

GUIDELINES ON MANAGEMENT OF BREAST LUMP

College of Surgeons of Sri Lanka 2007

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Introduction.

Carcinoma of the breast is the commonest cancer in Sri Lankan women. The incidence is rising according to the Cancer Control Statistics, The incidence in Sri Lanka for the year 2000 is 16.7 per 100,000 population. . Whilst this may not be as high as in western countries it is a matter of concern for us. The majority of women present with symptoms of apparently benign disease which needs careful evaluation so as not to miss a malignancy

STRATIFICATION OF GUIDELINES ACCORDING TO EDUCATIONAL STATUS

1. GUIDELINE FOR MIDWIVES
2. GUIDELINE FOR NURSES (COMMUNITY AND HOSPITAL SECTOR)
3. GUIDELINES FOR MEDICAL OFFICERS / SHO
4. GUIDELINE FOR POSTGRADUATES INCLUDING CONSULTANTS

1. GUIDELINES FOR MIDWIVES - (Certificate holders)

1.1 INFORMATION PACK

Information on closest referral centre
(MoH station / Hospital / Specialized
breast clinic)

Information regarding clinic days

Chart of a self breast examination

Data collection file / form

1.2 HISTORY

Any type of breast pain / Mastalgia

Any nipple discharge

Breast mass

Axillary mass

Irritation of the nipple and areola

Family history of any cancer

1.3 EXAMINATION

Breast examination – *diagram*

RECOMMENDATION

Only patients with any of the positive findings in
the above should be referred to the next tier.

All data collection forms to be submitted to the
MoH monthly.

Do it yourself

Monthly breast self-exam

1 Stand before a mirror. Inspect both breasts for anything unusual, such as any discharge from the nipples, puckering, dimpling, or scaling of the skin.

The next two steps are designed to emphasize any change in the shape or contour of your breasts. You should be able to feel your chest muscles tighten while doing these steps.

2 Watching closely in the mirror, clasp hands behind your head and press hands forward.

3 Next, press hands firmly on hips and bow slightly toward your mirror as you pull your shoulders and elbows forward.

Some women do steps 4 and 5 in the shower. Fingers glide over soapy skin, making it easy to concentrate on the texture underneath.



4 Raise your left arm. Use three or four fingers of your right hand to explore your left breast firmly, carefully, and thoroughly. Beginning at the outer edge, press the flat part of your fingers in small circles, moving the circles slowly around the breast. Gradually work toward the nipple. Be sure to cover the entire breast. Pay special attention to the area between the breast and the armpit, including the armpit itself. Feel for any unusual lump or mass under the skin. Repeat the exam on your right breast.



5 Gently squeeze each nipple and look for a discharge.



6 Steps 4 and 5 should be repeated lying down. Lie flat on your back, right arm over your head and a pillow or folded towel under your left shoulder. This position flattens the breast and makes it easier to examine. Use the same circular motion described earlier. Repeat on your right breast.



2. GUIDELINES FOR NURSES - (Diploma holder)

2.A COMMUNITY NURSES

2.1 INFORMATION PACK

Information on closest referral centre
(MoH station / Hospital / Specialized
breast clinic)

Information regarding clinic days

Chart of a self breast examination

Data collection file / form

2.2 HISTORY

Any type of breast pain / Mastalgia

Any nipple discharge

Breast mass

Axillary mass

Irritation of the nipple and areola

Family history of any cancer

Relative risk factors

Early age at Menarche

Late menopause

History of oral contraceptives use

History of HRT use

Parity

2.3 EXAMINATION

Breast examination – *diagram*

RECOMMENDATION

Only patients with any of the positive findings in the
above should be referred to the next tier.

Women only with relative risk factors should be discussed with
MoH for examination and investigation, if determined by MoH All
data collection forms to be submitted to the MoH monthly.

3. GUIDELINES FOR MEDICAL OFFICERS (Degree Holders)

3.1 HISTORY Attention needs to be paid to benign conditions such as nipple discharge and mastalgia as they could precede a cancer.

History should include all possible risk factors.

Age, early menarche, late menopause, parity, use of exogenous hormones, family history. (*see below*)

3.1.1 BREAST LUMP

All breast lumps detected should be referred to a surgical unit

3.1.2 NIPPLE DISCHARGE

Single duct, unilateral ,of whatever color should be referred to a surgical unit

Bilateral milky discharge

Assess FSH, LH and prolactin levels.

Reassure the patient.

If troublesome discharge, referred to a surgical unit

If FSH, LH or Prolactin levels are abnormal, refer to a Surgical Unit.

Purulent discharge Do culture / ABST.

Start appropriate antibiotics

If no response within one week, refer to a surgical unit

3.1.3 MASTALGIA

History should clearly differentiate pain arising from the chest wall or cardiac pain.

Unilateral noncyclical mastalgia should be referred to a surgical unit

Cyclical mastalgia should be treated with Evening Primrose Oil (EPO) 1000mg per day for a period of 4 months. **If no response, refer surgical unit.**

3.1.4 AXILLARY MASS

All axillary masses should be referred to a surgical unit

3.1.5 ALL OTHER COMPLAINTS – MAMMARY SINUSES, MASTITIS etc

All should be referred to a surgical unit

3.2 RISK FACTORS

3.2.1 FAMILY HISTORY

The following categories of women with a family history should be referred to a surgical unit

1. One first degree relative diagnosed with breast cancer < 40 years
2. Two first or second-degree relatives on the same side of the family diagnosed with breast and ovarian cancer at any age.
3. Three family members on the same side of the family with breast cancer at < 70 years
4. Four family members on the same side of the family with breast cancer at any age

5. Breast and ovarian cancer combinations within the same side of the family. A single person with a breast and ovarian cancer fulfils this criterion. Breast and ovarian combinations diagnosed in 4 or more relatives on the same side of the family is associated with a very high risk of the presence of a germline cancer predisposing gene
6. First degree relative with bilateral breast cancer
7. First degree relative with male breast cancer < age 60 years
8. Family members of rare high risk cancer syndromes e.g. Li-Fraumeni

3.2.2 EXOGENOUS HORMONES

Women over the age of 50 years should be discouraged to be on HRT. (WHO recommendation) unless with severe post menopausal symptoms.

