

Manchester Cancer - Guidelines for the Management of Breast Cancer

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Guidelines Group

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Introduction

These guidelines have been compiled to aid clinicians managing breast patients. They do not aim to replace national guidelines, but to highlight the most up-to-date guidelines, provide additional information, and detail any variance due to local factors.

Each section is updated separately by a panel of volunteers. If you wish to raise any points or provide any updates please contact the main author for the relevant chapter, so that your thoughts can be incorporated into the next version.

There are a number of important documents covering several sections:

NICE CG80 Early and local advanced breast cancer 2009 nice.org.uk/guidance/cg80

NICE CG81 Advanced breast cancer (update) 2014 guidance.nice.org.uk/cg81

Association of Breast Surgery 2005 Guidelines for the management of symptomatic breast disease
European Journal of Surgical Oncology 31: S1-S21

And ABS 2009 surgical guidelines for the management of breast cancer EJSO (2009)S1-S22

see guidelines archive of: associationofbreastsurgery.org.uk

Cancer Reform Strategy Department of Health 2007 mccn.nhs.uk

The London Cancer Alliance has produced their own guidance, Oct 2013, at

Patient Pathway and the Breast MDT

Referrals

All symptomatic breast patients should be offered an appointment to be seen within 14 days of GP referral (national target 93% actually seen), have a triple assessment on that visit if needed, have the results discussed at a Breast MDT, and be seen back with the results within 5 working days of the biopsy. Treatment should commence within 31 days of diagnosis/decision to treat (this date is usually the date the patient is seen with the results), and within 62 days of referral.

Patients should be assessed using:

Best Practice Diagnostic Guidelines for Patients Presenting with Breast Symptoms Department of Health 2010, see guidelines section of: www.associationofbreastsurgery.org.uk

Patients from the screening programme requiring surgery should be seen by a surgeon within 1 week of the decision to refer ($\geq 90\%$ minimum standard, 100% national target) and receive their first treatment within 62 days of the decision to recall. ($\geq 90\%$ minimum standard, 100% national target). Patients screened in a distant screening unit should be offered the option of treatment at their local hospital.

For further information about screening programme standards see:

NHS Cancer Screening Programmes Consolidated Guidance, 2005. NHSBSP 60
www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp60

The Breast MDT

National guidance is available at

www.cquins.nhs.uk/download.php?d=resources/measures/Breast_April2013.pdf

The Breast MDT should discuss

- All patients who have a triple assessment from symptomatic clinics, and biopsies from the NHSBSP (unless local protocols are in place to manage concordant benign assessments separately)
- All patients who have had surgery for breast cancer / DCIS / excision biopsy
- All newly diagnosed recurrent or metastatic breast cancers
- At least 100 new breast cancer patients per year

Any member of the MDT should also be able to add patients, eg complex imaging report, change in patient's circumstances,

The Breast MDT should meet at least once per week excluding bank holidays.

The Breast MDT needs a single named lead clinician who is also a core team member. The lead clinician should attend at least 2/3 of the network group meetings.

The core members should include at least:

- 2 designated Breast surgeons (each doing ≥ 30 breast cancer procedures/year)
- Clinical oncologist
- Medical oncologist if clinical oncologist does not give chemotherapy
- Imaging specialist (or a group as long as each meets required workload)
- Histopathologist (or a group, as long as each takes part in breast cancer EQA and meets workload requirements)
- Two specialist breast nurses
- MDT co-ordinator/secretary
- Person responsible for recruitment to clinical trials
- Person with level 2 psychological training (may be one of the above core members)

Note:

All consultants responsible for delivery of main treatment modalities should be core members. The core member for medical specialties should be a consultant but a non-consultant can cover.

To be quorate the meeting needs the following core members or their named deputies:

- 1 breast surgeon
- 1 clinical oncologist (plus 1 medical oncologist where clinical oncologist does not give chemotherapy)
- 1 imaging specialist
- 1 histopathologist
- 1 specialist breast nurse
- 1 MDT co-ordinator

If the MDT is not quorate it is at the discretion of the MDT whether to have a meeting or not. The MDT should be quorate at least 95% of the time. Each core member should attend $\geq 67\%$ meetings.

Some units may prefer to split the MDT into pre-operative, post-operative, and discussion meetings. Not all clinical groups need to attend all sections of the meeting (see below), however if separate meetings are held there needs to be a clear pathway whereby an expert opinion can be obtained for patients requiring it, eg an oncology opinion on neo-adjuvant chemotherapy.

	Symptomatic assessment	Screening assessment	Post-operative results	discussion	
Radiologist	y	y	y	y	
Surgeon	y	y	y	y	
Pathologist	y	y	y	n	
Breast care nurse	y	y	y	y	
Medical oncologist	n	n	y	y	
Clinical oncologist	n	n	y	y	

The MDT also should identify the following extended members to whom patients can be referred: Lymphoedema specialist, occupational therapists, physiotherapists, prosthesis service, psychologist, psychiatrist, genetics, plastic surgeon, palliative care, dietician

The outcome from the MDT should be recorded on a database eg Somerset, and a copy put in the patients records. Patients should be given written information about the MDT team.

