Sentinel Lymph-Node Biopsy for Endometrial Cancer Clinical Guideline

V1.0

June 2020
Summary

NEW DIAGNOSIS OF ENDOMETRIAL CANCER ON ENDOMETRIAL BIOPSY

GRADE 1
- CXR
- Mets?
  - Yes
  - No
    - TLH and BSO*

GRADE 2
- CT CAP
- Mets?
  - Yes
  - No
    - TLH, BSO* and bilateral SLNB

GRADE 3 / Type 2 tumours
- CT CAP
- MDT review
- Mets?
  - Yes
  - No
    - TLH, BSO* and bilateral SLNB

SLN detected?
  - Yes
  - No

Final histopathology discussed at MDT

** Until resources have been allocated for ultrastaging, all patients with G3 disease will proceed with full pelvic and para-aortic LND (when surgically appropriate)

* Laparoscopic surgery will be performed when technically possible
CXR – chest x-ray
CTCAP – CT chest, abdomen and pelvis
SLN – sentinel lymph node
MDT – multidisciplinary team meeting
1. **Aim/Purpose of this Guideline**

1.1. To provide guidance to clinicians on the use of sentinel lymph-node biopsy (SLNB) in patients with endometrial cancer.

1.2. To standardise the surgical management of women with endometrial cancer

1.3. This version supersedes any previous versions of this document.

1.4. **Data Protection Act 2018 (General Data Protection Regulation – GDPR) Legislation**

   The Trust has a duty under the DPA18 to ensure that there is a valid legal basis to process personal and sensitive data. The legal basis for processing must be identified and documented before the processing begins. In many cases we may need consent; this must be explicit, informed and documented. We can’t rely on Opt out, it must be Opt in.

   DPA18 is applicable to all staff; this includes those working as contractors and providers of services.

   For more information about your obligations under the DPA18 please see the ‘information use framework policy’, or contact the Information Governance Team rch-tr.infogov@nhs.net

2. **The Guidance**

2.1. Sentinel lymph node biopsy

   2.1.1. Sentinel lymph node biopsy (SLNB) is a procedure to determine whether cancer has spread into the lymphatics. The first lymph node that is drained by the tumour is called the sentinel lymph node. It has been available for many years and is widely used in breast, melanoma and vulva cancer care.

   2.1.2. There are many different methods for detection of SLN including injection of patent blue, radioactive Technicium\(^ {99} \) colloid and Indocyanine Green (ICG)

   2.1.3. ICG has health and safety advantages over radioactive Technicium\(^ {99} \) and has proven to be highly specific and sensitive in detecting SLNs.

2.2. Lymph-node metastasis in endometrial cancer

   2.2.1. Patients with endometrial cancer have a risk of metastasis to pelvic and para-aortic lymph-nodes. Overall the risk is thought to be around 5-10% however the risk of metastasis increases with higher grades and stage of the tumour.

   2.2.2. Presence of lymph-node metastasis determines the need for adjuvant treatment (chemotherapy and radiotherapy).
2.2.3. Pelvic and para-aortic lymph-node dissection (LND) is associated with increased intraoperative complications, such as increased operating time, increased blood loss, increased need for blood transfusion and increased visceral and blood vessel injury. There is also a risk of long-term morbidity, such as lymphoedema (permanent leg swelling), lymphocyst formation and lymphorrhoea (collection of lymph fluid within abdomen, often requiring drainage).

2.2.4. The use of SLNB enables accurate surgical staging of lymph-node metastasis and reduces the need for full LND.

2.2.5. The use of SLNB will therefore reduce short and long-term complications for patients with endometrial cancer

2.3. Eligibility for SLNB in endometrial cancer patients

- Informed consent obtained
- Grade 2 or 3 endometrial cancer on endometrial biopsy
- Patient deemed surgically fit
- Patient deemed suitable for adjuvant chemotherapy and radiotherapy if required
- No evidence of metastatic spread or suspicious enlarged pelvic or para-aortic lymph-nodes on pre-operative imaging
- No contraindication for ICG (see below)

2.4. Clinical application of ICG (Verdye)

2.4.1. If the above criteria are met the patient will be invited for a total hysterectomy (laparoscopic or open dependent on technical issues and uterine size) and bilateral salpingoophrectomy and SLNB

2.4.2. Each vial of Verdye contains 25mg of indocyanine green in powder form. This is reconstituted with 20mls of sterile water for injection (stock solution) to make a solution of 1.25mg/mL.