Any women with a family history of breast cancer should not take HRT. If HRT has to be started for severe post menopausal symptoms, it should be given for a **period not exceeding 5 years**.

3.2.3 OCP . Minimal risk. Slight increase in incidence for patients taking it for 5 years before the first pregnancy.

RECOMMENDATION

Attention needs to be paid to benign conditions such as nipple discharge and mastalgia as they could precede a cancer.

Any breast lump should be considered a cancer until proven otherwise **in a woman over 35 years**.

Presenting complaint and all risk factors should be documented in the clinic file / BHT

No surgery should be done on the breast unless supervised **or authorized** by a Consultant Surgeon

All women with above presentations recommend above for specialized referral, should be done within one week **to a surgical clinic**

All women with above risk factors should be referred within one month

If a 'Specialized Breast Clinic' is available, refer to this.

Could be referred directly to such clinics.

4. Guidelines for Post Graduate Degree Holders

4.1.1 BREAST LUMP

Triple assessment is utilized internationally to afford 99% accuracy for lesions which are not excised prior to diagnosis. This would negate false positives and avoid unnecessary breast surgery.

Triple assessment used in diagnosis of Breast lump

Record site accurately on a diagram

Record TNM staging

Clinically

D1= normal D2=benign lump, cyst or fibroadenoma

D3=indeterminate lesion

D4=suspicious of malignancy D5= clinically malignant lump

Imaging

Bilateral 2 view mammogram . **If a mammogram facility is not available then a breast uittrasound should be utilized. However it is not as accurate as a mammogram.**

Lateral/Magnification/paddle views if necessary

M1= normal M2=benign lump, cyst or fibroadenoma

M3=indeterminate lesion

M4=suspicious of malignancy M5=diagnostic of malignancy

Ultrasonography to assess breast lump(s) should be performed as the principle

investigation in women under the age of 35 years, or as further assessment in addition to mammography in women over the age of 35 years where appropriate.

U1= normal U2=benign lump, cyst or fibroadenoma
U3=indeterminate lesion
U4=suspicious of malignancy U5=diagnostic of malignancy

Cytology

Fine needle aspiration cytology (FNAC):

Ensure relevant clinical details & diagram on request form

State if previous RT **or chemo therapy** as this occasionally leads to false positives

This may be done stereotactically/ultrasound guided if lesion impalpable

Blue or green needle, 10-ml syringe, air dry slides and wet fix slides

DO NOT discard cyst fluid, send for assessment and re-examine for palpable residual mass

FNAC if residuum if present

C1= inadequate C2=benign breast cells

C3=indeterminate cytology

C4=suspicious of malignancy C5=diagnostic of malignancy

Core biopsy

This may be relevant for:

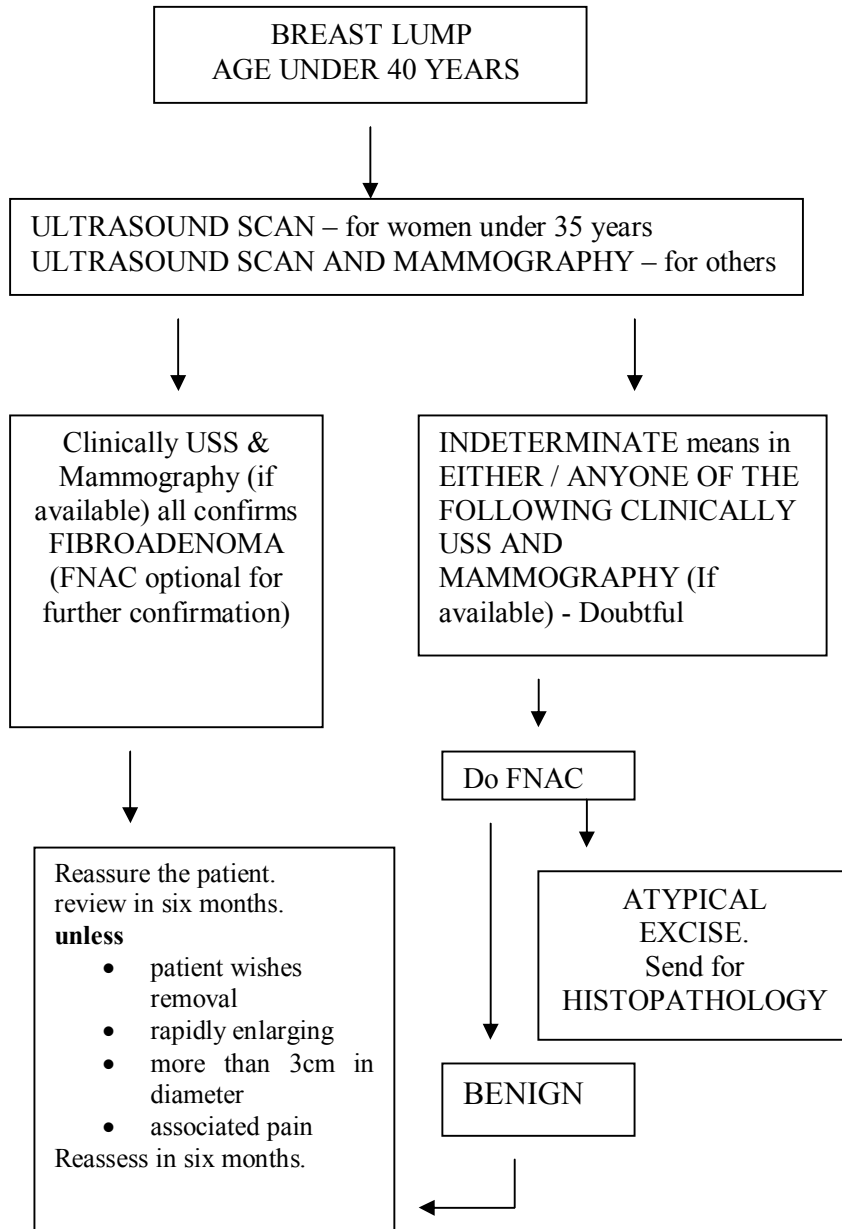
Tissue diagnosis prior to initiation of further management

