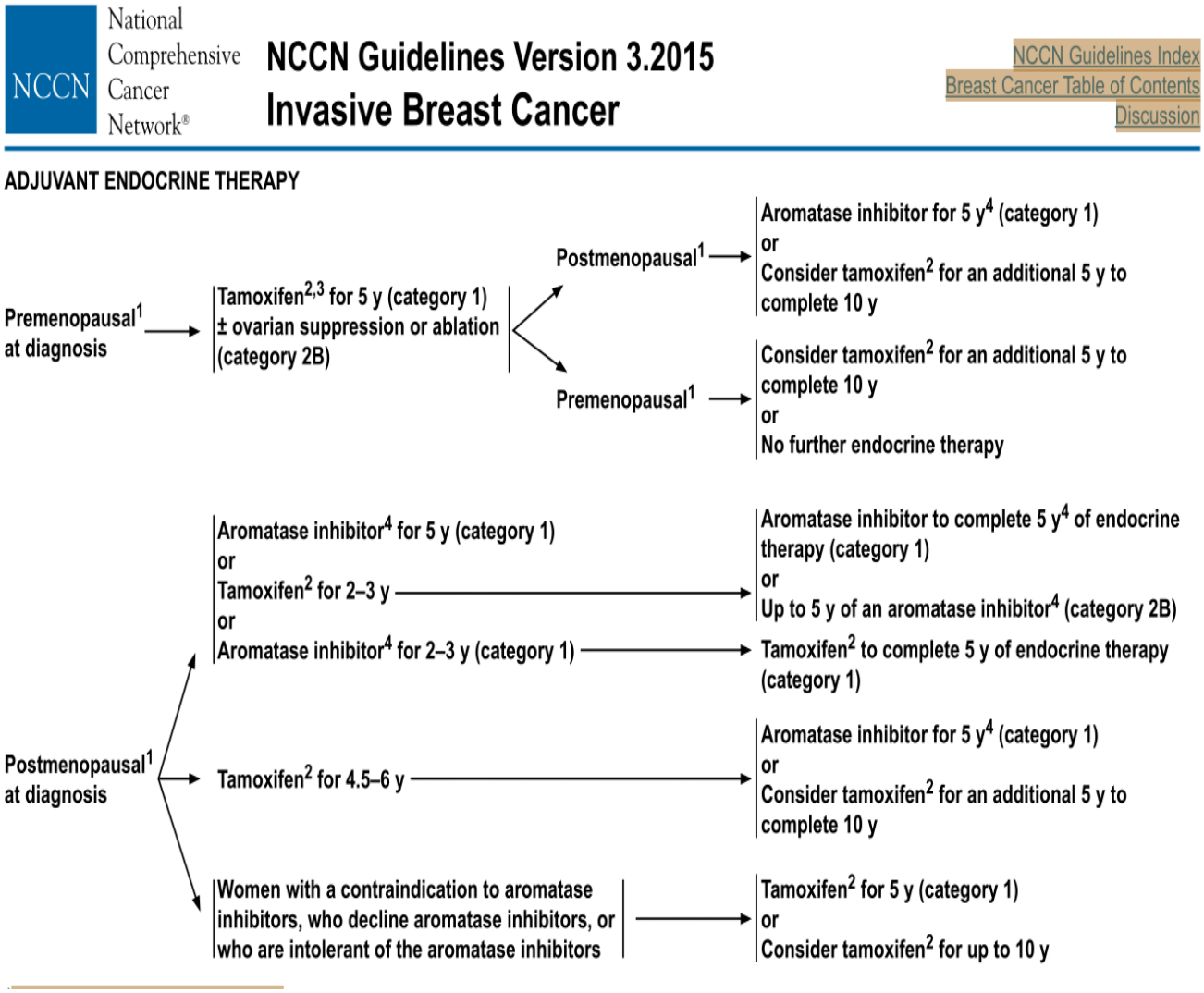
SYSTEMIC TREATMENT OF RECURRENT OR STAGE IV DISEASE
ER and PR NEGATIVE; or ER and/or PR POSITIVE and ENDOCRINE REFRACTORY; HER2 NEGATIVE



SYSTEMIC TREATMENT OF RECURRENT OR STAGE IV DISEASE
ER and PR NEGATIVE; or ER and/or PR POSITIVE and ENDOCRINE REFRACTORY; and HER2 POSITIVE



D.ADJUVANT HORMONE THERAPY



E.ADJUVANT CHEMOTHERAPY

NEOADJUVANT/ADJUVANT CHEMOTHERAPY[1,2,3,4]

Regimens for HER2-negative disease (all category 1)[5]

Preferred regimens:

- Dose-dense AC (doxorubicin/cyclophosphamide) followed by paclitaxel every 2 weeks
- Dose-dense AC (doxorubicin/cyclophosphamide) followed by weekly paclitaxel
- TC (docetaxel and cyclophosphamide)

Other regimens:

- Dose-dense AC (doxorubicin/cyclophosphamide)
- AC (doxorubicin/cyclophosphamide) every 3 weeks (category 2B)
- FAC/CAF (fluorouracil/doxorubicin/cyclophosphamide)
- FEC/CEF (cyclophosphamide/epirubicin/fluorouracil)
- CMF (cyclophosphamide/methotrexate/fluorouracil)
- AC followed by docetaxel every 3 weeks
- AC followed by weekly paclitaxel
- EC (epirubicin/cyclophosphamide)
- FEC/CEF followed by T

Regimens for HER2-positive disease[6,7,8]

Preferred regimens:

- AC followed by T + trastuzumab ± pertuzumab[9] (doxorubicin/cyclophosphamide followed by paclitaxel plus trastuzumab ± pertuzumab, various schedules)
- TCH (docetaxel/carboplatin/trastuzumab) ± pertuzumab

Other regimens:

- AC followed by docetaxel + trastuzumab ± pertuzumab[9]
- Docetaxel + cyclophosphamide + trastuzumab
- FEC followed by docetaxel + trastuzumab + pertuzumab[9]
- FEC followed by paclitaxel + trastuzumab + pertuzumab[9]
- Paclitaxel + trastuzumab[10]
- Pertuzumab + trastuzumab + docetaxel followed by FEC[9]
- Pertuzumab + trastuzumab + paclitaxel followed by FEC[9]

F.ADJUVANT RADIOTHERAPY

PRINCIPLES OF RADIATION THERAPY

Whole Breast Radiation:
Target definition includes the majority of the breast tissue, and is best done by both clinical assessment and CT-based treatment planning. A uniform dose distribution and minimal normal tissue toxicity are the goals and can be accomplished using compensators such as wedges, forward planning using segments, intensity-modulated radiation therapy (IMRT), respiratory gating, or prone positioning. The breast should receive a dose of 45–50 Gy in 23-25 fractions or 40–42.5 Gy in 15–16 fractions (short course is preferred). A boost to the tumor bed is recommended in patients at higher risk (age <50 and high-grade disease). This can be achieved with brachytherapy or electron beam or photon fields. Typical doses are 10–16 Gy at 2 Gy/fx. All dose schedules are given 5 days per week.

Chest Wall Radiation (including breast reconstruction):
The target includes the ipsilateral chest wall, mastectomy scar, and drain sites where possible. Depending on whether the patient has been reconstructed or not, several techniques using photons and/or electrons are appropriate. CT-based treatment planning is encouraged in order to identify lung and heart volumes and minimize exposure of these organs. Special consideration should be given to the use of bolus material when photon fields are used to ensure that the skin dose is adequate.