The following data should be recorded:

Pre-operative information

- side, quadrant, imaging abnormality (eg mass/microcalcification),size
- how best to localise if impalpable eg us skin mark/ us wire/ stereo localisation
- Axillary us
- Core: grade, type, LVI, ER.
- FNA result if done
- Suitability for WLE, immediate reconstruction, skin- or nipple- sparing mastectomy
- TNM stage if patient unlikely to proceed to surgery
- Trials that may be eligible for
- Name of keyworker

Post-operative information

- Tumour; side, size, grade, type, margins (clear/ how close / involved). Presence of DCIS, LVI
- ER, Her 2
- Nodes; number positive / total, whether macromet ($\geq 2\text{mm}$), micromet (0.2-2mm), or itc ($< 0.2\text{mm}$)
- TNM Staging
- Any further investigations (eg staging CT, oncotype DX)
- Any further treatment recommended (surgery, radiotherapy, chemotherapy, hormonal treatment) Trials that may be eligible for
- Plan to refer any relevant patients eg to CUP or TYA or sarcoma

RADIOLOGY

Manchester Cancer IMAGING GUIDELINES

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Diagnosis

The following guidance for investigation of possible breast cancer should be adopted:

- Assessment of patients referred from primary care:
 - Best practice diagnostic guidelines for patients presenting with breast symptoms, Willets, Michell, Lee, November 2010.
 - Further investigation of lesions with uncertain malignant potential:
 - The London Region Quality Assurance Reference Centre Guidance on Management of Indeterminate Breast Lesions (Appendix 1).
 - NICE clinical guidelines on early and advanced breast cancer.

Imaging standards for evaluation of malignancy

Mammography and ultrasound should be used as part of triple assessment where there are clinically suspicious or discrete findings present. Mammography is not routinely indicated in generalised lumpiness, pain or tenderness, or long-standing nipple retraction but may be worthwhile in women >40 years old with persisting non-suspicious breast symptoms.

Mammography

- Full field digital mammography with optimal image display on a mammography workstation should be used.
- The quality of mammography should adhere to NHS Breast Screening Programme (NHSBSP) standards ⁽¹⁾ with reference to training of staff, quality assurance and the Ionising Regulation (Medical Exposure) Regulations 2000 (IRMER).
- All diagnostic breast units should have access to digital stereotactic image guided biopsy and immediate specimen radiography on site.
- All breast units should be able to perform intra-operative specimen radiography.

Ultrasound

- Ultrasound is the imaging modality of choice for women under the age of 40.
- Ultrasound should also be performed when mammography is discordant with clinical findings and if there is a palpable lesion.
- High resolution ultrasound machines with pre-sets modified for breast imaging should be used.
- Ultrasound scanners should meet NHSBSP standards.⁽²⁾

Magnetic resonance imaging

- When used for screening in women with higher risk of breast cancer, MRI scanners should meet NHSBSP standards (NHSBSP, March 2012).
- MRI should be reported by clinicians with a specialist interest in breast MRI.

Approved Indications for MRI of the Breast

Breast MRI is recognised as a diagnostic tool which should be used as an adjunct to conventional breast imaging after full discussion with a breast radiologist or within the context of the breast multidisciplinary team (MDT) meeting.

The following are recommended indications for breast MRI, which are supported by the published literature (NICE 2009, EUSOMA 2010, EUSOBI 2008):

- **Pre-operative staging** MRI of both breasts is not routinely performed, but may be useful for planning treatment in selected patients:
 - if there is discrepancy regarding the extent of disease from clinical examination, mammography and ultrasound assessment. MRI may act as an additional problem-solving tool in assessing tumour characteristics such as size, extent or multifocality.
 - if breast density precludes accurate mammographic assessment
 - to assess the tumour size if breast conserving surgery is being considered for invasive lobular cancer.
- **Assessment of the contralateral breast in patients with Invasive Lobular Cancer.** Currently this is not a specified indication by NICE but is recommended by both EUSOMA and EUSOBI. It is thought MRI detects occult lesions in the contralateral breast in 3-5% of patients. However, a recent study has shown this figure may be similar in invasive ductal cancer, questioning the logic of using MRI in ILC only. This has major resource implications and individual units should decide on the basis of access to breast MRI within their own service.
- **Recurrence vs scar** Mature scar can morphologically resemble malignancy. At approximately 9 months post-surgery, mature scar should not enhance, whereas recurrent tumour usually shows a typical malignant enhancement pattern.
- **Occult primary tumour/malignant axillary nodes** The primary tumour may be occult on conventional imaging. Less than 1% of breast cancers present with involved axillary nodes but with normal conventional imaging.
- **Response to chemotherapy** MRI can document tumour response to chemotherapy. A baseline pre-treatment MRI is required to document initial tumour location, size and imaging characteristics. An interim scan should be planned following 2/3 cycles of treatment. The tumour may require coil localisation or skin tattoo if there appears to be significant response, or potential for complete response. An end of treatment scan completes the assessment of response.
- **Breast implant imaging** MRI may be used for assessment of implant integrity in cases of suspected leak or rupture, and to assess potential malignancy in an implanted breast.
- **Screening in high-risk groups** NICE guideline 41 (October 2006) recommends annual contrast enhanced breast MRI for screening in a clearly defined cohort of women with a positive family history of breast cancer. The risk criteria of women who would qualify for screening are clearly set out in this guidance. This screening is also a requirement of the Cancer Reform Strategy (CRS, 2008). Breast MRI is recognised as a suitable screening investigation in the cohort of women who have had exposure to supra-diaphragmatic radiotherapy. The screening for this cohort of high-risk women will be undertaken by the NHS Breast Screening Programme (NHSBSP).
- **Post-operative assessment/post-radiotherapy** MRI can be misleading in the immediate and short-term post-operative period, and within 18 months of radiotherapy. Scanning during this time should only be in selected patients, after discussion with a breast radiologist or following discussion within a breast MDT and consideration of the limitations of such imaging.

