NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedures consultation document

Minimally invasive radical hysterectomy for early stage cervical cancer

Cervical cancer develops in the lower part of the womb (uterus) where it joins the top of the vagina (an area called the cervix). Early stage cervical cancer is in the cervix only or has spread to the top of the vagina. In a radical hysterectomy the cervix, uterus and some structures connected to them are removed. In this procedure, the surgery is done through the abdomen using a tube with a camera on the end (laparoscope), known as keyhole or minimally invasive surgery. A robot may be used to help with the procedure. The aim is to completely remove the cancer.

NICE is looking at minimally invasive radical hysterectomy for early stage cervical cancer. This is a review of NICE's interventional procedures guidance on laparoscopic radical hysterectomy for early stage cervical cancer.

NICE's interventional procedures advisory committee met to consider the evidence and the opinions of specialist advisers, who are consultants with knowledge of the procedure.

This document contains the draft guidance for consultation. Your views are welcome, particularly:

- comments on the draft recommendations
- information about factual inaccuracies
- additional relevant evidence, with references if possible.

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others.

This is not NICE's final guidance on this procedure. The draft guidance may change after this consultation.

After consultation ends, the committee will:

- meet again to consider the consultation comments, review the evidence and make appropriate changes to the draft guidance
- prepare a second draft, which will go through a resolution process before the final guidance is agreed.

Please note that we reserve the right to summarise and edit comments received during consultation or not to publish them at all if, in the reasonable opinion of NICE, there are a lot of comments or if publishing the comments would be unlawful or otherwise inappropriate.

Closing date for comments: 23 July 2020

Target date for publication of guidance: December 2020

1 Draft recommendations

1.1 Evidence on minimally invasive radical hysterectomy for early stage cervical cancer shows that there are no short-term safety concerns.

- The evidence on efficacy for tumours 2 cm or larger shows that minimally invasive radical hysterectomy has shorter disease-free and overall survival compared with open hysterectomy surgery. Therefore, this procedure should not be used for tumours 2 cm or above.
- The evidence on efficacy for tumours smaller than 2 cm is inconclusive for disease-free and overall survival compared with open hysterectomy surgery. Therefore, for tumours smaller than 2 cm this procedure should only be used in the context of research.

2 The condition, current treatments and procedure

The condition

2.1 Cervical cancer is the second most common cancer in women under 35 years in the UK. The most common symptoms are

abnormal vaginal bleeding or discharge, and discomfort during intercourse.

2.2 The International Federation of Gynecology and Obstetrics system is used to stage cervical cancer from 1 to 4. Early stage cervical cancer includes stage 1 (cancer confined to the cervix) to stage 2A (tumour has spread down into the top of the vagina).

Current treatments

2.3 Radical hysterectomy (also known as Wertheim's hysterectomy) is the most common surgical treatment for cervical cancer. It is conventionally done through an incision in the abdomen or through the vagina. It includes removing the uterus and supporting ligaments, cervix, upper vagina, the pelvic lymph nodes and sometimes the para-aortic lymph nodes.

2.4 Radiotherapy may be used, with or without surgery, and is usually combined with chemotherapy.

The procedure

2.5 Minimally invasive radical hysterectomy for early stage cervical cancer is done using general anaesthesia. A uterine manipulator is inserted through the vagina and attached to the uterus and cervix. The abdomen is insufflated with carbon dioxide, and several small incisions are made to provide access for the laparoscope and surgical instruments. A robot may be used to assist with the procedure. A hysterectomy is done by dividing the round ligaments, accessing the broad ligaments, dividing the uterine vessels and mobilising the uterus out of its peritoneal coverings by dividing the uterosacral ligaments. If the ovaries are to be left in position, the utero-ovarian ligaments are transected. The pelvic lymph nodes and sometimes the para-aortic lymph nodes are removed through 1 of the abdominal incisions or through the vagina. The upper vagina, cervix and uterus are removed through the vagina.

2.6 The technique is distinct from laparoscopically assisted vaginal hysterectomy, which uses laparoscopic division of the infundibulopelvic ligaments and the uterine vessels before a vaginal hysterectomy is done.

2.7 A nerve-sparing radical hysterectomy is a modified technique that preserves pelvic nerves to prevent bladder dysfunction.

2.8 The aim is to remove all the cancer. The suggested benefits of the laparoscopic approach are shorter length of stay in hospital, shorter recovery period and minimal abdominal scarring.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 19 sources, which was discussed by the committee. The evidence included 1 randomised controlled trial (reported in 2 publications), 8 non-randomised comparative studies, 1 cohort study, 2 systematic reviews and 5 case reports. Data from the National Cancer Registration and Analysis Service was also reviewed by the committee. The evidence is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The professional experts and the committee considered the key efficacy outcomes to be: overall survival, disease-free survival, tumour recurrence, quality of life and need for postoperative chemotherapy or radiotherapy.

3.3 The professional experts and the committee considered the key safety outcomes to be: mortality, unintentional damage to adjacent structures such as the bowel or ureter, and tumour seeding.

3.4 A submission from a patient organisation was discussed by the committee.

Committee comments

3.5 The committee was advised that there could be seeding of malignant cells from the cervix during the procedure related to using a manipulator to position the cervix, and that this needs further investigation.

3.6 The committee felt that research into variations in the technique designed to reduce the risk of tumour seeding or other potential causes of long-term tumour recurrence may be appropriate.

3.7 The committee was advised that there may be some patients for whom the risks of an open procedure are such that, after careful consideration by a multidisciplinary team and with appropriate patient consent, minimally invasive radical hysterectomy could be offered.

Tom Clutton-Brock
Chair, interventional procedures advisory committee
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