Regional Nodal Radiation:
Target delineation is best achieved by the use of CT-based treatment planning. For the paraclavicular and axillary nodes, prescription depth varies based on the anatomy of the patient. For internal mammary node identification, the internal mammary artery and vein location can be used as a surrogate for the nodal locations, which usually are not visible on imaging. Dose is 50–50.4 Gy, given as 1.8–2.0 Gy fraction size (± scar boost at 2 Gy per fraction to a total dose of approximately 60 Gy); all dose schedules are given 5 days per week. Based on the modern post-mastectomy radiation randomized trials and other recent studies, consider including the internal mammary lymph nodes when delivering regional nodal irradiation. CT treatment planning should be utilized in all cases where radiation therapy is delivered to the internal mammary lymph node field.

Accelerated Partial Breast Irradiation (APBI):
Preliminary studies of APBI suggest that rates of local control in selected patients with early-stage breast cancer may be comparable to those treated with standard whole breast RT. However, compared to standard whole breast radiation, several recent studies document an inferior cosmetic outcome with APBI. Follow-up is limited and studies are ongoing. Patients are encouraged to participate in clinical trials. If not trial eligible, per the consensus statement from the American Society for Radiation Oncology (ASTRO), patients who may be suitable for APBI are women 60 y and older who are not carriers of *BRCA 1/2* mutation treated with primary surgery for a unifocal T1N0 ER-positive cancer. Histology should be infiltrating ductal or a favorable ductal subtype and not associated with EIC or LCIS, and margins should be negative. Thirty-four Gy in 10 fractions delivered twice per day with brachytherapy or 38.5 Gy in 10 fractions delivered twice per day with external beam photon therapy is prescribed to the tumor bed. Other fractionation schemes are currently under investigation.

Optimizing Delivery of Individual Therapy:
It is important to individualize delivery of radiation therapy and considerations such as patient positioning (ie, prone vs. supine) during administration of radiation therapy.

Neoadjuvant Chemotherapy:
Indications for radiation therapy and fields of treatment should be based on the worst stage pretreatment or post-treatment tumor characteristics in patients treated with neoadjuvant chemotherapy.

MANAGEMENT OF AXILLA IN BREAST CANCER – CHANGING CONCEPTS

In the recent decades, the surgical management of axilla has seen a drastic change from radical approach to the more conservative approach. Initially, a radical axillary dissection was the norm for any patient undergoing mastectomy for breast cancer. However, with the identification of devastating complication of lymphedema and possible nerve injuries during radical axillary dissection, there was a gradual shift from radical approach to a conservative approach. The landmark trial which paved the thought for a conservative approach to axilla was NSABP 04 trial started in 1971. It enrolled nearly 1700 women, among them 1079 were with clinically negative axillary nodes who underwent radical mastectomy, total mastectomy without axillary dissection but with postoperative radiation or total mastectomy with axillary dissection if nodes became clinically positive. It also included 586 women with clinically positive axillary nodes who underwent

radical or total mastectomy, without axillary dissection but with postoperative radiation. There no significant survival difference among the three groups of women with clinically negative nodes, or between those with positive nodes. This absence of survival benefit in patients undergoing axillary dissection made oncologists think whether the side effects outweigh the benefits in an axillary dissection.

With the introduction of the concept of sentinel lymph node by Gould et al. in 1960 in a patient with parotid cancer, the management protocols for various cancers saw a sea of change. Cabanas further did research on sentinel node concept in Penile cancer and popularized it. The technique of radiolocalisation presently used widely for Breast cancer was pioneered by Dr.James C Alex MD, FACS and Dr.David N Krag, MD – University of Vermont Medical Centre. Ever since, sentinel lymph node biopsy has invited wide research and clinical

applications in breast cancer. One of the landmark clinical trials was conducted by Veronesi et al. in 2010 presenting the 10 year followup of single institute trial to compare outcomes in patients who received no axillary dissection with sentinel node was negative with patients who received complete axillary dissection. The results revealed remarkable advantages in preservation of normal axillary nodes with good oncological outcomes. They recommended to discard axillary dissection unless the sentinel node was positive. From a minimal surgical approach, oncologists began to think of offering a multimodality approach to axilla even if the sentinel nodes were positive. Thus was conducted the EORTC 10981-22023 AMAROS – a randomized, multicenter, open label phase 3 non inferiority trial by Mila Donker eta al. Early breast cancer patients (T1-2) with no palpable lymphadenopathy were included in this study and were allocated to receive either axillary lymph node dissection or axillary radiotherapy in case of positive sentinel node. The primary end

point was non inferiority of 5 year axillary recurrence. It was 0.4% in axillary lymph node dissection group versus 1.19 % after axillary radiotherapy. So this trial suggested comparable oncological outcomes for patients treated with axillary dissection and axillary radiotherapy after positive sentinel node. These were Early breast cancer patients with no palpable lymphadenopathy. A trial conducted on similar lines was the National Surgical Adjuvant Breast and Bowel Project trial (NSABP-32). It was a prospective randomized phase III trial designed to compare the oncological outcomes in patients undergoing Sentinel Node dissection with those of Axillary dissection in clinically node negative patients. 5611 women with operable N0 breast cancer were enrolled. At the end of 8 years, there was no significant difference in Overall Survival (OS) between patients who received Sentinel node dissection with Axillary dissection. There was no significant difference in Disease Free survival (DFS) or locoregional control between two groups. The results suggested

that Sentinel Node dissection should serve as the standard of care over Axillary dissection in clinically node negative patients as it provides equivalent OS and DFS while minimizing morbidity.

OBSERVATIONS

This study was conducted in Govt. Stanley Medical College & Hospital from January 2014 to September 2015. As per the methodology already described, the patients coming under inclusion criteria were studied and following observations were made and results arrived at.

Total number of patients enrolled in study – 40

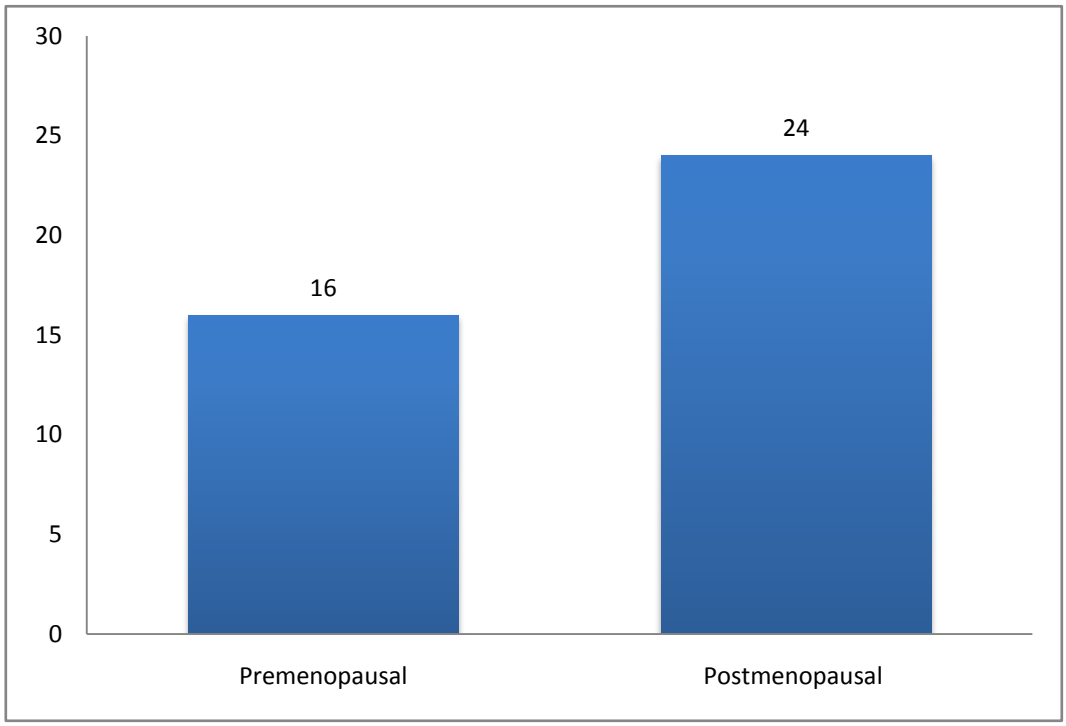
The collected patient data were analysed with the help of statistical tools. The observations were tabulated, interpreted and results were arrived at. The following headers show the criteria under which the patient data were categorized and studied. The interpretation of these data and results follow.