Documentation and reporting standards

Imaging should be reported by clinicians with a specialist interest in breast imaging and experience in specific modality interpretation. Where relevant, reports should include information on:

- breast density
- imaging features of lesion
- size of lesion (longest dimension at least)
- site of lesion (quadrant and distance from the nipple)
- multifocality/multicentricity (including distance between foci, and whole size)
- assessment of the axilla
- change from previous images (e.g. in monitoring tumour response to treatment) – comparable measurement should be stated on consecutive images
- level of suspicion with reference to the UK 5-point scoring system ⁽³⁾
- the reporting clinician(s).

Pre-operative localisation

Optimal surgical excision should be supported by pre-operative localisation in all cases when conservative treatment is planned and the cancer is not clearly palpable. Ultrasound is the imaging method of choice with stereotactic localisation for lesions seen only on mammography. The wire tip should transfix the lesion (minimum standard: should lie within 1cm of the lesion), and a skin marker should be placed over the lesion. A skin marker alone is helpful when the cancer is palpable. Images and a report should be available to the surgeon prior to the operation.

Intra-operative specimen radiography is mandatory for impalpable lesions requiring radiological localization and recommended for all wide local excision procedures. Dedicated equipment (eg, digital specimen radiography cabinet) should be available so that a radiograph can be taken of the specimen and reported to or by the surgeon within 20 minutes ⁽⁴⁾.

Staging

The standard of care with respect to the axilla is sentinel lymph node biopsy (SNLB) if the axillary lymph nodes appear normal. It is important therefore to perform preoperative ultrasound of the axilla in order to detect overt nodal involvement and prevent unnecessary SLNB and then a further axillary procedure. Nodes with a cortical thickness of >3mm or with eccentric focal cortical thickening or architectural disruption are suspicious of metastatic involvement, and nodes with a cortical thickness of 2.3-3mm are indeterminate. Confirmation of nodal involvement with FNAC or core biopsy is recommended.

Routine staging for metastatic disease at presentation has a low detection rate and has not been demonstrated to confer a survival benefit. However women presenting with locally advanced breast cancer (T3 or T4 disease and inflammatory breast cancer) or clinical evidence of metastatic disease should undergo staging with CT of the thorax, abdomen and pelvis (with IV contrast to demonstrate the liver in the portal venous phase) and isotope bone scanning, as the presence of metastatic disease may influence the choice of treatment and subsequent follow up. It may be appropriate to consider staging for a lesser extent of disease if the cancer is triple negative on core biopsy ⁽⁵⁾. In addition, patients who are found at surgery to have four or more metastatic axillary lymph nodes

(N2) should be considered for CT staging. Staging should also be considered in recurrent cancer in the ipsilateral breast.

The TNM system (UICC TNM 7, Appendix 2) has not been in widespread use in the UK for breast cancer staging but is now being used more frequently and its use is encouraged. It is recommended that TNM staging is recorded following primary surgery (this will usually be a combination of pathological T and N stage and clinical M stage). TNM stage should also be reported if preoperative CT staging is performed.

Surveillance of cancer patients and women at increased risk of cancer

Surveillance strategies (6)

There is evidence to suggest a survival benefit for women who undergo surveillance mammography after treatment for breast cancer. Hard evidence to support one mammographic follow up regime over another is lacking. The NICE Breast Cancer Quality Standard published in August 2011 should be followed as a minimum:

Women treated for early breast cancer have annual mammography for 5 years after treatment ⁽⁷⁾. After 5 years, women who are 50 or older receive breast screening according to the NHS Breast Screening Programme timescales, whereas women younger than 50 continue to have annual mammography until they enter the routine NHS Breast Screening Programme. The age at which screening should cease is unclear. It is recommended that ipsilateral screening should cease when it is considered co-morbidities would make the detection of an asymptomatic recurrence unhelpful.

In women who have undergone mastectomy, the evidence for early detection influencing outcome reduces and the risk of over-diagnosis increases with age. Routine mammographic surveillance of the contralateral breast is not recommended after the age of 75 years. ⁽⁷⁾

- Mammography should be delayed for 6 weeks after cessation of lactation because of the reduced sensitivity of the denser breast. The NHSBSP recommends that ultrasound may be used as an alternative screening modality while women are breast feeding.
- Consider annual MRI for women under the age of 40.
- Patients at underlying increased risk should follow the appropriate NHSBSP guidance if it offers more intensive screening during or after the initial surveillance period.
- Routine surveillance imaging of the post-mastectomy reconstructed breast is not indicated.

High-risk surveillance (8)

See Appendix 3

Moderate increased risk surveillance (9)

- Women at moderately increased risk should be offered annual mammography between the ages of 40 and 50.
- Any other surveillance strategy should only be part of an approved trial (e.g. FH02).

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Appendices

Appendix 1: London Region Quality Assurance Reference Centre Guidance on Management of Indeterminate Breast Lesions

(January 2012)

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Background

In 2008/09, 275 women in London were referred for diagnostic surgery following NHS Breast Screening Programme (NHSBSP) screening mammography. Eighty-two women had a final diagnosis of malignant disease, and 193 women had benign changes. Most of these operations were precipitated by a pre-operative diagnosis of an indeterminate lesion such as papilloma, radial scar or atypia, which carry an associated risk of malignancy. The vast majority of these diagnoses were made with needle core biopsy (NCB) which, by necessity, will have only sampled a small volume of tissue. The increasing use of vacuum-assisted wider bore biopsies (VABs) means that it is now possible to manage these cases without surgery.¹ However, the management of the patient following a biopsy diagnosis of indeterminate pathology may be complex, and the Quality Assurance team concluded that clarification would be helpful.

