

Section 1. Case record information

Record ID

RedCap record ID

PLEASE KEEP A LOCAL SECURE RECORD OF THIS, WITH THE CORRESPONDING NHS NUMBER.

(This is your RedCap unit ID+record number, e.g. MFT001.)

Name of person entering data

(Please state full name for citation purposes)

Name of consultant in charge of patient

(Please state full name for citation purposes)

Patient age at diagnosis

Date of cancer diagnosis

(This is the date of the reported biopsy result.)

Date of first cancer surgery

(If patient on 'bridging' neoadjuvant endocrine therapy, then leave blank for now, and return to fill out when surgery date available.)

Where was surgery performed?

- Red zone (operating theatre in acute care trust caring for COVID19 patients)
- Green zone (operating theatre in cold site OR in private provider aiming to be COVID19 free site)

Presentation

- Screen - detected
- Symptomatic

Stage (T)

- Tis (DCIS or LCIS)
- T1mi (≤ 1 mm)
- T1a (> 1 mm but ≤ 5 mm)
- T1b (> 5 mm but ≤ 10 mm)
- T1c (> 10 mm but ≤ 20 mm)
- T2 (> 20 mm but ≤ 50 mm)
- T3 (> 50 mm)
- T4a (Extension to the chest wall, not including only pectoralis muscle adherence/invasion)
- T4b (Ulceration and/or ipsilateral satellite nodules and/or edema of the skin)
- T4c (both T4a and T4b)
- T4d (Inflammatory carcinoma)

(This

is

the

pathological

AJCC

stage

for

those

that

have

had

surgery

and

clinical

stage

for

those

not

having

surgery:

<https://cancerstaging.org/references-tools/deskreferences/>

Stage (N)

- N0
 N1 (cN1=movable ipsilateral Level I & II axillary lymph node, pN1=macrometastases in 1-3 axillary lymph nodes)
 N1mi (pN1=micrometastases only)
 N2 (cN2=Metastases in fixed/matted ipsilateral Level I, II axillary lymph nodes, pN2=macrometastases in 4-9 axillary lymph nodes)
 N3 (cN3=metastases infraclavicular, supraclavicular or internal mammary lymph nodes, pN3=Metastases in 10 or more axillary lymph nodes)
 (This is the pathological AJCC stage for those having surgery and clinical stage for those not having surgery:
<https://cancerstaging.org/references-tools/deskreferences/>

Stage (M)

- M0
 M1
 MX

In view of the COVID-19 pandemic, was the management of this patients breast cancer:

- Standard
 Altered, due to COVID-19

Has the patient been tested for SARS-CoV2?

- Yes - tested positive
 Yes - tested negative
 Not tested
 Unknown
 Symptomatic, but not tested.

What was the diagnosis of COVID19 based on?

- SARS-CoV-2 antigen (RT-PCR)
 CXR (e.g. consolidation)
 CT (e.g. ground-glass)

Date tested positive for SARS-CoV2

If the first test was positive. Was a second test done?

- Yes
 No

If first test was positive, what was the date of the second test?

WHO performance status

- 0= able to carry out all normal activity without restriction
- 1= restricted in strenuous activity but ambulatory and able to carry out light work
- 2= ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% of waking hours
- 3= symptomatic and in a chair or in bed for greater than 50% of the day but not bedridden
- 4= completely disabled; cannot carry out any self-care; totally confined to bed or chair

Section 2. Category of ALTERED management

What was the ALTERED management plan (pre-operatively)?

- Altered pre-operative imaging assessment (including biopsy)
- Omitted neoadjuvant chemotherapy, when standard management would have included this
- Patient having 'incomplete' or 'altered' neoadjuvant chemotherapy
- Patient with hormone receptor positive cancer having 'bridging' endocrine therapy due to a potential delay in surgery
- Patient given neo-adjuvant radiotherapy
- Standard management
(CAN TICK MORE THAN ONE.)

What was the altered imaging/diagnostic pathway?