2.4.3. Once anaesthetised, patients undergoing SLNB will have 2-4mls of ICG stock solution (2.5mg-5mg ICG) injected into the cervix using a spinal needle.

2.4.4. The position of cervical injections and the volume required are at the surgeons discretion. As an example, superficial (depth of 1-2mm) and deep (depth of 10-15mm) cervical injections at 3 o’clock and 9 o’clock position.

2.4.5. ICG is a prescription only medicine. It must be prescribed on the patients JAC drug chart documenting the dose administered.

2.4.6. One vial of ICG stock solution per patient.

2.4.7. Adequate time should be allowed for the SLN to be identified.
2.4.8. Contraindications & cautions

2.4.8.1. ICG should not be used for any patients with a known hypersensitivity or allergic reaction to ICG or iodine.

2.4.8.2. ICG is contraindicated for patients with untreated hyperthyroidism, autonomic thyroid adenomas or pregnancy.

2.4.8.3. A copy of the summary of product characteristics (SPC) can be found here: https://products.mhra.gov.uk/?&product=true&page=1&search=VERDYE

2.4.9. If the SLN is not identified then a side specific pelvic lymph-node dissection (LND) will be performed +/- para-aortic LND for those with high grade disease (grade 3/ type 2 tumours) on biopsy.

2.4.9.1. Until resources for ultrastaging have been allocated all G3 patients will proceed with pelvic and para-aortic LND (see section 2.5.18).

2.4.10. If the SLN is not identified for patients with G2 disease, the patient will have a hysterectomy only.

2.4.11. Any clinically suspicious lymph-nodes should be removed irrespective of the grade of tumour.

2.5. Histopathological examination

2.5.1. Ultrastaging is recommended for histopathological examination of the SLN. At present there are insufficient resources in the histopathology laboratory to ultrastage the lymph nodes.

2.5.2. Until ultrastaging is possible all grade 3 endometrial cancers will have full pelvic and para-aortic lymphnode dissection and the sentinel lymph node will be processed as “separate LN”.

2.5.3. Once resources are in place for ultrastaging the protocol followed will be as per The British Association of Gynaecological Pathologists Protocol of SLN.

2.5.3.1. Single H&E section of each slice of SLN, with minimal trimming to avoid tissue wastage, should be examined in the first instance.

2.5.3.2. If this is single section H&E is negative for tumour, SLN-Ultrastaging (US) should be carried out following the protocol as below.

2.5.3.3. Two additional pairs of sections are cut at 50 micron intervals.
2.5.3.4. One section from each of the two pairs is stained with H&E and the other with immunohistochemistry (IHC) for a broad spectrum cytokeratin (CK), AE1/AE3 is currently widely used.

2.5.3.5. If SLN is accompanied by a full lymphadenectomy, there is no need to carry out SLN-US.

2.6. Adjuvant therapy

2.6.1. All women with endometrial cancer following surgery are discussed at the weekly Gynaecology MDT.

2.6.2. Final histopathology will be reviewed and recommendations for adjuvant treatment will be discussed.

3. Monitoring compliance and effectiveness

<table>
<thead>
<tr>
<th>Element to be monitored</th>
<th>Incidence of positive SLNB</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Incidence of recurrence of endometrial cancer</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lead</th>
<th>J Borley (Consultant Gynaecological Oncologist) and Gynaecology MDT</th>
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<table>
<thead>
<tr>
<th>Tool</th>
<th>QA in histopathology in regards to ultrastaging protocol</th>
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<tr>
<td></td>
<td>Database collection.</td>
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<table>
<thead>
<tr>
<th>Frequency</th>
<th>As required</th>
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<th>Reporting arrangements</th>
<th>Information shared at Gynaecology MDT</th>
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</thead>
</table>