Aims

It is recognised that cases are considered on a case-by-case basis. The aim of this document is to provide guidance for the multidisciplinary team in the management of these cases.

If malignancy is identified either pre- or post-operatively, the management is determined by the nature of the malignant pathology. If atypia is seen with other lesions (papilloma, radial scar) then the recommendations for atypia should be followed (excision of a representative sample of the atypia).

Non-pleomorphic lobular neoplasia is a coincidental finding in many cases. In such cases, the radiographic abnormality prompting assessment should be managed appropriately, but follow-up is indicated because of the increased risk of developing cancer.¹⁶

Pleomorphic lobular carcinoma in situ (LCIS) should be considered as malignancy (as ductal carcinoma in situ (DCIS) is considered as malignancy) and surgical management is indicated,

although vacuum biopsy may be considered with a view to upgrading the pathology in selected cases.

The vacuum biopsy advisory group considered that there are separate roles for VAB in the primary diagnosis of certain groups of imaging findings and for the further diagnosis of abnormalities already biopsied by NCB or fine needle aspiration (FNA) cytology. The common principle for achieving adequate diagnosis is retrieval of sufficient tissue. The recommendation of the vacuum biopsy advisory group is that for abnormalities that are often associated with an indeterminate diagnosis (mainly calcifications but also distortions and some asymmetries and small masses), the primary diagnostic approach should be to use VAB as the primary biopsy technique to either to excise the whole abnormality (e.g. 5mm cluster of calcification) or obtain a minimum of 2g of tissue (Table A1.1). For indeterminate lesions already diagnosed as indeterminate at NCB (e.g. atypical ductal hyperplasia (ADH), papillary lesion, mucinous lesion, radial scar) the option of VAB excision of a minimum of 5g of tissue should be considered, even if the histology shows atypia (to confirm that only atypia is present or to potentially upgrade to DCIS and/or invasive breast cancer).

Table A1.1: Lesions considered suitable for use of vacuum assisted biopsy as the primary diagnostic technique

Radial distortion with no mass on ultrasound
Calcification
Soft tissue lesion with presumed diagnosis of papilloma

The management recommendations for lesions that correspond to the mammographic abnormality are given in Table A1.2. However, on occasion, an indeterminate lesion is identified in a biopsy that was taken for a mammographic abnormality which proves to be benign, and such coincidental lesions are considered separately in Table A1.3.

Table A1.2: Recommended management of indeterminate lesions where the pathology corresponds to the mammographic abnormality

	Non-operative	Follow-up	Operative	Follow-up
Solitary papilloma, well-defined discrete lesions	Preferred: vacuum-assisted excision to remove lesion	None if imaging lesion is totally removed and no atypia	Local excision, fully excised	None
Multiple peripheral papillomas	Diagnostic vacuum excision of index lesion	Standard increased risk surveillance policy*	Remove lesion (consider risk-reducing surgery)	Standard increased risk surveillance policy*
Radial scar <2cm	Preferred for lesions <2cm: at least 12 VACB core biopsies to sample lesion. If atypia, then surgical excision recommended	None	MDM may elect to recommend excision for lesion >2cm**	None if no atypia. If atypia standard increased risk surveillance policy*
Atypical ductal proliferation (ADH) (1cm or less of calcification)	VACB – if no DCIS and lesion fully removed, consider further vacuum assessment of site	Standard increased risk surveillance policy* (marker to be placed)	Preferred – to remove area of mammographic abnormality	Standard increased risk surveillance policy*
Extensive calcification >1cm with Atypical ductal proliferation on initial biopsy	Vacuum biopsy of more than one area	If no DCIS, refer for diagnostic biopsy	Diagnostic biopsy of most suspicious area	If only atypia from representative surgical sample, standard increased risk surveillance policy*
Lobular neoplasia (atypical lobular hyperplasia/LCIS) not pleomorphic LCIS or LCIS with necrosis	Assess mammographic abnormality and manage accordingly	Standard increased risk surveillance policy*	LCIS – remove imaging abnormality unless already diagnosed as benign by vacuum	Standard increased risk surveillance policy*

* At present, the recommended follow-up for women at increased risk is five years annual mammography, after which women are returned to routine NHSBSP screening.²

** López-Medina et al.³ showed that the proportion of the radial scar volume involved by carcinoma ranged from 3.7% to 16.2% (mean, 8.3%) and was located invariably at the periphery of the lesion. As a consequence, even very extensive sampling might theoretically miss malignant foci.