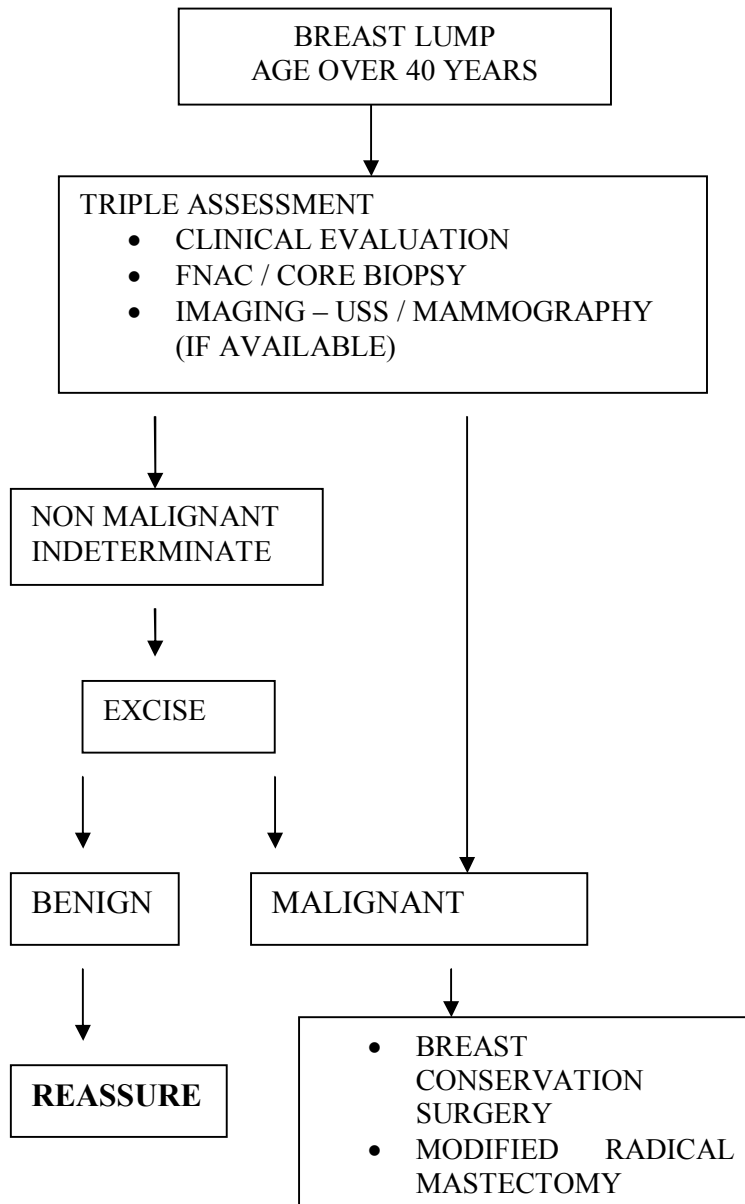
Where FNAC has proved unhelpful

For receptor status (**Should be done if facility is available**)

B1= inadequate B2=benign breast tissue

B3=indeterminate pathology B4=suspicious of malignancy B5=diagnostic of malignancy





5 . Management of benign breast disease

Cystic disease:

Palpable cyst should be aspirated. and fluid sent for cytology.

Fluid should be sent for cytology where the fluid is uniformly blood stained.

The area should be re-examined to exclude an underlying mass. If a residual mass is present, a needle aspirate of the solid component should be sent for cytology. Ultrasound examination may be helpful for additional assessment in patients with a residual solid component.

Fibroadenoma:

In lesions <3 cm biopsy may be avoided if all features are consistently benign on triple assessment. (In older patients)

Excision should be considered for:

Age >40 years

Lesions >3 cm

Rapidly enlarging lesions

Patient reassurance/preference

Nipple discharge:

Blood stained:

Full triple assessment to exclude carcinoma, including ultrasonography of the retroareolar tissue. Smears of the nipple discharge should be sent for cytology. If benign, may

represent a papilloma. Consider surgical excision by microdochectomy or major duct excision. If malignant, treatment as appropriate.

Persistent troublesome symptomatic non-bloodstained nipple discharge:

Consider surgical excision by microdochectomy or major duct excision.

Non-blood stained mild or intermittent discharge could be managed conservatively, having completed triple assessment, with avoidance of self-manipulation of nipple discharge.

Purulent:

Obtain specimen for cytology & microscopy/culture

Milky:

Consider measuring serum prolactin

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Breast pain:

The following therapies are suggested in order of use:

Oil of Evening Primrose/Vitamin B6

Danazol

Bromocriptine

Tamoxifen

LHRH analogues

Pain Clinic

Excision of painful area

Periductal mastitis:

Prescribe a course of flucloxacillin and metronidazole

Flucloxacillin could be substituted for co-amoxiclav

Advise abstaining from smoking

Mammary fistula:

Excision of major ducts and fistula. Peri-operative antibiotic cover. Consider allowing to

heal by secondary intention. (Implications for breast-feeding).