OBSERVATIONAL STATISTICS

Table 1. Enrolled patients and their menopausal status

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

Fig.1. Menopausal status of patients under study



Age group (in years)	Number of patients
20-30	1
31-40	3
41-50	**17**
51-60	12
>60	7
Total	40

Table 2.Age wise distribution of patients

Fig 2.Age wise distribution of patients in %

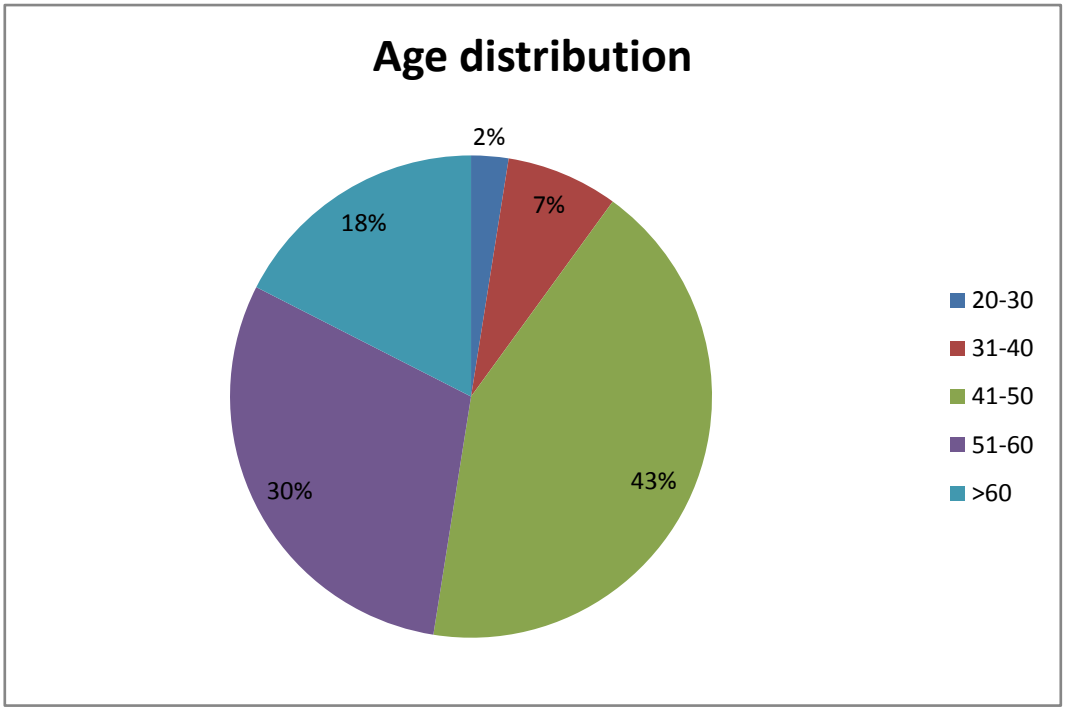


Fig.3. Size distribution of tumor as per pT stage

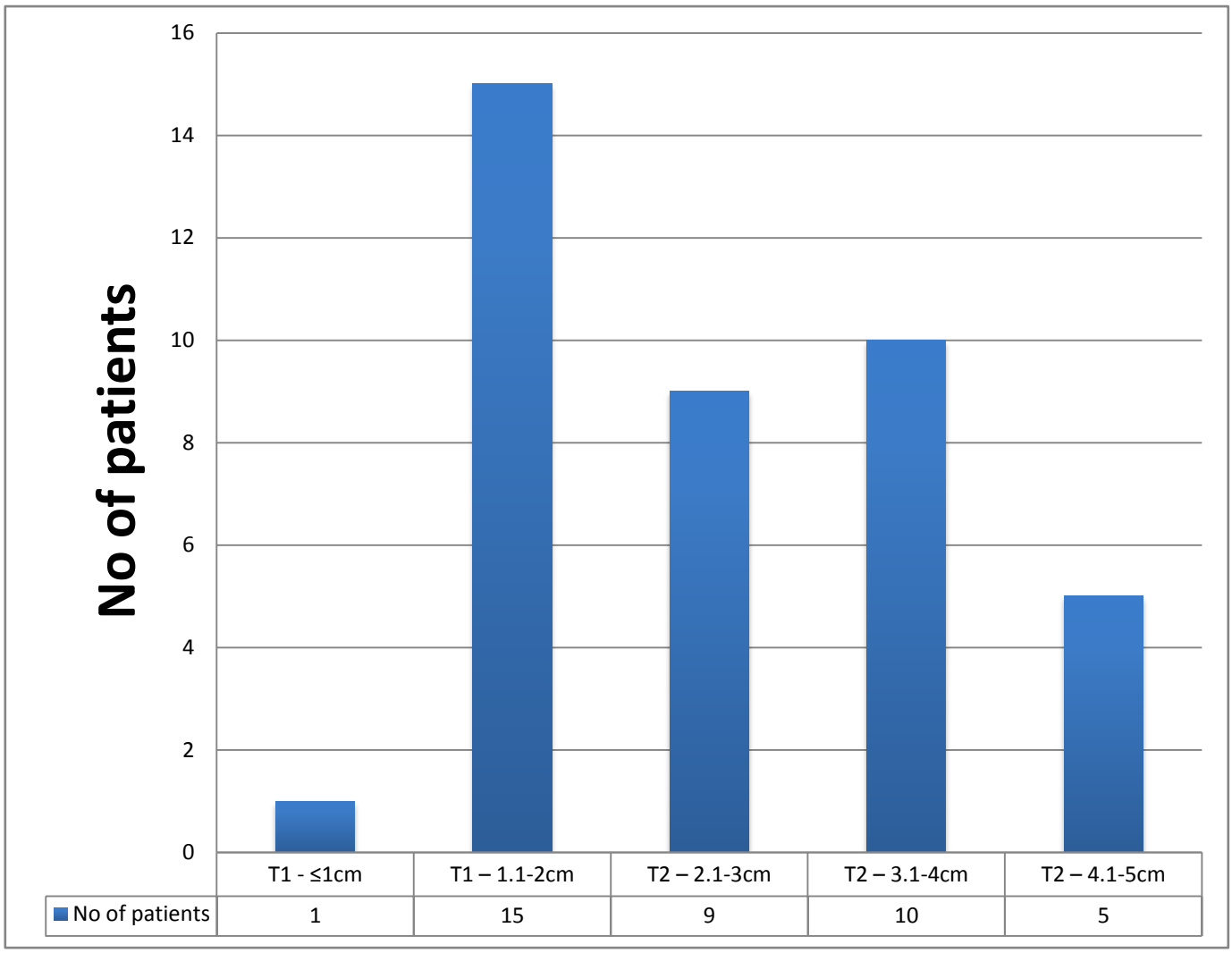


Fig.4. Histology of the tumor

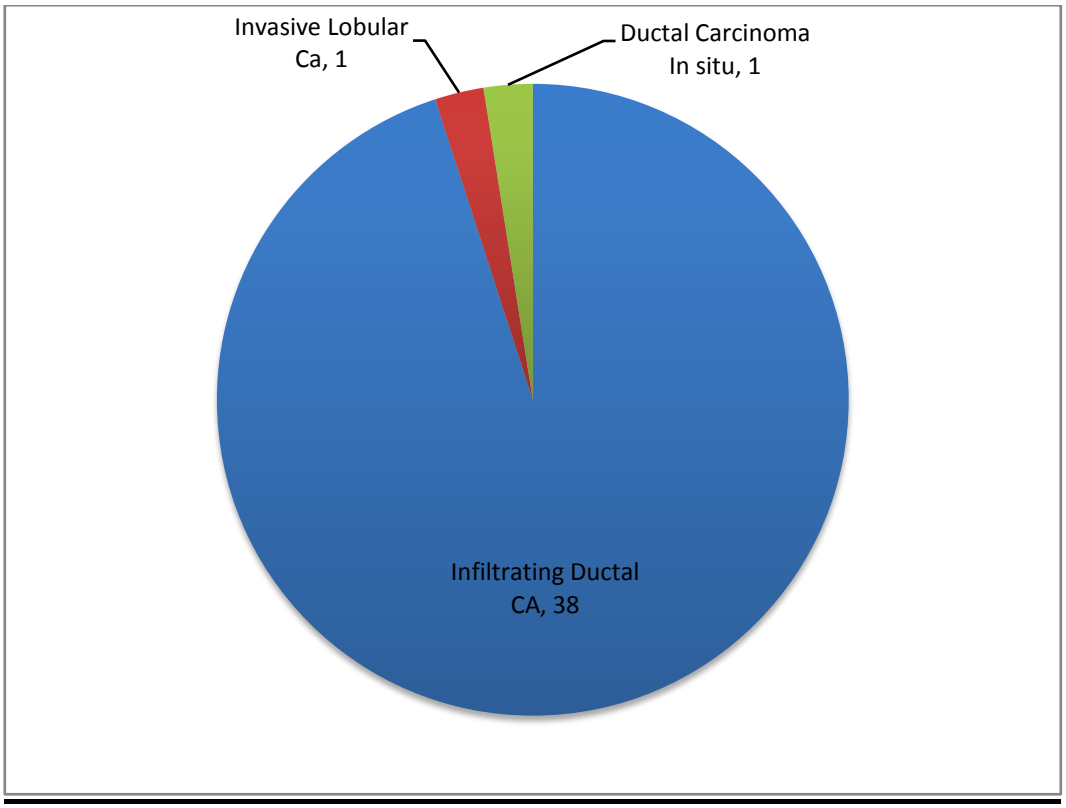
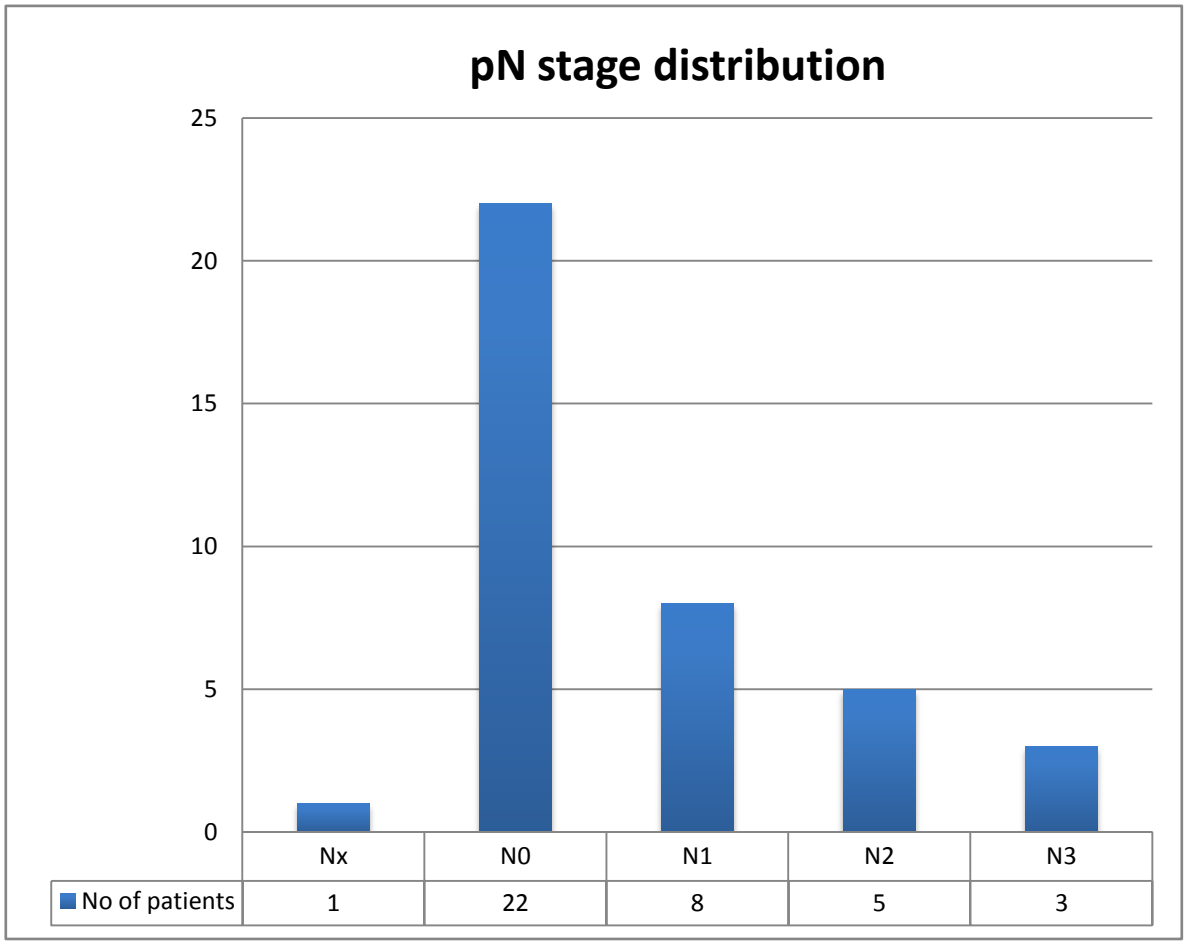


Table 3. Histology of the tumor under study

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

Fig.5 Pathological Nodal status among the patients studied



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

I. **N stage identified by clinical examination compared with N stage identified by Pathological Examination**

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

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: [C] = conventional [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

Fig.6 STATISTICAL RATIOS FOR CLINICAL EXAMINATION

II. 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

Values entered:

	Condition		
	Absent	Present	Totals
Test Positive	5	16	21
Test Negative	19	0	19
Totals	24	16	40

	Estimated Value	95% Confidence Interval	
		Lower Limit	Upper Limit
Prevalence	0.4	0.252811	0.566089
Sensitivity	1	0.759265	1
Specificity	0.791667	0.572935	0.92064
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	0.761905	0.524503	0.908828
False Positive	0.238095	0.091172	0.475497
For any particular negative test result, the probability that it is:			
True Negative	1	0.790795	1
False Negative	0	0	0.209205
likelihood Ratios: [C] = conventional [W] = weighted by prevalence			
Positive [C]	4.8	2.200591	10.469916
Negative [C]	0	0	NaN
Positive [W]	3.2	1.435586	7.132977
Negative [W]	0	0	NaN

Fig.7. STATISTICAL RATIOS FOR SONOMAMMOGRAM

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.