Table A1.3: Table A1.3: Recommended management of indeterminate lesions where the indeterminate pathology is coincidental and not predicted by imaging

	Non-operative	Follow-up	Operative	Follow-up	
Solitary papilloma	Preferred: vacuum-assisted excision to remove radiologically visible lesion	None if imaging lesion is totally removed	Local excision	None	
Multiple papillomas	Diagnostic vacuum excision of index lesion	Standard increased risk surveillance policy*	Remove lesion. For recurrent lesions consider prophylactic surgery	Standard increased risk surveillance policy*	
Radial scar	No action needed if no corresponding mammographic abnormality	None	No action needed	None	
Atypical ductal proliferation	VACB recommended to exclude DCIS, if minimal atypia only – follow up	Standard increased risk surveillance policy*	Operative biopsy preferred if severe atypia (pre-operative VACB may be used to identify DCIS)	Standard increased risk surveillance policy*	
Lobular neoplasia (non-pleomorphic)	VACB suitable for lobular neoplasia	Standard increased risk surveillance policy*	Operative biopsy for mammographic abnormality if needed	Standard increased risk surveillance policy*	

* At present the recommended follow-up for women at increased risk is five years annual mammography, after which women are returned to routine NHSBSP screening.⁴

Notes on management of lobular neoplasia and columnar cell change

Needle core biopsy

Issues relating to lobular neoplasia in needle core biopsies have recently been reviewed.^{5,6} The EUSOMA working group⁷ considered lobular neoplasia to be most frequently a co-incidental finding in a core biopsy and therefore advised that multidisciplinary discussion was essential to determine management, as is advocated by others.⁸ Diagnostic surgical excision of lobular neoplasia has been advocated.⁹

A recent review of the literature revealed an upgrade of 20% for LCIS and 13% for atypical lobular hyperplasia (ALH) to carcinoma when excised.¹⁰ Concerns have been raised about underestimation of cancer,^{10–12} even with stereotactic vacuum-assisted biopsy,⁹ and this has led to the recommendation of diagnostic surgical excision for all such lesions from some groups.⁵ It must be appreciated that much of the data is retrospective and that not all studies have considered radiological-pathological discordance as a factor resulting in upgrade, as found by some.^{6,13–15} What is required are large prospective studies with all factors included.

There is general agreement, although limited robust data, that pleomorphic LCIS should be subjected to therapeutic excision; in essence treated as DCIS and therefore categorised as B5a on needle core biopsy. In one series of 12 cases diagnosed on needle core biopsy, ILC was found in three cases on subsequent excision.¹⁷ There is a need for larger studies to confirm that this does represent a more aggressive disease.

Columnar cell lesions in breast core biopsies

Cores bearing columnar cell lesions (CCL) are typically sampled for the histological assessment of mammographic microcalcifications. As for other such specimens, these should be examined at multiple (at least 3) levels. If columnar cell change or hyperplasia only is found, without atypia, the lesions should be regarded as within the constellation of fibrocystic change and categorised as B2, benign.

CCLs with atypia should be regarded as flat epithelial hyperplasia and classified as B3, of uncertain malignant potential. Lesions with more complex architecture should also be regarded as an atypical epithelial proliferation and also regarded as B3, of uncertain malignant potential. As for all such screen-detected lesions, multidisciplinary discussion should be undertaken to correlate radiological, clinical and histopathological findings. Data on risk of finding adjacent associated malignancy are extremely limited.

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Appendix 2: TNM Reporting of Staging Investigations

Primary tumour

Site: state left or right; quadrant of the breast

Carcinoma in situ	Tis
Tumour >0.1cm but ≤0.5cm	T1a
Tumour >0.5cm but ≤1cm	T1b
Tumour >1cm but ≤2cm	T1c
Tumour >2cm but ≤5cm	T2
Tumour >5cm	T3
Any size with extension to chest wall (excl. pec. major)	T4a
Any size with ulceration, ipsilat. skin nodules, skin oedema	T4b
Both 4a and 4b	T4c
Inflammatory carcinoma	T4d

Nodal status

Regional nodes: axillary (ipsilateral)

Level I – lateral to pectoralis minor

Level II – behind pec. minor inc. the interpectoral nodes

Level III – apical and medial to pec. minor

- infraclavicular (ipsilateral)
- internal mammary (ipsilateral)
- supraclavicular (ipsilateral)

Metastasis in movable ipsilateral level 1 or 2 axillary node(s)	N1
Metastasis in fixed/matted ipsilateral level 1 or 2 axillary node(s)	N2a
Metastasis in ipsilateral internal mammary nodes in absence of axillary node mets	N2b
Metastasis in ipsilateral infraclavicular node(s)	N3a
Metastasis in internal mammary and axillary nodes	N3b
Metastasis in supraclavicular node(s)	N3c

Metastases

State specifically: non-regional nodes, lung, liver, adrenals,
kidneys, bone, brain, marrow, pleura, peritoneum, skin other.

M1

Appendix 3: High-risk Surveillance Imaging Protocols

Risk	Ages	Surveillance protocol	Frequency	Notes
a) BRCA 1 or b) BRCA2 carrier or c) not tested, equivalent high risk	20-29 30-39 40-49 50+	n/a MRI MRI + Mammography Mammography +/- MRI	n/a Annual Annual Annual	Review MRI annually on basis of background density
TP53 (Li-Fraumeni)	20+	MRI	Annual	No mammography
A-T homozygotes	25+	MRI	Annual	No mammography
A-T heterozygotes	40-49 50+	Mammography Mammography	18-monthly Routine screening (3-yearly)	Routine screening from 50
Supradiaphragmatic radiotherapy-irradiated below age 30	30-39 40-49 50+	MRI MRI +/- Mammography Mammography +/- MRI	Annual Annual Annual	Surveillance commences at 30, or 8 years after first irradiation, whichever is the later. Review MRI annually on basis of background density

Notes:

All mammography must be direct digital mammography to optimise dose and sensitivity.

All MRI must be carried out in accordance with NHSBSP Technical Guidelines for Magnetic Resonance Imaging for the Surveillance of Women at High Risk of Developing Breast Cancer: publication number 68, January 2012.