Inflammatory Swelling

Usual presentation at edge of areolar mimicking infection. Generally resolves without antibiotics over 3 weeks. Suggest: aspirate if abscess, consider repeat aspiration and antibiotics (surgery second choice as 1/3 get fistula)

Send aspirate for bacteriology – ask to look for anaerobes

If you consider infection treat appropriately

Surgery only for abscess or to exclude cancer

Consider possibility of self inflicted disease.

Discrete or dominant breast lump

All discrete or dominant breast lumps should be subject to full triple assessment and treated accordingly.

Mammography is rarely indicated under the age of 35 years of age, where ultrasound is the imaging investigation of choice.

Discharge / Follow up policy for Benign disease

- No risk factors – discharge
- In all women decision should be made within 3 months to biopsy or discharge
- Patients 35 – 50 years with risk factor (atypical hyperplasias: multiple intraduct papillomas) consider follow up with mammography every year
- Patients with family history – see referral guidelines earlier
- Over 50 years discharge with advice about participation in national screening

6 Management of malignant breast disease

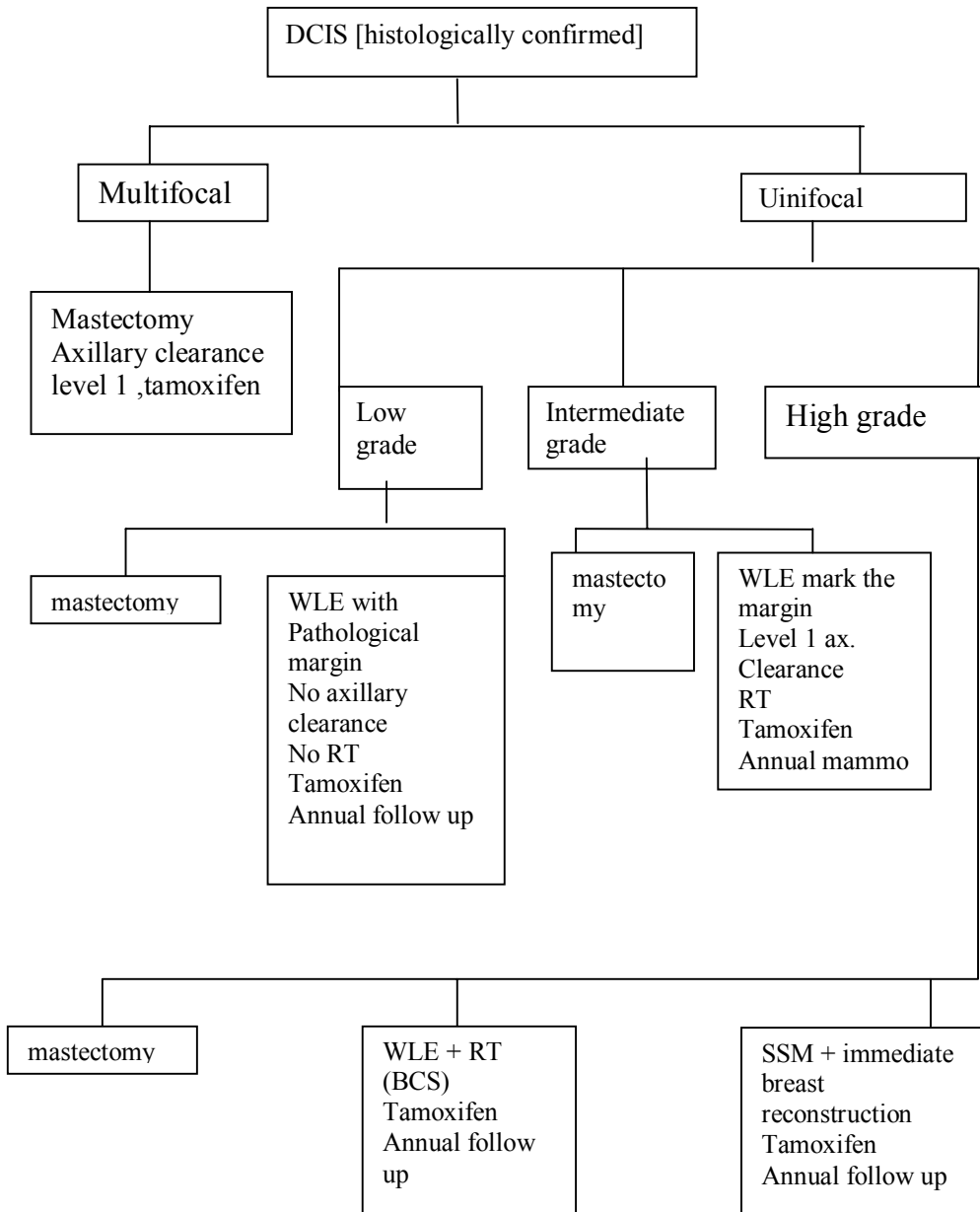
Management of early breast cancer

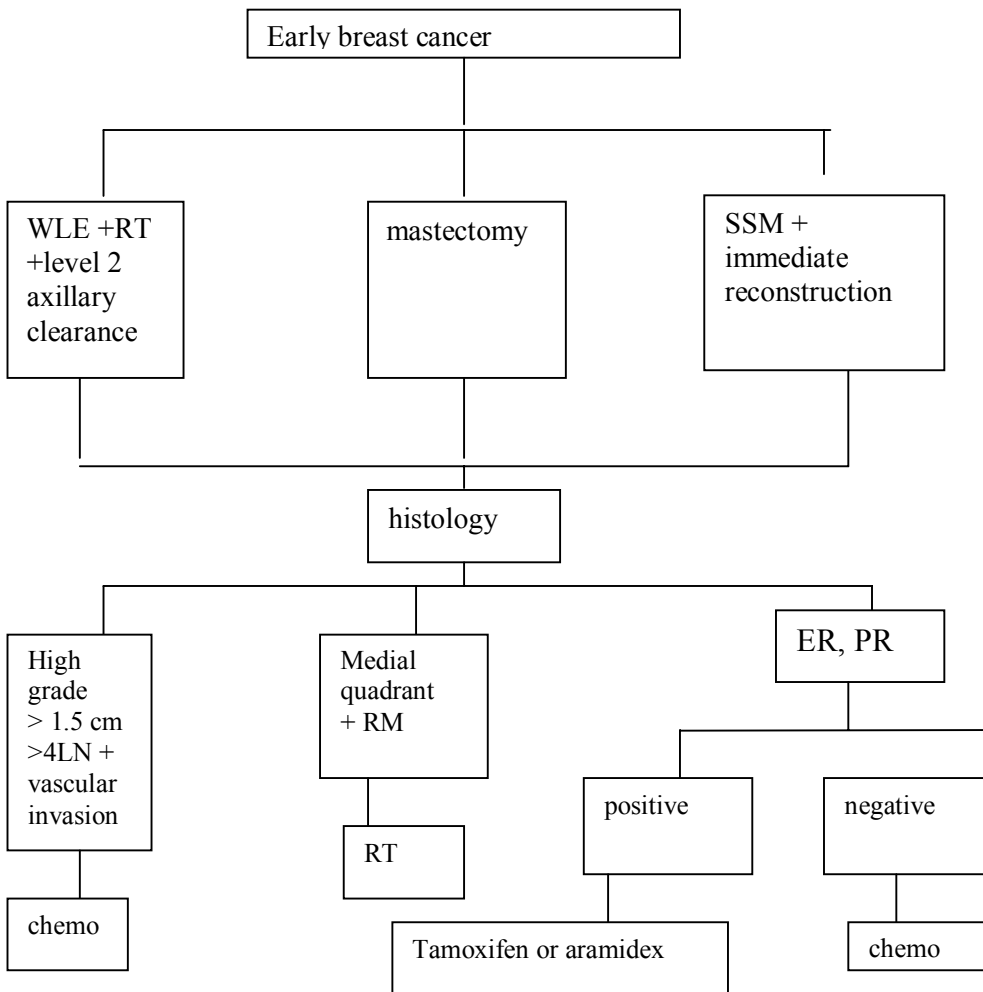
**Identify if this patient has EARLY BREAST CANCER
or LATE BREAST CANCER**

EARLY...Means a

**lesion less than 5 cms clinically and
no ipsilateral lymph nodes or with mobile lymph
nodes. Screen detected in situ cancers are in this
early category.**

**Late.. means a
lesion clinically over 5 cm,
fixed large axillary nodes ipsilaterally,
or evidence of metastatic disease.**





Primary Local Treatment

Surgery is primary treatment **in early breast cancer**

Surgery is the initial treatment

The options are;

Conservative .Breast Conservation Surgery (BCS)

A MAMMOGRAM IS MANDATORY BEFORE BCS CAN BE OFFERED.

Wide local excision and axillary dissection (level 2) is needed.

**ALL MARGINS MUST BE MARKED FOR HISTOLOGICAL CONFIRMATION
A LEVEL 2 AXILLARY CLEARANCE IS REQUIRED IN ALL INVASIVE CANCERS.**

If any margin is positive, after discussion with an oncologist options are

- 1. re-ecxision of margins,**
- 2. conversion to mastectomy**
- 3 Scar boost**

Adjuvant breast radiotherapy with boost to tumor bed must always follow surgery.

Mastectomy

1. If conservative surgery not feasible or appropriate: e.g. multifocal disease, extensive associated DCIS or large primary.
2. If patient prefers it to wide local excision and radiotherapy
3. If recurrent disease after previously optimally treated breast conservation