I. 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

Table 4. Tumor size distribution in N0 disease

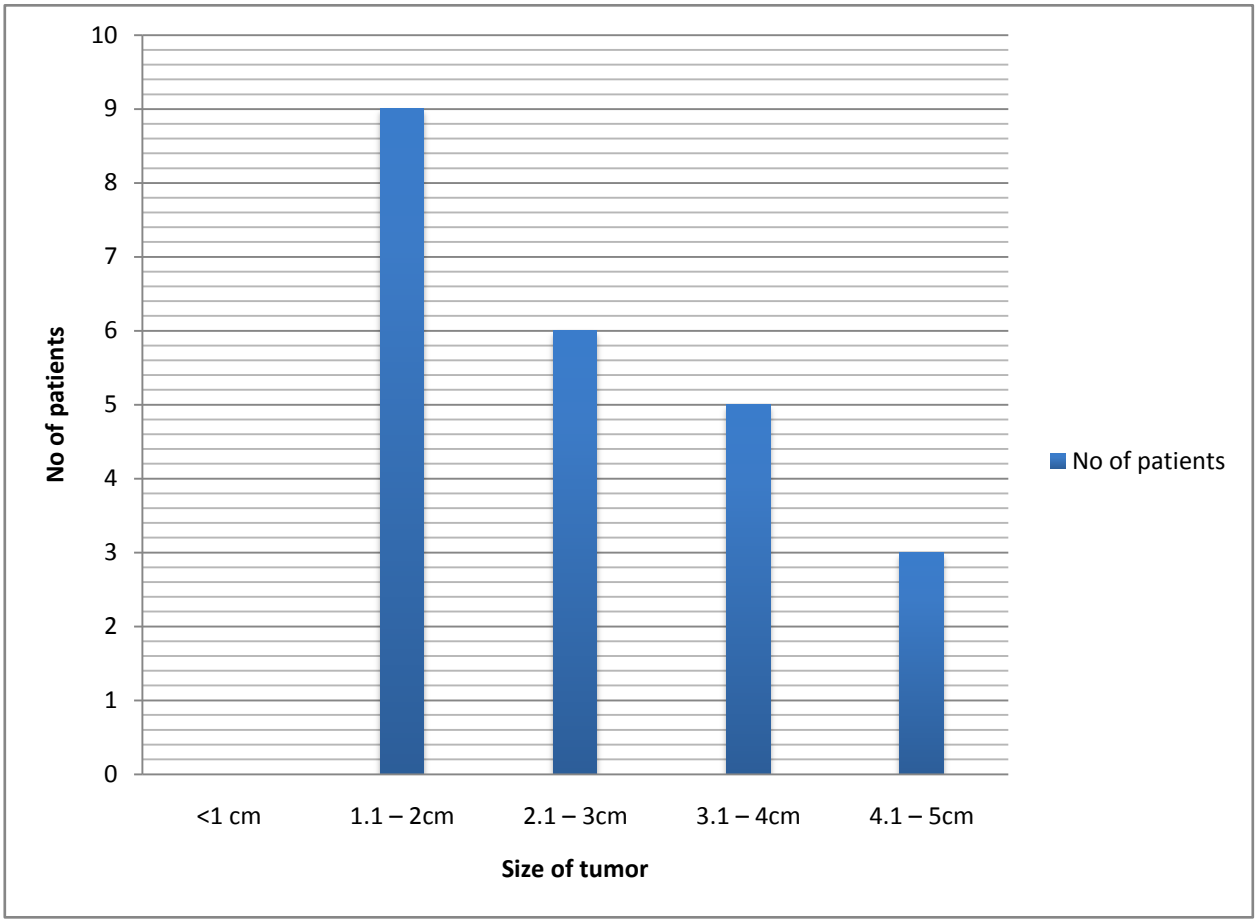


Fig.8. Tumor size distribution in N0 disease

II. Grading of N0 tumors

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

Table 5. Tumor size distribution in N0 disease

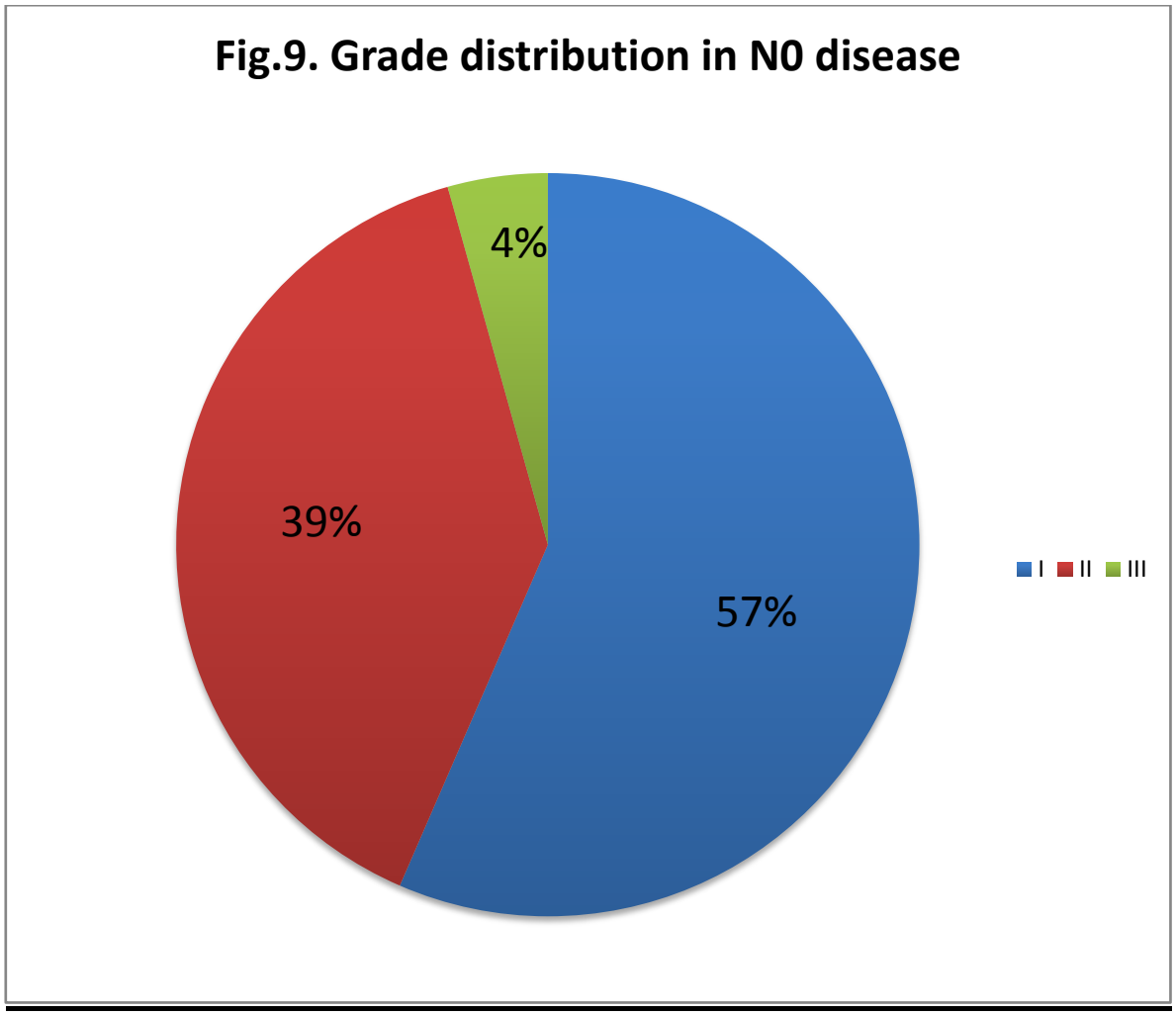


Fig.9. Grade distribution in N0 disease
4%
39%
57%
I
II
III

III. Age distribution of N0 tumors

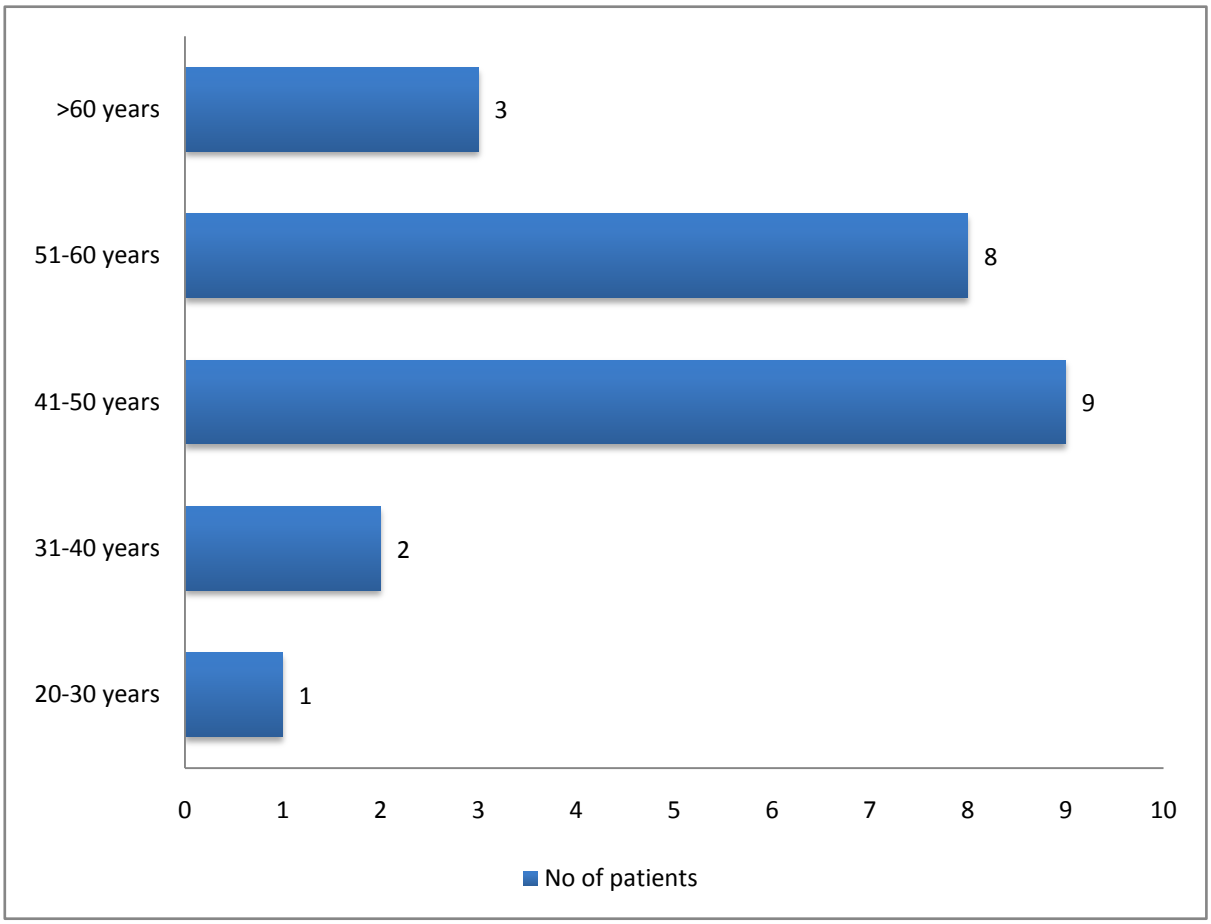


Fig.10. Age distribution in N0 tumors

IV. Receptor Status in N0 tumors

There was a high prevalence of ER positivity and

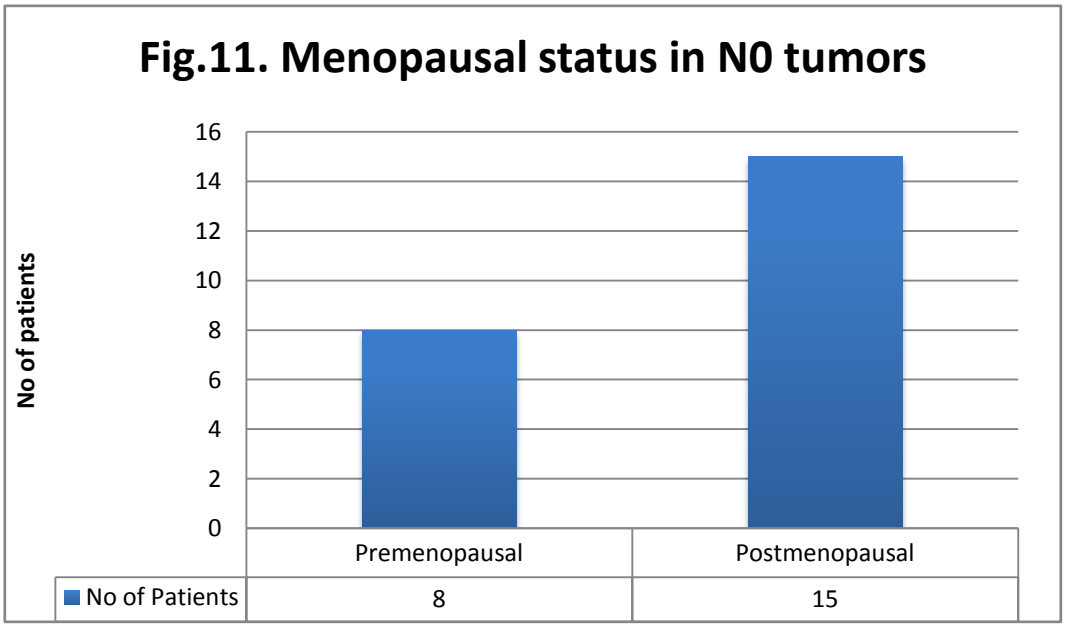
Her2neu negativity among the 23 N0 tumors studied.

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

Table 6. Receptor status in N0 tumors

V. Menopausal status in N0 tumors



RESULTS & SUMMARY

In this study conducted at Govt. Stanley medical College & Hospital with the described study group, following results were obtained:

1. There was a higher prevalence of post menopausal subjects in the study group constituting 60% of the study group (24 out of 40 patients).

2. 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.

3. 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.

4. 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

5. 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.

6. 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.

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

8. 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.

CLINICAL IMPLICATION& 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 Breast

cancer 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

Methods:

- tumors with T stage T1 or less
- Grade I tumors
- ER positive and Her2 neu negative tumors
- postmenopausal patients

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 not

include the advantage or disadvantage of any of the described modalities.

BIASING FACTORS:

1. Selection bias - small sample size
2. Observer bias during histopathological examination
3. Recall & Response bias- some patients could not ascertain confirmation of details of age and menopausal status.
4. Digit preference bias – age rounded off by patients to the nearest whole number.
5. Reporting bias – more lenience towards premonitioned result and suppression of contradictory facts.