Background density assessment for continuation of MRI should be based on individual clinical judgement.

Where a woman cannot tolerate MRI, she and her lead radiologist should discuss and agree potential alternatives (e.g. wide scanners).

Screening should be suspended during pregnancy until about 6 weeks after cessation of lactation, due to the fact that the high density of the lactating breast inhibits interpretation of the image.

Ultrasound should not be used as a routine screening or surveillance technique.

For waiting time purposes, the 62-day wait period begins with the decision to recall for assessment. Where two screening examinations take place (mammography and MRI) the clock starts when the

second examination is reported, provided that no other investigation has been deemed necessary after the initial mammography. If an abnormality is seen on the first examination then this should be investigated immediately, and the 62-day wait begins straight away.

Supradiaphragmatic radiotherapy means any treatment in the area of the thorax.

Untested but equivalent high risk would be as defined by a geneticist.

PATHOLOGY GUIDELINES

Author:

Mark Pearson

Oct 2015

Comprehensive national guidelines for breast pathology have been published and these should be followed:

Non-operative diagnosis:

Guidelines for Non-operative Diagnostic Procedures and Reporting in Breast Cancer Screening
NHSBSP Publication No 50 (June 2001) – forthcoming update 2015

<http://www.cancerscreening.nhs.uk/breastscreen/publications/qa-08.html>

Excision specimens (includes assessment of oestrogen and progesterone receptors):

Guidelines for pathology reporting in breast disease NHSBSP Publication No 58 (January 2005) –
forthcoming update 2015

<http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp58.html>

Supplementary guidelines for columnar cell lesions and the spectrum of changes that can be seen in these epithelial proliferations, lobular neoplasia, micrometastases and isolated tumour cells in axillary lymph nodes, the use of basal/myoepithelial markers in diagnostic practice and oestrogen receptor testing in ductal carcinoma in situ:

Current issues in diagnostic breast pathology

Rosemary A Walker, Andy Hanby, Sarah E Pinder, Jeremy Thomas,

Ian O Ellis, National Coordinating Committee for Breast Pathology Research

Subgroup, On behalf of members of the National Coordinating Committee for

Breast Pathology *J Clin Pathol* 2012 65: 771-785

[http://www.mccn.nhs.uk/fileuploads/File/771.%20Pathology%20Articles%20\(Nov%202012\).pdf](http://www.mccn.nhs.uk/fileuploads/File/771.%20Pathology%20Articles%20(Nov%202012).pdf)

HER2 assessment:

Updated UK Recommendations for HER2 Assessment in Breast Cancer

Emad A Rakha, Sarah E Pinder, John MS Bartlett and Ian O Ellis

On behalf of the National Coordinating Committee for Breast Pathology

J Clin Pathol doi:10.1136/jclinpath-2014-202571

http://jcp.bmj.com/content/early/2014/12/08/jclinpath-2014-202571.full?g=w_jcp_open_tab

Service requirements:

Quality Assurance Guidelines for Breast Pathology Services

July 2011 (2nd edition) | ISBN 978 1 84463 072 1

<http://www.cancerscreening.nhs.uk/breastscreen/publications/nhsbsp02.html>

Key performance indicators (including turnaround times):

Key Performance Indicators – Proposals for implementation
Royal College of Pathologists July 2013

http://www.rcpath.org/Resources/RCPATH/Migrated%20Resources/Documents/K/RCPATHKPIproposals_Jul13.pdf

Surgery

ABS 2007 Onco-plastic breast surgery- a guide to good practice EJSO 33 (2007) S1-S23

ABS/BAPRAS 2012 Onco-plastic Breast Reconstruction Guidelines for best practice

Referral for free flaps; contact details of plastic surgeons

Introduction

- Management of these patients should be discussed in the MDT
- DCIS is the as pre-cancerous lesion identified within the breast. The aim of surgical management is to achieve 2 mm of DCIS free margin. If this is not achieved, the patients should be offered further excision of margin(s).
- DCIS can be unicentric or multi centric. Unicentric DCIS of less than 4cm on multi centric with a total area of 4cm can be offered breast conserving surgery. Therapeutic mammoplasty can be considered for larger areas if necessary expertise are available.
- If conservation surgery is successful, it is essential the patient has yearly mammograms for at least the first 5 years to provide early detection of any recurrence.
- Patients who are undergoing mastectomy for DCIS should be offered the option of reconstruction and this may be carried out at the same time as mastectomy. Mastectomy should be offered to the patients with extensive DCIS or inability to achieve DCIS free margins after re-excision of margins.

Sentinel Node Biopsy for DCIS

By definition all axillary nodes should be negative in patients with DCIS and therefore sentinel node biopsy is not necessary. However, in certain circumstances sentinel node biopsy should be considered. These are presented below and such patients should be discussed at MDT level.

1. DCIS > 5cm - 50% of these patients will harbour invasive disease within the area of DCIS
 2. DCIS presenting as a mass lesion – either a clinical mass or a radiological mass lesion
 3. DCIS of high grade in premenopausal patients
 4. When doing Mastectomy for DCIS
- Adjuvant Radiotherapy for DCIS
 - Whole breast radiotherapy reduces the risk of ipsilateral breast relapse after complete excision of DCIS. Randomised trials indicate adjuvant radiotherapy approximately halves the risk of recurrent DCIS and invasive disease [Fisher B, 1998, Julien JP, 2000, UKCCCR DCIS Working party, 2003].
 - Radiotherapy should be offered to patients at an increased risk of recurrence and this essentially constitutes all women with high-grade DCIS tumours. Other risk factors for

recurrence include tumour size, close margins and presence of comedo necrosis [Silverstein 2003].