Immediate or delayed breast reconstruction could be offered in all cases.

Consider post mastectomy radiotherapy to skin flaps and ipsilateral supraclavicular fossa in stage II cancer and locally advanced disease (stage III)

Mastectomy scars should be carefully planned prior to surgery.

Ideal scars should not go beyond the anterior axillary line and not beyond the sternal border. This is due to consideration of radiotherapy boundaries if required in further management

Axillary dissection (invasive disease only)

Routinely to

1. Stage and treat axilla
2. Avoid the need for axillary radiotherapy
3. Optimal local tumour control

Exceptions are:

- Frail or patients > 75 years unless clinically involved
- Previous surgery or radiotherapy to the axilla

Staging investigations, as appropriate

In patients with early breast cancer without symptoms:

FBC, LFT, calcium, chest x-ray.

Ultrasound scan abdomen.

CT scan and bone scan where indicated.

Locally advanced disease (Usually T3 or T4)

- Treat with primary medical therapy.
- If residual mass after treatment either breast conservation or
- mastectomy +/- reconstruction.
- The axilla should be treated either with axillary clearance, especially in the presence of palpable axillary disease.
- Radiotherapy to the skin flaps / supraclavicular fossa as appropriate.
- Endocrine therapy if ER positive.
- Selected patients with stage IV disease may be treated by chemoradiation for local control.

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Treatment and management using adjuvant systemic therapy

Patients eligible for adjuvant systemic therapy are:

- All patients with pathological node positive disease < 65 years
- Patients age 65 – 70 are offered this treatment at the discretion of the clinician depending upon performance status, level of risk, motivation etc.
- Patients without node positive disease but with one or more of the following:
 1. Grade III histology
 2. Vascular invasion
 3. > 2 cm diameter

4 ER(-)

- Patients <40 years unless grade I
- Any other patient outside these categories who appears to have high risk disease on individual criteria (e.g. borderline indications but ER-)

Adjuvant chemotherapy:

To be given before or concurrently with R/T, if this is also part of treatment plan

1. Record patient height and weight and calculate surface area
2. Obtain written consent
3. Consider wig referral if alopecia likely

4. Assess cardiac function in those due to receive an anthracycline.
5. Assess serum creatinine and 3rd space for those due to receive methotrexate.
6. FBC and all toxicity score should be recorded.