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MASTER CHART

Sl	Name	age	IP	Clinical T size	Clinical N stage	Radiological N stage (after Mammogram)	Revised Clinicoradiological Stage	Histology And Grade	Pathological T size	Nodes postive for mets/nodes dissected	ER/PR/Her2neu	Pathological Stage
1	Bagavathy	65	1515076	T2	N0	N1	T2N1M0	IDC/II	2x1x1cm	1/9	+/-/-	pT2N1a Mx
2	Salaithmary	68	1512171	T2	N0	N0	T2N0M0	DCIS/II	5x5x2 cm	0/9	+/-/-	pTisN0Mx
3	Pushpa	40	1517551	T2	N0	N0	T2N0M0	IDC/II	2.5x2x2.cm	0/9	+/-/+	pT2N0Mx
4	Renuga	53	1517368	T2	N1	N1	T2N1M0	IDC/II	3x3x2.5cm	1/11	-/+/+	pT2N1aMx
5	Rosy	51	1515066	T2	N1	N1	T2N1M0	IDC/II	2x1.5x1.5cm	1/5	+/+/-	pT2N1M0
6	Neelavathy	45	1518142	T2	N1	N1	T2N1M0	IDC/II	4x3x2.5cm	3/8	+/+/-	pT2N1aMx
7	Magimamary	42	1507241	T2	N0	N1	T2N0M0	IDC/I	2x1.5x2cm	0/8	+/+/-	pT2N0Mx
8	Karishma	44	1509282	T2	N1	N1	T2N1M0	IDC/II	4x3.5x4.2cm	7/22	+/-/+	pT2N2aMx
9	Ragapunitha	42	1508530	T2	N1	N1	T2N1M0	IDC/I	3.5x3x1.5cm	0/9	+/-/-	pT2N0Mx
10	Padmini	45	1524782	T2	N1	N1	T2N1M0	IDC/I	2x3.5x5cm	15/17	+/+/-	pT3N3aMx
11	Ranganayagi	42	1531082	T2	N0	N0	T2N0M0	IDC/Mucinous	1.5x1.5x1cm	0/9	+/+/-	pT1aN0Mx
12	Kavita	30	167992	T2	N0	N0	T2N0M0	IDC/I	3.5x2.2.5cm	0/8	+/-/-	pT2N0Mx
13	Rahimbee	65	1529071	T2	N0	N0	T2N0M0	IDC/I	2x1.5x1cm	0/5	+/+/-	pT1cNoMx
14	Chinnamma	56	1541412	T2	N1	N0	T2N1M0	Cis	1.5x1.5x2.5	0/8	-/-/-	pTisN0Mx
15	Kalyani	47	1539414	T2	N1	N1	T2N1M0	IDC/II	2x1x1 cm	12/12	-/-/-	pT2N3aMx
16	MumtazBegm	50	1509336	T2	N1	N0	T2N1M0	IDC/II	4.5x4x4cm	0/10	-/-/-	pT2N0Mx
17	Visalatchi	70	1510348	T2	N0	N0	T2N0M0	IDC/II	4.5x3.5x2.5	0/4	+/-/-	pT2N0M0
18	Mary	55	1510010	T2	N1	N0	T2N1M0	IDC/II	2x2x1.5cm	0/17	+/-/+	pT2N0Mx
19	Jothi	39	1510652	T2	N0	N1	T2N1M0	IDC/III	4x3x2cm	4/4	-/-/+	pT3N2aMx
20	Prema	45	1575115	T2	N1	N1	T2N1M0	IDC/II	2.5x2x1.5 cm	2/7	-/-/-	pT2N1Mx

	Name	age	IP	Clinical T size	Clinical N stage	Radiological N stage (after Mammogram)	Clinico radiological Stage	Histology and grade	Pathological T size	Nodes postive for mets/nodes dissected	ER/PR/Her2 neu	Pathological Stage
21	Susila	47	1538709	T1	N0	N0	T1N0M0	ILC/II	1.5x1.5x1cm	0/9	+/-/-	pT1cN0Mx
22	Gunavathy	55	1517309	T2	N1	N1	T2N1M0	IDC/II	3.5x3.1cm	0/13	-/-/-	PT2N2Mx
23	Indrani	62	1517746	T2	N0	N0	T2N0M0	IDC/I	2x2x1cm	0/0	+/-/-	pT2NxMx
24	Rani	55	1527096	T2	N0	N0	T2N0M0	IDC/I	4x2.7x2cm	0/20	-/-/-	pT2N0Mx
25	Saroja	42	1505818	T1	N1	N1	T1N1M0	IDC/II	1x1x1cm	4/9	-/-/-	pT1bN2aM0
26	Seemahari	42	1527069	T2	N1	N0	T2N1M0	IDC/I	1.5x1.1cm	0/9	+/-/-	pT1cN0M0
27	Ryanabegum	32	1538766	T2	N0	N0	T2N0M0	IDC/I	4x4x1.5cm	0/4	+/+/-	pT2N0Mx
28	Shanthi	50	1505818	T2	N0	N0	T2N0M0	IDC/II-IV	2x1.5x2cm	0/4	-/+/+	pT2N0Mx
29	Fathima	45	1520044	T2	N0	N0	T2N0M0	IDC/Papillary	4x3x2cm	0/12	+/-/-	pT2N0Mx
30	Sornakani	48	1521356	T1	N1	N0	T2N1M0	IDC/I	1.5x1x1cm	0/9	+/-/-	pT1cN0Mx
31	Ponammal	45	1525631	T2	N0	N1	T2N0M0	IDC/I	2x2x1.5cm	2/6	+/-/-	pT2N1aMx
32	Pushpavalli	56	1525246	T2	N0	N1	T2N0M0	IDC/I	2.5x2x1cm	0/7	-/-/+	pT2N0Mx
33	Rani	60	1522364	T2	N1	N1	T2N1M0	IDC/I	2.5x2x1cm	14/14	+/-/-	pT2N2Mx
34	Lakshmi	65	1544471	T1	N1	N1	T1N1M0	IDC/II	1.5x1.5x1cm	0/17	+/-/+	pT1N0Mx
35	Sairabee	55	1511655	T2	N0	N0	T2N0M0	IDC/II	2.5x2x1.5cm	0/10	-/-/+	pT2N0Mx
36	Chinapappa	60	1470784	T2	N1	N0	T2N1M0	IDC/II	4x3x3cm	0/20	+/+/-	pT2N0Mx
37	Gunasili	70	1501375	T1	N1	N1	T1N1M0	IDC/II	2x1.5x1cm	2/11	+/-/-	pT1cN1aMx
38	Papathi	45	150476	T1	N0	N1	T1N0M0	IDC/II	1.5x1.5x3cm	2/22	+/+/+	pT2N1Mx
39	Govindammal	55	1520152	T2	N1	N1	T2N0M0	IDC/I	2.5x1x1cm	0/8	-/+/-	pT2N0Mx
40	Neelaveni	55	1504544	T2	N1	N1	T2N1M0	IDC/II	2x1x1cm	12/13	-/-/+	pT1cN3aMx

GOVT.STANLEY MEDICAL COLLEGE, CHENNAI- 600 001

INFORMED CONSENT

DISSERTATION TOPIC: "*A COMPARATIVE STUDY BETWEENPREOPERATIVE AXILLARY LYMPH NODE STATUS WITH POSTOPERATIVE HISTOPATHOLOGICAL DIAGNOSIS IN OPERABLE CASES OF BREAST CANCER*"

PLACE OF STUDY: GOVT. STANLEY MEDICAL COLLEGE, CHENNAI

NAME AND ADDRESS OF PATIENT:

I, _____ have been informed about the details of the study in my own language.

I have completely understood the details of the study. I am aware of the possible risks and benefits, while taking part in the study.

I understand that I can withdraw from the study at any point of time and even then, I will continue to receive the medical treatment as usual. I understand that I will not get any payment for taking part in this study.

I will not object if the results of this study are getting published in any medical journal, provided my personal identity is not revealed.

I know what I am supposed to do by taking part in this study and I assure that I would extend my full co-operation for this study.