- No adjuvant radiotherapy is required for women who have undergone mastectomy for DCIS.

Lobular Carcinoma In Situ (Lcis)

- Marker of increased risk of invasive breast cancer
- Usually an incidental finding
- Close monitoring advised (annual screening)
- There is no indication for adjuvant hormone therapy outside clinical trials
- Pleiomorphic LCIS may need open diagnostic biopsy

The Surgical Management Of Invasive Breast Cancer

- The patient's treatment should have been discussed in the diagnostic MDT.
- All appropriate surgical treatment options, including sentinel lymph node biopsy, axillary node clearance, axillary node sampling, wide local excision, therapeutic mammoplasty, mastectomy, immediate or delayed reconstruction should be discussed and made available and documented in patient case notes.
- If an appropriate option is not locally available the patient should be offered this option and referred appropriately
- Surgical technique is to be of the standard set out by the Royal College of Surgeons.
Indications for surgical treatment
(Breast Cancer Management Guidelines Christie Breast Disease Group, Section 3.2, p7 - 8)
- Numerous randomised clinical trials have demonstrated no differences in overall survival or distant metastases in women with operable breast cancer treated with mastectomy compared to those treated with breast-conserving surgery followed by adjuvant radiotherapy [Fisher 1989, Veronesi 1990, Jacobson 1995, Blichert-Toft 1990]
- The aim of breast conserving surgery is removal of the primary tumour with clear histological margins. It is recommended that the margins of excision are examined by the pathologist following "inking" of the specimen and that the specimen is orientated to ensure that the appropriate margin can be identified (if one is involved). If the lesion is screen detected and impalpable (and therefore surgical excision is radiologically guided) it is mandatory to perform a specimen X-ray intraoperatively (NHS Breast Screening Programme recommendation). Based on the findings of the intra-operative X-ray, if the margin(s) in question is (are) deemed to be close to the tumour/ calcifications, operating surgeon may decide to perform further margin excision at the same time. Where clear excision margins cannot be achieved, re-excision or mastectomy is advised.

- The size of the tumour that can be excised with adequate cosmesis depends on the size of the breast. For example a 2cm tumour in a small breast may not be suitable for breast conservation. Conversely, a 4cm tumour in a lady with large breasts may be suitable for a therapeutic mammoplasty utilizing for example “reduction-type” incisions. Patients opting for this type of surgery should be warned that if the tumour margins are involved then a completion mastectomy would be required unless the surgeon can be confident of exactly where the involved margin is sitting within the remodelled breast. Contralateral reduction surgery can be carried out at the same time but again the patient should be warned about asymmetry following radiotherapy to the affected breast. If the patient has a large tumour but requires conservation she may be offered preoperative systemic therapy (see section 5).
- The use of titanium surgical clips to localise the tumour bed is recommended to facilitate the planning tumour bed boost and partial breast radiotherapy. Clips should be positioned in pairs at the medial, lateral, superior, inferior and deep cavity edges at the time of surgery.

Special Points of Surgical Patient Management

- Wide local excision, no further excision needed if there is no tumour at the margins
- Clips to mark the cavity in all patients (to aid radiotherapy planning)
- Orientation of specimen is important for margins assessment
- Clearance of margins must be documented and discussed at MDT

Mastectomy

Patient selection

- Multi focal or multicentric disease affecting more than one quadrant
- Tumour central and behind nipple (can consider central or grissotti excision oncoplastic techniques)
- Size of breast would give unacceptable cosmetic result with conservation surgery
- Recurrence after breast conservation and RT
- Patient refuses breast radiotherapy or is contraindicated
- Patient choice
- Incomplete wide local excision despite 2 attempts at breast conserving surgery
- Extensive in-situ component
- Relative contraindications to adjuvant radiotherapy, ie.
 - 1st or 2nd trimester pregnancy
 - Active scleroderma
 - Active systemic lupus erythematosus

Surgical Management of Axilla

(Breast Cancer Management Guidelines Christie Breast Disease Group, Section 3.8, p11 - 12)

The intention of axillary surgery is to provide control of disease within the axilla and to provide prognostic information for the patient which may be of importance in planning subsequent treatment. Axillary lymph node status remains the most powerful prognostic indicator for early breast cancer.

Axillary surgery is indicated for all patients with invasive breast cancer, but is not routinely indicated for patients with pure DCIS (see above).

There are two principle surgical approaches:

- Sentinel node biopsy in which the sentinel node is identified and excised. It is not appropriate if palpable axillary nodes are present. Patients with negative nodes require no further axillary treatment while those with positive nodes (macrometastases only, no further surgery for micrometastasis or isolated tumour cells) go on to have a surgical clearance of the axilla, or, where this is not possible, then nodal radiotherapy.
- Level III axillary clearance in which all lymph nodes up to the apex of the axilla are removed.