Adjuvant Tamoxifen

In ER+ or PgR+ patients

Dosage is 20 mg daily and duration is 5 years

1. Check that the patient is not taking oral anticoagulants.
2. Ask patient to report unusual vaginal bleeding or change in vision.
3. Watch for menopausal symptoms

Ovarian suppression (OS):

Premenopausal patients unsuitable for tamoxifen or chemotherapy may be considered for OS.

Methods:

- Laparoscopic oophorectomy is preferred, especially in likely BRCA1 carriers.
- Radiotherapy
- LHRH ANALOGUES (Zoladex)

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Radiotherapy

Ductal carcinoma in-situ

Indications for radiotherapy to the breast (excluding axilla) include:

- High grade or comedo DCIS treated by breast conservation surgery. Complete surgical excision with clear margins is essential.
- Intermediate risk DCIS e.g. 15-40mm grade II DCIS treated by breast conservation surgery. Complete surgical excision with clear margins is essential.

Radiotherapy **is NOT** usually required:

- For small focus (e.g. <1cm) of low grade DCIS widely excised (e.g.>1cm margin)
- Following mastectomy for DCIS

All patients should be fully informed of treatment options and all cases should be discussed at multidisciplinary review

Small (T1) invasive cancers:

If completely excised, node –ve, grade 1 ductal carcinoma and pT 20 mm radiotherapy to the whole breast may be recommended.

Radiotherapy should be scheduled to start no later than 4 weeks after surgery in patients not receiving adjuvant chemotherapy.

In patients receiving adjuvant chemotherapy radiotherapy should be scheduled to start 4 weeks after completion if anthracyclines were used.

For patients receiving CMF or MMT radiotherapy can be given concurrently or at the end of chemotherapy, at the discretion of the consultants involved.

Radiotherapy – skin care guidelines:

- Patients can wash normally using an unperfumed, mild soap.
- Topical application of aqueous cream is recommended. Deodorant and perfumed skin care products are not recommended.
- Baby Talcum Powder may be applied if required.

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- Clothing should be comfortable. Underwear should be the correct size. Natural fibres are recommended.
- Maintenance of “normal” nutrition and hydration status is encouraged throughout treatment.
- Sun exposure during treatment is discouraged.

Post treatment patients are advised to avoid direct sun exposure until any acute skin reactions have subsided. Subsequent use of a high protection factor sun block is recommended.

Patients are advised to continue usual activities during treatment whenever possible, including swimming.

Individualised approach to pruritis assessment e.g. hydrocortisone 1% is recommended for topical application twice daily to symptomatic areas. Consider stronger topical steroid preparations (as recommended by the radiotherapist) if pruritis is not relieved by hydrocortisone 1%.

Individualised approach to analgesia assessment e.g. paracetamol may be recommended when appropriate. Coproxamol and/or non-steroidal anti-inflammatory drugs may also be indicated if discomfort is not relieved by paracetamol.

Management of moist desquamation:

1. Refer to nursing staff for dressing assessment.
2. Assess wound dimensions, colour, appearance and the nature of any exudate.
3. If signs of infections are evident (e.g. underlying cellulitis, delayed healing, severe discomfort), swab wound. Oral antibiotics as indicated.
4. Use aseptic irrigation technique to clean wound with 0.9% normal saline.

5. Dressing assessment.

- Minimise the use of adherent material and bandages.

- If surrounding skin is fragile, a thin hydrocolloid sheet can also be used on which to fasten tape.

7. On completion of treatment when possible consider the suitability of applying Hydrocolloid sheet, a thin dressing/ which may remain unchanged for 3 – 4 days or until dressings lift off easily.

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Follow up

Patients diagnosed with breast cancer will be followed up according to Breast Unit protocol in the Outpatients Department.

Several randomised trials have demonstrated that frequent hospital based follow up with detailed investigations have little, if any clinical benefit. This is because patients themselves are usually the first to notice symptoms or signs of recurrence.

Patients with proven benign breast disease **do not** need any routine follow up.

The only exceptions to this are:

- Women who are also at significant increased risk by virtue of a strong family history or those with no family history and biopsy proven atypical hyperplasia or lobular carcinoma in situ.
- Patients who have some abnormal results but not a confirmed diagnosis of cancer for a single follow up appointment within 12 months. This would include for example borderline lesions or C2 M3 results.

Current follow-up outpatient schedule:

3 monthly clinical assessment for first 2 years
6 monthly clinical assessment from years 3 to 5
12 monthly clinical assessment from years 5 – 10 years
Annual mammography

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Treatment and Management of Local recurrence; no distant metastases**Chest wall recurrence - operable:**

If no previous radiotherapy and operable, consider excision +/- reconstruction. Consider post operative radiotherapy to chest wall.

Chest wall recurrence – inoperable:

If on endocrine therapy, consider 2nd line endocrine manipulation if ER+ve.
If good response endocrine therapy, consider debulking surgery.

If poor or no response to hormonal treatment, consider chemotherapy.

Options include:

- Chemonaive: standard treatment
- Previously had CMF: MM, FEC or AC
- Anthracycline resistant: Consider Taxane

Consider radiotherapy if in previously untreated patients.

Breast Recurrence:

- If after WLE and RT and operable, for mastectomy +/- reconstruction.
- If inoperable and recurrence on first line endocrine therapy, treat with chemotherapy as above to debulk. Consider also second line endocrine therapy.
- If after WLE alone, treatment schedule should also include the axilla

Restage the patient. At presentation.