- No MRI performed for lobular cancer / dense breasts
- Altered imaging assessment of response to neo-adjuvant chemotherapy
- Incidental/satellite ipsilateral lesion not assessed with biopsy
- Altered management of B3 (indeterminate) lesions
- Other

Other altered imaging assessment

What was the ALTERED management plan (surgical)? THIS IS AT THE TIME OF CONSENT FOR SURGERY.

- Patient expected to have / has had, a delay in surgery (>31 days from diagnosis)
- Patients having breast conserving surgery with NO/UNKNOWN planned radiotherapy (when standard management would have included adjuvant radiotherapy)
- Simple mastectomy in a patient whose standard therapy would otherwise have been breast conservation followed by adjuvant radiotherapy
- Simple mastectomy performed, with a view to delayed reconstruction, in a patient who would have been offered immediate reconstruction
- Patient with confirmed high risk, having mastectomy, who are not having synchronous contralateral risk-reducing mastectomy.
- Patient who would usually have margin re-excision surgery for close margins (based on local protocols), who do not have further surgery.
- Patient who would usually have completion axillary clearance for sentinel node macro-metastases, who do not have further surgery
- Patient who would usually have a sentinel node biopsy for incidental invasion found during surgery for DCIS, but has not had this.
- Standard management
(CAN TICK MORE THAN ONE. 'ALTERED' treatment is defined as deviation from local unit protocols.)

What was the ALTERED management plan (adjuvant)?

- Patient who would usually have adjuvant radiotherapy, but have not been offered this
- Patient having 'altered' radiotherapy, with 5 fractions
- Patient who would usually have adjuvant chemotherapy, but have not been offered this
- Patient who would usually have adjuvant targeted (e.g. herceptin) therapy, but have not been offered this
- Genomic testing (e.g. ONCOTYPE) used outside of NICE guidelines (2018) to direct adjuvant chemotherapy
- Standard management ('ALTERED' treatment is defined as deviation from local unit protocols. CAN TICK MORE THAN ONE.)

Section 3. Altered management plan (as a result of the COVID-19 pandemic)

1a. Pre-operative treatment [Pre-COVID]

- Surgery first
 - Neoadjuvant chemotherapy
 - Neoadjuvant endocrine therapy
 - Primary endocrine therapy
 - Neoadjuvant radiotherapy
- (This is the standard planned treatment, that the patient would have undergone in normal circumstances, prior to the COVID pandemic)

1b. Pre-operative treatment [COVID-ALTERED]

- Surgery first
 - Neoadjuvant chemotherapy
 - Neoadjuvant chemotherapy, but 'incomplete' or 'altered'
 - Neoadjuvant endocrine therapy
 - Primary endocrine therapy
 - Neoadjuvant radiotherapy
- (This is the ALTERED treatment plan as a result of the COVID pandemic)

2a. Surgical treatment - Breast [Pre-COVID]

- Breast conserving surgery
 - Simple mastectomy
 - Skin sparing or nipple-sparing mastectomy and immediate reconstruction
 - Consideration of Breast conserving surgery following neoadjuvant chemotherapy
- (This is the standard planned treatment, that the patient would have undergone in normal circumstances, prior to the COVID pandemic)

2b. Surgical treatment - Breast [COVID-ALTERED]

- Breast conserving surgery
 - Simple mastectomy
 - Skin sparing mastectomy or nipple sparing mastectomy and immediate reconstruction
 - Consideration of Breast conserving surgery following neoadjuvant chemotherapy
- (This is the ALTERED treatment plan as a result of the COVID pandemic)

3a. Surgical treatment - Axilla [Pre-COVID]

- No axillary surgery
 - Sentinel node biopsy
 - Axillary clearance
 - Consideration of axillary preservation (targeted axillary dissection) following neoadjuvant chemotherapy
- (This is the standard planned treatment, that the patient would have undergone in normal circumstances, prior to the COVID pandemic)