Sentinel node biopsy

- This technique should be considered for patients in whom there is no palpable axillary lymphadenopathy.
- The axilla should be assessed using a “triple assessment” approach i.e. clinical examination followed by ultrasound scan and FNA/core biopsy of nodes with an abnormal appearance on ultrasonic assessment. Following such an assessment those patients with cytologically proven axillary node metastases should proceed directly to level 3 axillary node clearance. Those patients with no palpable axillary nodes and normal ultrasound appearances of the axillary node architecture can proceed to sentinel lymph node biopsy.
- The issue with the sentinel node technique is the risk of a false negative and then subsequent axillary recurrence. Surgeons performing sentinel node biopsy need, therefore, to be able to demonstrate a false negative rate of 5% or less. To improve accuracy, both radioisotope and blue dye localisation should be performed. If blue dye is used patients need to know the very rare but potentially serious side effect of anaphylaxis. If the sentinel node biopsy is positive, either axillary radiotherapy or axillary clearance will be necessary.

Axillary Clearance

The extent of axillary dissection is defined with reference to the pectoralis minor muscle:

- Level I - lower axilla up to the lower lateral border of the pectoralis minor.
- Level II - axillary contents up to the medial border of the pectoralis minor.
- Level III - axillary contents extending to the apex of the axilla. Level III axillary clearance is absolutely indicated for the following patients

- cytologically proven axillary lymph node metastases

Level III axillary clearance is relatively indicated for the following patients and should be discussed at MDT level on a case by case basis

- patients with previous axillary surgery and current ipsilateral breast cancer diagnosis
- patients with inflammatory breast cancer
- patients receiving neo- adjuvant chemotherapy for very large / advanced breast cancer
- patients wishing to completely eliminate the possible need for a second axillary operation if node procedure yields a positive node (could have axillary irradiation).

Reconstruction after mastectomy

(Breast Cancer Management Guidelines Christie Breast Disease Group, Section 3.8, p11 - 12)

- Reconstruction is oncologically safe. Oncological clearance should take precedence over cosmetic considerations.
- All patients should be offered reconstruction – immediate or delayed.
- If immediate reconstruction is being considered, consider SLNB first in LD, bio-matrix and implant & abdominal flap reconstructions. This is not necessary for tissue expanders.
- Immediate reconstruction may not be suitable for the following groups as many of these patients may also require post-operative radiotherapy.
 - Patients with primary tumours >4cm
 - Node positive tumours
 - Locally advanced disease
 - Inflammatory cancers (absolute contraindication)
 - Large cancers down-staged by neo-adjuvant chemotherapy
 - Where there is clear pre-operative evidence of extensive lymphatic/lympho vascular space invasion
 - In the presence of severe co-morbidity
- Smokers and medically unfit may not be suitable for reconstruction
- It must be recognised that breast reconstruction is not a single operation to completion. Further minor operations will be required which can include nipple and areola complex reconstruction and symmetrisation procedures.

- Patients considering breast reconstruction should have the techniques, limitations, complications, and outcomes fully discussed, as well as expectations and aesthetic ambitions. Additionally the specialist breast care nurse will spend time talking to the patient and they will be shown photographs of different outcomes to help them make their choices. The risk of potentially delaying adjuvant treatment should be explored to ensure an oncological balance is achieved and that the patient is informed prior to consent. All patients undergoing breast reconstruction must have pre-operative and post-operative photographs both for the medical records and for medico-legal reasons.
- For women where there are local issues in providing breast reconstruction there should be arrangements made by that trust to refer to the most appropriate unit in a timely manner especially when immediate reconstruction is required. For those women who are keen on using abdominal wall tissue for reconstruction they can be referred as per the GMCCN immediate breast reconstruction pattern (see below) for consideration of a free flap e.g. DIEP (deep inferior epigastric perforator)
- Any reconstruction option selected by a patient and not available locally needs to be referred as per the network protocol.

Oncology

See doc: MC Breast Oncology Guidelines 2016 (available on Manchester Cancer website)

Survivorship and Follow up

Patients with breast cancer *and* a high risk family history are eligible for increased surveillance.

Brachial plexus problems can be referred to The Christie.

Family History

NICE has produced comprehensive guidelines on stratifying risk and the management of near-population, moderate, and high risk groups.

See NICE CG 164 Familial Breast Cancer (2013) www.nice.org.uk/guidance/cg164

Patients referred to secondary care to discuss family history do not need to be seen within the 2 week target, and can be seen by a doctor, or allied health professional with specialist training. The patient should be given individually tailored information; surveillance imaging and referral onwards to the regional genetics centre should be arranged when appropriate.

The regional genetics centre is:

Manchester Centre for Genomic Medicine

6th floor, St Mary's Hospital, Oxford Road, Manchester M13 9WL.

Tel 0161 276 6506, fax 0161 276 6145

Patients eligible for MRI surveillance should have the MRI in a Unit that regularly does screening MRIs.

Patients requesting risk reducing surgery should be seen in the regional genetics centre to confirm that surgery is likely to be beneficial and for counselling, before returning to their original hospital for risk reducing surgery.

Some moderate and high risk patients may request chemoprevention with tamoxifen or raloxifene. High risk patients would usually discuss this with the regional genetics centre. Moderate risk patients can discuss this in secondary care, and the pros and cons weighed up. Chemoprevention should not be prescribed if there is a history of previous breast cancer, thromboembolic disease, or endometrial cancer. The GP or secondary care can prescribe (unlicensed indication) Tamoxifen 20mg/day (alternatively raloxifene 60mg/day if post menopausal and uterus intact) for 5 years. There is no recommended age to start the treatment; most women should defer treatment until they have completed their families but for some young women it offers an alternative to risk reducing mastectomies. Likewise there is no recommended upper age limit but decisions to commence therapy should be taken in the context of competing morbidities.

MISCELLANEOUS

Sarcoma follow up for phyllodes tumours at SMUHT

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