Recurrence in the presence of metastatic disease:

Seek optimum balance between relief of cancer morbidity and systemic treatment toxicity. The least toxic treatment should be used first. Endocrine treatment options should be reviewed.

In selected asymptomatic patients, a watch policy may risk rapid development of uncontrollable symptoms. In these cases 'prophylactic palliation' may be justified.

Age, performance status, sites of disease, and previous treatment affect the first line modality used. Avoid treatments associated with side-effects worse than those caused by a patient's cancer.

Before introducing a change in systemic therapy, document nature and severity of symptoms for subsequent subjective assessment of patient response.

Nominate marker lesions for objective assessment of patient response. Ensure bidimensional measurements documented, making use of diagrams and photographs as appropriate.

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Before changing hormone therapy, consider waiting 1 month to assess for a worthwhile withdrawal response.

Endocrine therapy:

1st line Tamoxifen 20 mg OD.

2nd/3rd line Anastrozole 1 mg OD or
megestrol acetate 80 mg BD or
medroxyprogesterone 400 mg BD.

Patients who have recurred while on first line therapy can proceed to second line therapy.

Patients who recur more than 1 year after tamoxifen exposure could be re treated using the same medication as an alternative to second line agents.

Chemotherapy:

1. Record patient height and weight and calculate surface area.
2. Obtain written consent.
3. Consider wig referral if alopecia likely.
- 4 Assess cardiac function in those due to receive an anthracycline.
5. Assess serum creatinine and 3rd space for those due to receive methotrexate.
6. FBC and all toxicity scores should be recorded.

Standard chemotherapy regimens:

- CMF - 28 day cycle - 6 cycles.
- FEC - 21 day cycle - 6 cycles.
- MM - 21 day cycle - 6 cycles.

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Chemotherapy - assessment of response, performance status and toxicity

UICC response criteria for locally advanced and metastatic breast cancer.

Measurement/evaluation of lesions-

Breast - superficial and palpable lesions should be measured in cm along 2 axes, one being the longest and the other the longest perpendicular to it. Superficial lesions should also be photographed with a ruler for scale. For diffuse infiltration, it is recommended that cutaneous marks be made 10 cm apart centred on the nipple. The distance between

these marks is measured after digital compression of the breast and recorded.

Skin - Individual lesions should be measured as above. Diffuse lesions should be photographed.

Lymph nodes - superficial nodes should be measured as above. For mediastinal nodes, treat as a unidimensional measurement taken at a defined thoracic level.

Lymphoedema - The limb circumference should be measured at a stated distance above and below the olecranon.

Bone - Individual lesions can be evaluated from selected films. Comparison of sequential bone scans can provide further information although it should be noted that both progression and regression can lead to an increase in uptake.

Lung - nodular disease can be measured bidimensionally from a plain radiograph. Diffuse disease should be evaluated and compared on serial chest radiographs although it is recognised that comparisons may be difficult.

Pleural effusion - Extent should be recorded by PA and lateral chest radiographs. The frequency and volume yield of thoracocentesis should be noted.

Liver - Histological confirmation is desirable when this is the first site of metastases.

Clinical measurement of the liver should be undertaken with the patient supine. The inferior border of the liver should be recorded as a vertical distance below the costal margin or xiphisternal notch at a fixed distance from the midline and/or at the midline.

The same reference point must be used subsequently at the same phase of respiration (quiet respiration or deep inspiration). It should be remembered that a right pleural effusion can affect the liver position.

Ascites - The abdominal girth should be measured at a fixed point. Weight should be recorded periodically. The frequency and volume yield of paracentesis should be noted together with any diuretic requirements.

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Abdominal mass - Clinical bidimensional measurements supplemented by CT and/or ultrasound.

Nervous system - record neurological deficit. Serial CT scans are useful for quantifying response.

The suggested UICC response criteria are very similar to the W110 recommendations (see below) but do not stipulate a 4 week period of observation.

It is suggested for multiple measurable lesions that 8 or more representative ones are recorded for assessing response.

WHO response criteria (1979):

All measurements should be taken using a ruler or calipers and recorded in metric notation.

Anatomical diagrams and/or colour photographs should be used for visible/palpable disease. They should bear the patient's hospital number and have a ruler for scale. If both measurable and unmeasurable lesions co-exist in a patient, the response of each should be recorded separately. The overall response should take account of both parameters.

In patients with measurable disease, the poorest response designation shall prevail.

For multiple lesions, if there are an equal or greater number of complete/partial responses than 11 "no change" designations, the overall designation will be a partial response.

Baseline measurements may be recorded by:

- Bidimensional measurements (surface area approximation) - multiply the longest diameter by the greatest perpendicular diameter. For multiple lesions in a single organ, sum the products of the diameters for all measured lesions.

- Unidimensional measurements - for liver enlargement, sum the three distances of the inferior liver edge from the xiphoid notch and right and left costal margins in the respective midclavicular lines. For other lesions, record the single measurable dimension.

Response criteria **for measurable disease:**

- Complete response - The disappearance of all known disease determined by 2 observations not < 4 weeks apart.
- Partial response - 50% or more decrease in total tumour size determined by 2 observations not < 4 weeks apart. There must be no new lesions or progression of any lesion.

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- No change - < 50% decrease in total tumour size or < 25% increase in one or more measurable lesions.
- Progressive disease - 25% or more increase in size of one or more measurable lesions, or the appearance of new lesions.

Response criteria for unmeasurable disease:

- Complete response - Complete disappearance of all known disease for at least 4 weeks.
- Partial response - Estimated decrease in tumour size of 50% or more for at least 4 weeks.
- No change - No significant change for at least 4 weeks. This includes stable disease, estimated decrease of < 50% and lesions with estimated increase of < 25%.
- Progressive disease - Appearance of any new lesion not previously identified or estimated increase of 35% or more in existing lesions.