-
- 3b. Surgical treatment - Axilla [COVID-ALTERED]
- No axillary surgery
 - Sentinel node biopsy
 - Sentinel node biopsy using blue dye only
 - Axillary clearance
 - Consideration of axillary preservation (targeted axillary dissection) following neoadjuvant chemotherapy
(This is the ALTERED treatment plan as a result of the COVID pandemic)
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- 4a. Adjuvant Chemotherapy [Pre-COVID]
- No
 - Yes
 - Oncotype
(This is the standard planned treatment, that the patient would have undergone in normal circumstances, prior to the COVID pandemic)
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- 4b. Adjuvant Chemotherapy [COVID-ALTERED]
- No
 - Yes
 - No, based on Oncotype DX score
 - Yes, based on Oncotype DX score
(This is the ALTERED treatment plan as a result of the COVID pandemic)
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- 5a. Adjuvant targeted anti-HER2 therapy [Pre-COVID]
- No
 - Yes
(This is the standard planned treatment, that the patient would have undergone in normal circumstances, prior to the COVID pandemic)
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- 5b. Adjuvant targeted anti-HER2 therapy [COVID-ALTERED]
- No
 - Yes
(This is the ALTERED treatment plan as a result of the COVID pandemic)
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- Adjuvant anti-HER2 targeted therapy
- Trastuzumab only
 - Pertuzumab only
 - Combination therapy
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- 6a. Adjuvant Radiotherapy [Pre-COVID]
- No
 - Yes
(This is the standard planned treatment, that the patient would have undergone in normal circumstances, prior to the COVID pandemic)
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- 6b. Adjuvant Radiotherapy [COVID-ALTERED]
- No
 - Yes
 - Yes, but hypofractionation (usually, 5 fractions)
 - Yes, but boost not given
(This is the ALTERED treatment plan as a result of the COVID pandemic)
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- 7a. Adjuvant Endocrine therapy [Pre-COVID]
- No
 - Yes
(This is the standard planned treatment, that the patient would have undergone in normal circumstances, prior to the COVID pandemic)

7b. Adjuvant Endocrine therapy [COVID-ALTERED]

- No
- Yes
(This is the ALTERED treatment plan as a result of the COVID pandemic)

Section 4. Further (anonymised) patient demographic and cancer-specific information

If bilateral or multifocal cancer, please enter data for the cancer for which an 'altered' pathway of management was recommended (bilateral), or the largest lesion (multifocal).

Size of lesion (largest dimension, in mm)

(This is the size of the largest lesion on pathological excision, or if the patient has not had surgery, enter '0')

Menopausal status

- Pre-menopausal
 Peri-menopausal
 Post-menopausal
 (In unknown, consider age 52 as cut-off for post-menopausal)

Size of lesion on MMG (largest dimension, in mm)

Size of lesion on USS (largest dimension, in mm)

Size of lesion on MRI (largest dimension, in mm)

Histological type

- Ductal
 Lobular
 Mixed ductal/lobular
 Other

Grade

- 1
 2
 3

ER status

- Positive
 Negative

ER Allred score

- 0
 1
 2
 3
 4
 5
 6
 7
 8

PR status

- Positive
 Negative

HER2 status

- Positive
 Negative

Ki67 (%)

Number of nodes with macro metastases (on pathological excision)?

Number of nodes with micro metastases (on pathological excision)?

Co-morbidities

- None
- Hypertension
- Diabetes (type 1 or 2)
- Current Smoker
- Ex-smoker
- Cardiac: IHD/Previous MI/Coronary stent/Heart failure
- Respiratory: COPD/Asthma/Bronchitis
- Immunosuppressive disorder
- Musculoskeletal disorder
- Obesity
- Chronic liver disease/failure
- Alcohol excess
- Peripheral vascular disease
- Stroke / Hemiplegia
- Other current cancer - not metastatic
- Other current cancer - metastatic

Section 5. Outcome data

THE FOLLOWING QUESTIONS RELATE TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

PLEASE ENSURE THAT THE DATA FIELDS ARE COMPLETED IN SECTION 4.

IF THERE ARE NO QUESTIONS DISPLAYED, THEN THIS CATEGORY DOES NOT APPLY TO THIS PARTICULAR PATIENT.

THIS QUESTION RELATES TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

Date started on NET? _____

THIS QUESTION RELATES TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

What hormone therapy was prescribed?