Name and Address of the Volunteer:

Signature/Thumb impression of the Volunteer Date:

Witnesses:(Signature, Name & Address)

Name and signature of investigator:

PROFORMA

NAME : **AGE /SEX:** **IP NO:SL. NO:**

- **ADDRESS WITH CONTACT NUMBER:**
- **DATE OF ADMISSION**
- **HISTORY OF PRESENTING ILLNESS:**

H/O lump in breast

Onset

Progression

Associated symptoms

Nipple Discharge

Nipple Retraction

h/oTrauma

h/o Fever

H/o abdominal pain,jaundice

H/o headache,back pain

H/o Loss of Weight,Loss of Appettite

PAST HISTORY:

Whether a known case of DM/hypertension/asthma/TB/epilepsy/cardiac illness

H/o similar episodes in the past, if any:

H/o major illness/ hospital admissions, if any:

H/o drug intake/contraceptive usage,if any:

PERSONAL HISTORY:

Age of menarche

Children

Breast fed: Yes/No

menopause:

FAMILY HISTORY:

H/o similar complaints in mother,grandmother,female siblings,if any

H/o Prostatic illness in father,if any

CLINICAL EXAMINATION:

General examination

Local Examination:

Breast and Axilla

Arm,Chest wall,Supraclavicular fossa

Systemic examination:

CVS; RS; CNS; Abdomen; Spine and Cranium

Clinical diagnosis:

INVESTIGATIONS:

CBC

RFT

HIV

HBsAg

Anti-HCV

Blood Grouping & Typing

BT/CT:

Chest X-Ray

ECG

USG Breast/Mammogram

FNAC/Trucut Biopsy

USG ABDOMEN:

FINAL DIAGNOSIS:

After MRM,

Post op HPE reports as per CAP protocol.

INSTITUTIONAL ETHICAL COMMITTEE, STANLEY MEDICAL COLLEGE, CHENNAI-1

Title of the Work	:	A comparative study between preoperative axillary lymphnode status with postoperative histopathological diagnosis in operable cases of Breast Cancer .
Principal Investigator	:	Dr. Aravind Menon.K
Designation	:	PG MS (General Surgery)
Department	:	Department of General Surgery Government Stanley Medical College, Chennai-01

The request for an approval from the Institutional Ethical Committee (IEC) was considered on the IEC meeting held on 13.01.2015 at the Council Hall, Stanley Medical College, Chennai-1 at 2PM

The members of the Committee, the secretary and the Chairman are pleased to approve the proposed work mentioned above, submitted by the principal investigator.

The Principal investigator and their team are directed to adhere to the guidelines given below:

1. You should inform the IEC in case of changes in study procedure, site investigator investigation or guide or any other changes.
2. You should not deviate from the area of the work for which you applied for ethical clearance.
3. You should inform the IEC immediately, in case of any adverse events or serious adverse reaction.
4. You should abide to the rules and regulation of the institution(s).
5. You should complete the work within the specified period and if any extension of time is required, you should apply for permission again and do the work.
6. You should submit the summary of the work to the ethical committee on completion of the work.

K Vasantha

MEMBER SECRETARY,
IEC, SMC, CHENNAI

MEMBER SECRETARY
ETHICAL COMMITTEE,
STANLEY MEDICAL COLLEGE
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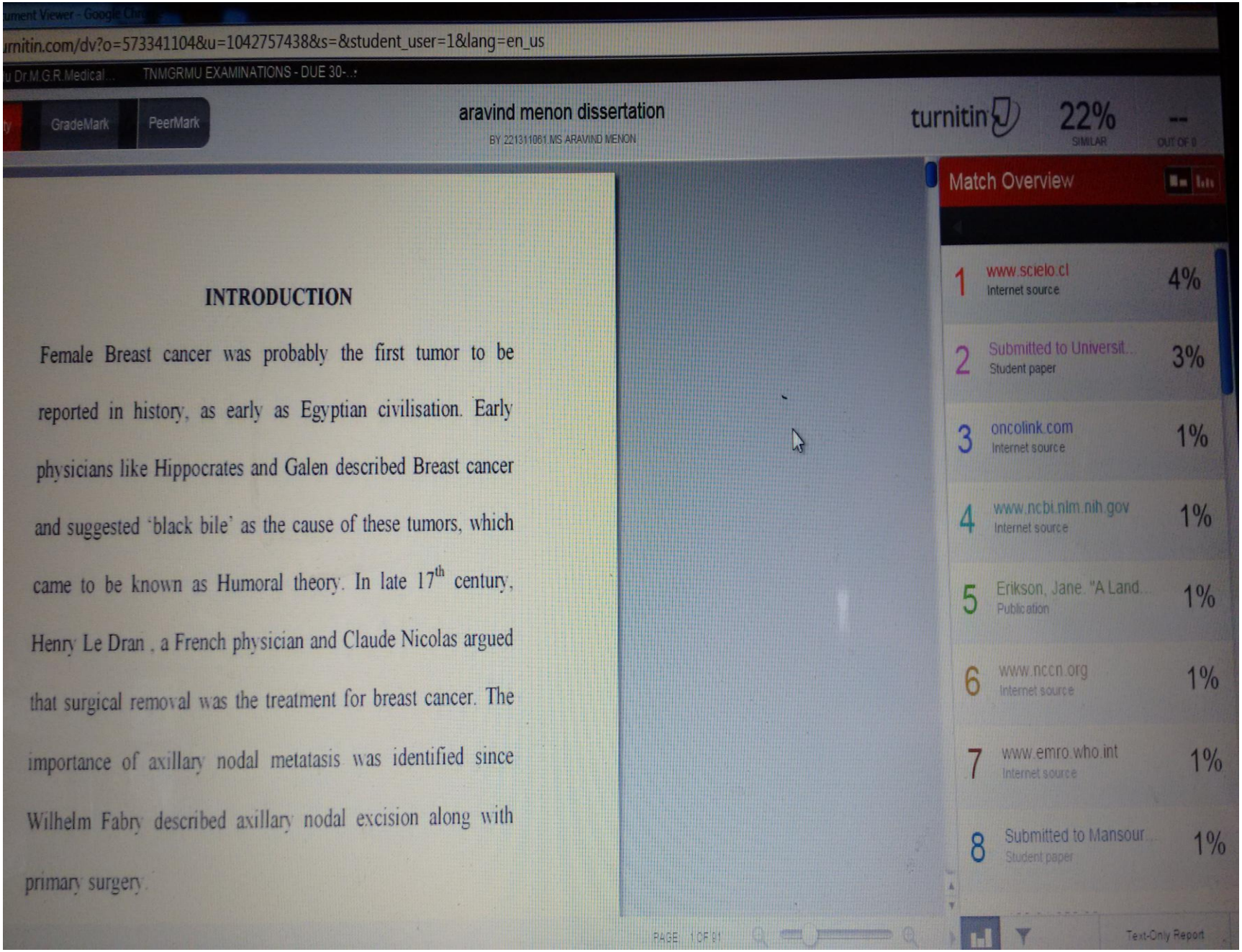
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INTRODUCTION
Female Breast cancer was probably the first tumor to be reported in history, as early as Egyptian civilisation. Early physicians like Hippocrates and Galen described Breast cancer and suggested 'black bile' as the cause of these tumors, 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.
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Text-Only Report

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

ABSTRACT

Breast cancer is one of the commonest cancers among the female population in India. It has a varied spectrum spectrum of presentation and when detected early, a curative surgery can be offered to the patient. The most important prognostic factor determining the local recurrence is the axillary lymph node status. Management of axilla in Brest cancer has evolved from a radical approach to more conservative approaches like Sentinel lymph node biopsy. This study encompasses patients diagnosed with early Breast cancer upto Stage IIb. All these patients were evaluated preoperatively with Clinical examination, Sonomammogram and subjected to Modified Radical Mastectomy with Adjuvant Chemotherapy. Preoperative axillary lymph node status were compared with the histopathological staging and the sensitivity and specificity of Clinical Breast examination and Sonomammogram were calculated and the latter was found to be superior. A specific subset of population with distinct characteristics in which no pathological axillary node metastasis was detected was defined. Thus a subgroup ideal for a conservative approach to axilla was identified and defined in this study.

KEYWORDS

Breast cancer
Axilla
Sonomammogram
Mastectomy
Sentinel node