<table>
<thead>
<tr>
<th>Acting on recommendations and Lead(s)</th>
<th>Gynaecology MDT</th>
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</table>

| Change in practice and lessons to be shared | Required changes to practice will be identified and actioned within 3 months. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders |

4. Equality and Diversity

4.1. This document complies with the Royal Cornwall Hospitals NHS Trust service Equality and Diversity statement which can be found in the ‘Equality, Inclusion & Human Rights Policy’ or the Equality and Diversity website.

4.2. Equality Impact Assessment

The Initial Equality Impact Assessment Screening Form is at Appendix 2.
### Appendix 1. Governance Information

<table>
<thead>
<tr>
<th>Document Title</th>
<th>Sentinel Lymph-Node Biopsy for Endometrial Cancer Clinical Guideline V1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date Issued/Approved:</td>
<td>13 March 2020</td>
</tr>
<tr>
<td>Date Valid From:</td>
<td>June 2020</td>
</tr>
<tr>
<td>Date Valid To:</td>
<td>June 2023</td>
</tr>
<tr>
<td>Directorate / Department responsible (author/owner):</td>
<td>J Borley Consultant Gynaecological Oncologist</td>
</tr>
<tr>
<td>Contact details:</td>
<td>01872 252729</td>
</tr>
<tr>
<td>Brief summary of contents</td>
<td>Guidance for sentinel lymph-node biopsy in endometrial cancer</td>
</tr>
<tr>
<td>Suggested Keywords:</td>
<td>Endometrial cancer. Sentinel lymph-node biopsy</td>
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<tr>
<td>Target Audience</td>
<td>RCHT</td>
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<td></td>
<td>✔</td>
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<tr>
<td>Executive Director responsible for Policy:</td>
<td>Medical Director</td>
</tr>
<tr>
<td>Date revised:</td>
<td>New Document</td>
</tr>
<tr>
<td>This document replaces (exact title of previous version):</td>
<td>New Document</td>
</tr>
<tr>
<td>Approval route (names of committees)/consultation:</td>
<td>Gynaecological Oncology MDT and Obs and Gynae Specialty Meeting Women and Childrens Services Medication Practice Committee</td>
</tr>
<tr>
<td>Care Group General Manager confirming approval processes</td>
<td>Debra Shields</td>
</tr>
<tr>
<td>Name and Post Title of additional signatories</td>
<td>Not Required</td>
</tr>
<tr>
<td>Name and Signature of Care Group/Directorate Governance Lead confirming approval by specialty and care group management meetings</td>
<td>{Original Copy Signed} Name: Caroline Amukusana</td>
</tr>
<tr>
<td>Signature of Executive Director giving approval</td>
<td>{Original Copy Signed}</td>
</tr>
<tr>
<td>Publication Location (refer to Policy on Policies – Approvals and Ratification):</td>
<td>Internet &amp; Intranet ✔ Intranet Only</td>
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Related Documents:

1. British Gynaecology Cancer Society consensus statement “Sentinel LN”
2. The British Association of Gynaecological Pathologists “Protocols for Pathological Processing of Sentinel Lymph nodes in Endometrial, Vulval and cervical Carcinomas”
https://www.thebagp.org/resources/

Training Need Identified? No

Version Control Table

<table>
<thead>
<tr>
<th>Date</th>
<th>Version No</th>
<th>Summary of Changes</th>
<th>Changes Made by (Name and Job Title)</th>
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<tbody>
<tr>
<td>10/02/2020</td>
<td>V1.0</td>
<td>Initial version</td>
<td>Dr Jane Borley</td>
</tr>
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</table>

All or part of this document can be released under the Freedom of Information Act 2000