Response criteria for bone metastases:

- Complete response - Complete disappearance of all bone lesions on x-ray or scan for at least 4 weeks.

- Partial response - Partial decrease in size of lytic lesions, recalcification of lytic lesions or decreased density of blastic lesions for at least 4 weeks.
- No change - Because of the slow response of bone lesions, this designation should not be applied until at least 8 weeks have passed from the start of therapy.
- Progressive disease - Increase in size of existing lesions or appearance of new lesions.

Karnofsky performance score:

100 Normal. No complaints. No evidence of disease.

90 Able to continue normal activity. Minor symptoms/signs.

80 Normal activity with effort. Some symptoms/signs.

70 Self caring. Unable to continue normal activity or do active work

60 Requires occasional assistance but able to care for most of needs.

50 Requires considerable assistance and frequent medical care.

40 Disabled. Requires special care and assistance.

30 Severely disabled. Hospitalisation indicated although death not imminent.

20 Very sick. Hospitalisation and active supportive treatment necessary.

10 Moribund. Fatal processes progressing rapidly.

0 Dead.

WHO performance score:

0 Normal activity without restriction.

1 Strenuous activity restricted. Ambulatory and can do light work

2 Up and about > 50% of waking hours. Self caring but unable to work.

3 Confined to bed or chair > 50% of waking hours. Limited self care.

4 Confined to bed or chair. Unable to care for self Completely disabled.

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**Metastatic disease - special problems:
Radiotherapy for localized painful bone metastases:**

Consider palliative radiotherapy, e.g. an 8 Gy single fraction unless otherwise specified by a clinical oncologist.

If cortex eroded on major weight bearing bone, consider referral for orthopaedic pinning.

After fixation, give 20Gy in 54 to surgical pin.

Patients with multiple bone secondaries can be considered for Clodronate.

Cerebral metastases:

Patients with solitary metastases on CT should undergo MRI.

Those with solitary brain metastases on MRI should be considered for neurosurgical referral for excision followed by whole brain radiotherapy +/- stereotactic boost.

Surgery should also be considered when:

The diagnosis is in doubt.

A large cystic metastasis is causing symptoms.

Those receiving radiotherapy should be prescribed 20Gy in 5 fractions to the whole brain.

Dexamethasone 8 - 16 mg daily may relieve cerebral oedema and be continued during radiotherapy.

Wig fitting should be arranged.

Refer for physiotherapy and occupational therapy if appropriate.

Spinal Cord Compression:

Define block using MRI. MRI exclusion criteria include:

- Previous cranial aneurysm surgery.
- History of penetrating eye injury with metal.
- Cardiac pacemaker.
- Severe claustrophobia.

All patients with a spinal block covering 3 vertebrae or less should be discussed with a neurosurgeon if fit for surgery.

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A clinical oncologist should be notified as soon as a case is identified in case urgent radiotherapy is required.

Those having radiotherapy will be prescribed 20 Gy in 5# or 30 Gy in 10#.

Consider prophylactic heparin in view of high risk of DVT.

Refer for physiotherapy and occupational therapy.

Malignant pleural effusion:

Symptomatic patients should be admitted and the effusion drained.

Consider talc pleurodesis as first line therapy if fit for thoracoscopy.

A tetracycline or bleomycin pleurodesis should be performed if unsuitable for surgery but only after full drainage.

Consider referral for pleuro-peritoneal shunt if effusion recurs following chemical pleurodesis.

Ascites:

Ascites should be drained by insertion of an intra-peritoneal drain.

Liver capsule pain: This should be treated with dexamethasone 4 - 16 mg po daily, analgesia and appropriate systemic treatment.

Meningeal disease:

Treatment is with methotrexate 12.5 mg weekly intrathecally.

These patients may require radiotherapy for symptomatic disease.

Malignant hypercalcaemia: - Day ONE of symptomatic hypercalcaemia:

Confirm with senior colleagues that active management is appropriate.

Measure U & E, and serum creatinine, calcium and albumin.

Use standard correction factor for serum albumin i.e.
corrected calcium = measured calcium + [(40 - serum albumin) x 0.021].

All patients with symptomatic hypercalcaemia should receive 24 hours iv rehydration with normal saline (3 - 6 litres per day for an adult).

Since the renal failure associated with hypocalcaemia is frequently due to dehydration, administration of IV fluids

may bring about rapid symptomatic improvement. Caution is necessary when rehydrating a patient with established renal failure.

Malignant hypercalcaemia: Day TWO onwards:

1. If corrected serum calcium >2.6 mmol/l measured that day then:
Infuse clodronate 1500mg in 500ml N. saline over four hours
2. Continue IV rehydration (unless or until adequate oral intake is re-established).
3. Monitor electrolyte and fluid balance for 3 - 5 days when serum Ca may be expected to fall. If there is no response after 7 days the patient should be retreated.
4. If no effective change to tumor management has been made, serum Ca is likely to rise again within two to four weeks.
5. Retreatment with i.v. clodronate may be appropriate after 14 - 21 days.
6. If the patient's serum creatinine is > 1.5 x normal, treatment with an appropriate dose of iv pamidronate should be discussed with senior colleagues.

APPENDIX

Recommended screening protocol (Can be adopted only when adequate mammography is available throughout the country)

- Screening mammography and clinical examination every 12 months from the age of 35 years of age **for women with a strong family history.**
 - From age 50 – 69 years, screening mammography and clinical examination is offered every 18 months **if the woman requests it**
 - In women whose relatives developed breast cancer under the age of 35 years, clinical examination should start annually 5 years before the index case. **Mammography is not usually indicated in women under the age of 35 years.**
 - Breast self examination should be taught and reinforced at every clinic follow-up visit in this cohort of women
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