- Anastrozole
- Letrozole
- Exemestane
- Tamoxifen
- Zoladex

THIS QUESTION RELATES TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

Pre-operative Lymph node status

- Normal lymph nodes on USS OR reactive nodes on biopsy
- Abnormal lymph nodes on USS, core biopsy shows metastatic disease
- Abnormal lymph nodes on USS, FNA shows metastatic disease

THIS QUESTION RELATES TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

Was a clip placed in the lesion?

- No
- Yes

THIS QUESTION RELATES TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

Length of time on NET (in days) _____

This will be automatically calculated using the date started NET above and and date of surgery in section 1.

THIS QUESTION RELATES TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

Was follow-up imaging performed prior to surgery (following a period of NET)?

- No
- Yes, USS
- Yes, MMG
- Yes, MRI

THIS QUESTION RELATES TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

Size of lesion on MMG on follow-up imaging (largest dimension, in mm) _____

THIS QUESTION RELATES TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

Size of lesion on follow-up USS (largest dimension, in mm)

THIS QUESTION RELATES TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

Size of lesion on follow-up MRI (largest dimension, in mm)

THIS QUESTION RELATES TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

- Yes
 No

Was Ki67 repeated on a second core biopsy or the surgical excision specimen.

What was the repeat Ki67?

THIS QUESTION RELATES TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

What was the rationale for choosing the date of surgery?

- This was the planned date, when sufficient theatre capacity became available
 Surgery expedited due to early availability of theatre capacity
 Surgery expedited due to lack response
 Surgery expedited due to intolerance of NET or compliance
-

THIS QUESTION RELATES TO PATIENTS ON NEOADJUVANT 'BRIDGING' ENDOCRINE THERAPY (NET).

In patients with a pre-NET plan for mastectomy, was adequate down staging achieved to accommodate for breast conservation instead?

- No - patient proceeded with planned mastectomy
 Yes - patient had breast conserving surgery
 Yes - but patient elected to have mastectomy
-

THE FOLLOWING QUESTIONS RELATE TO PATIENTS WHO HAVE TESTED POSITIVE FOR SARS-CoV-2.

PLEASE ENSURE THAT THE DATA FIELDS ARE COMPLETED IN SECTION 4.

IF THERE ARE NO QUESTIONS DISPLAYED, THEN THIS CATEGORY DOES NOT APPLY TO THIS PARTICULAR PATIENT.

What was the patient's BMI?

THE FOLLOWING QUESTION RELATES TO PATIENTS WHO HAVE TESTED POSITIVE FOR SARS-CoV-2.

What was the impact of the patient's COVID19 infection on their management pathway?

- No impact
- Delay in Surgery, but surgery still primary treatment
- Conversion to neoadjuvant chemotherapy, and delayed surgery
- Conversion to 'bridging' neoadjuvant endocrine therapy, and delayed surgery
- Admission to hospital resulting in delay in breast surgery (>31 days) due to discharge to rehab etc.
- Death

THE FOLLOWING QUESTION RELATES TO PATIENTS WHO HAVE TESTED POSITIVE FOR SARS-CoV-2.

Was the patient admitted to the hospital following a diagnosis of COVID-19?

- No - managed at home
- Yes - Ward
- Yes - HDU
- Yes - ICU

If HDU/ICU support required, what respiratory support was needed ?

- Advanced respiratory support (IMV, ECMO)
- Basic respiratory support (NIV / CPAP, high flow O2)
- Cardiovascular support (inotropes, etc)
- Renal support - CVVHD
- Proning

THE FOLLOWING QUESTION RELATES TO PATIENTS WHO HAVE TESTED POSITIVE FOR SARS-CoV-2.

Were any COVID19 specific medical treatments employed?

- Azithromycin
- Hydroxychloroquine
- Macrolides
- Steroids
- Interferon-beta-1a
- Tocilizumab (anti-IL-6R)
- Anakinra (Anti-IL-1Ra)
- Sarilumab (anti-IL-6R)
- Lopinavir-Ritonavir
- Oseltamivir
- Convalescent plasma
- Remdesivir