This document is to be retained for 10 years from the date of expiry.
This document is only valid on the day of printing

Controlled Document
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# Appendix 2. Initial Equality Impact Assessment Form

<table>
<thead>
<tr>
<th>Name of the strategy / policy / proposal / service function to be assessed</th>
<th>Sentinel Lymph-Node Biopsy for Endometrial Cancer Clinical Guideline V1.0</th>
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</thead>
<tbody>
<tr>
<td>Directorate and service area:</td>
<td>Women’s and Childrens Services</td>
</tr>
<tr>
<td>New or existing document:</td>
<td>New</td>
</tr>
<tr>
<td>Name of individual completing assessment:</td>
<td>J Borley</td>
</tr>
<tr>
<td>Telephone:</td>
<td>01872 252729</td>
</tr>
</tbody>
</table>

1. Policy Aim*  
*Who is the strategy / policy / proposal / service function aimed at?*  
Guidance of the use of sentinel lymph-node biopsy for patients with endometrial cancer

2. Policy Objectives*  
To guide clinicians on the use and protocol for sentinel lymph-node biopsy in those with endometrial cancer

3. Policy – intended Outcomes*  
To standardise the surgical management of endometrial cancer

4. *How will you measure the outcome?*  
See section 3

5. Who is intended to benefit from the policy?  
Patients with endometrial cancer

6a Who did you consult with  

<table>
<thead>
<tr>
<th>Workforce</th>
<th>Patients</th>
<th>Local groups</th>
<th>External organisations</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
<td></td>
</tr>
</tbody>
</table>

b). Please identify the groups who have been consulted about this procedure.  
Peninsula Gynaecology MDT  
Derriford Gynaecological Oncologists  
British Gynaecology Cancer Society  
Pharmacy department, RCHT

What was the outcome of the consultation?  
National guidance to be met. Guideline was approved.
7. The Impact
Please complete the following table. If you are unsure/don’t know if there is a negative impact you need to repeat the consultation step.

<table>
<thead>
<tr>
<th>Equality Strands:</th>
<th>Yes</th>
<th>No</th>
<th>Unsure</th>
<th>Rationale for Assessment / Existing Evidence</th>
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<tbody>
<tr>
<td><strong>Age</strong></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Sex</strong> (male, female, trans-gender / gender reassignment)</td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Race / Ethnic communities /groups</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td>Any information provided should be in an accessible format for the patient’s/carer’s needs – i.e. available in different languages if required/access to an interpreter if required</td>
</tr>
<tr>
<td><strong>Disability</strong> - Learning disability, physical impairment, sensory impairment, mental health conditions and some long term health conditions.</td>
<td>✓</td>
<td></td>
<td></td>
<td>Those patients/carers with any identified additional needs will be referred for additional support as appropriate - i.e to the Liaison team or for specialised equipment. Written information will be provided in a format to meet the family’s needs e.g. easy read, audio etc</td>
</tr>
<tr>
<td><strong>Religion / other beliefs</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td>All staff should be aware of any beliefs that may impact on the decision to treat</td>
</tr>
<tr>
<td><strong>Marriage and Civil partnership</strong></td>
<td>✓</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Pregnancy and maternity</strong></td>
<td>✓</td>
<td></td>
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<tr>
<td><strong>Sexual Orientation, Bisexual, Gay, heterosexual, Lesbian</strong></td>
<td>✓</td>
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</tbody>
</table>

You will need to continue to a full Equality Impact Assessment if the following have been highlighted:
- You have ticked “Yes” in any column above and
- No consultation or evidence of there being consultation- this excludes any policies which have been identified as not requiring consultation. or
- Major this relates to service redesign or development

8. Please indicate if a full equality analysis is recommended. | Yes | No | ✓ |
9. If you are not recommending a Full Impact assessment please explain why.

Not indicated
This EIA will not be uploaded to the Trust website without the approval of the Policy Review Group.

A summary of the results will be published on the Trust’s web site.