

Maximal cytoreductive surgery for advanced ovarian cancer

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg757

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the [Yellow Card Scheme](#).

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with

those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG470.

1 Recommendations

- 1.1 Evidence on the safety and efficacy of maximal cytoreductive surgery for advanced ovarian cancer is adequate to support using this procedure provided that standard arrangements are in place for clinical governance, consent and audit. Find out what standard arrangements mean on the NICE interventional procedures guidance page.
- 1.2 Patient selection should be done by a specialist gynaecological cancer multidisciplinary team, which may include surgeons from other specialities.
- 1.3 The procedure should be done by a team of surgeons with appropriate expertise. The procedure should only be done in accredited specialised units.
- 1.4 For auditing the outcomes of this procedure, the main efficacy and safety outcomes identified in this guidance can be entered into NICE's interventional procedure outcomes audit tool (for use at local discretion).

2 The condition, current treatments and procedure

The condition

- 2.1 Early symptoms of ovarian cancer can be similar to those of other pelvic or abdominal conditions and include persistent bloating, pain in the pelvis and lower abdomen, urinary frequency and urinary urgency. Ovarian cancer is usually at stage 3 or 4 when it is diagnosed and the outcome is generally poor. The overall 5-year survival rate for ovarian cancer is about 43%, and is lower for people with more advanced disease. The stage of the disease at diagnosis is the most important factor affecting outcome and is defined by the International Federation of Gynecology and Obstetrics (FIGO) system:
- Stage 1 (A to C): the tumour is confined to the ovary.
 - Stage 2 (A, B): the tumour involves 1 or both ovaries and has extended into the pelvis.
 - Stage 3 (A to C): the tumour involves 1 or both ovaries with microscopically confirmed peritoneal metastasis outside the pelvis, or regional lymph node metastasis (if cancer cells are found only in fluid taken from inside the abdomen the cancer is stage 2).
 - Stage 4 (A, B): there is distant metastasis beyond the peritoneal cavity (if ovarian cancer is only found on the surface of the liver and not within the liver itself, then the cancer is stage 3).
- 2.2 The FIGO stage does not fully take into account the tumour load and disease extent in advanced disease.

Current treatments

- 2.3 [NICE's guideline on the recognition and initial management of ovarian cancer](#) describes the initial management options. The main treatments for advanced ovarian cancer are surgery to remove all macroscopic

residual disease (residual disease is cancer left behind at the end of cytoreductive surgery; this type of surgery is also known as debulking) and chemotherapy. Standard surgery usually involves, as a minimum, bilateral salpingo-oophorectomy, total abdominal hysterectomy and omentectomy. Maximal cytoreductive surgery uses additional surgical procedures, including upper abdominal surgery, with the aim of achieving no residual disease. The most important factors affecting outcomes after surgery are responsiveness to platinum-based chemotherapy and the amount of residual disease.

- 2.4 Conventional imaging techniques cannot accurately predict the distribution or volume of disease before surgery. Therefore, the only definitive assessment of the distribution or volume of disease found in the abdomen and pelvis is done at the time of surgery. Currently, no objective tools exist to select people for surgery and a decision for surgery will depend on many factors, including fitness, patient choice, availability of surgeons with appropriate expertise and resource levels.

The procedure

- 2.5 The aim of maximal cytoreductive surgery for advanced ovarian cancer is to safely remove all identifiable disease, to improve survival, compared with surgery that leaves residual disease. It is a development and extension of standard surgery for ovarian cancer.
- 2.6 The precise differences between standard, radical and maximal cytoreduction procedures are not well defined. Surgical complexity scores, such as the Aletti system, have been developed to try to quantify the complexity of surgery. Each procedure that is done during the surgery is allocated a score:
- total hysterectomy and bilateral salpingo-oophorectomy: 1
 - omentectomy: 1
 - pelvic lymphadenectomy: 1
 - para-aortic lymphadenectomy: 1

- pelvic peritoneum stripping: 1
- abdominal peritoneum stripping: 1
- rectosigmoidectomy anastomosis: 3
- large bowel resection: 2
- diaphragm stripping or resection: 2
- splenectomy: 2
- liver resection: 2
- small bowel resection: 1.

The total score can then be used to categorise the surgery into low complexity (1 to 3), intermediate complexity (4 to 7) or high complexity (8 and above).

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 16 sources, which was discussed by the committee. The evidence included 4 systematic reviews, 10 cohort studies, 1 non-randomised comparative study and 1 case series. It is presented in the [summary of key evidence section in 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, progression free survival, residual tumour after surgery and quality of life after surgery.
- 3.3 The professional experts and the committee considered the key safety outcomes to be: perioperative death, organ failure, thromboembolism, wound complications and unanticipated need for a stoma.

- 3.4 Fourteen commentaries from people who have had this procedure were discussed by the committee.

Committee comments

- 3.5 The committee noted that in the published literature different terms are used to describe this procedure, such as ultra-radical, extensive and maximal effort cytoreductive surgery.
- 3.6 The procedure involves extensive surgery with a risk of significant complications including death.
- 3.7 There needs to be detailed preoperative assessment of the person's fitness to have maximal cytoreductive surgery and postoperative arrangements should include the availability of intensive care.
- 3.8 The committee was informed that a national prehabilitation programme for anyone offered this procedure would be useful.
- 3.9 The extent of disease may not be apparent until surgery has started and it may be that maximal cytoreductive surgery is not possible.
- 3.10 The committee noted that the surgical techniques used in this procedure have evolved since the last NICE interventional procedures guidance on this subject was issued.
- 3.11 There have been developments in chemotherapy and other systemic treatments for ovarian cancer since the last NICE interventional procedures guidance on this subject was issued.
- 3.12 The committee encourages centres doing this procedure to submit data to an appropriate register.
- 3.13 The committee was pleased to receive patient commentary and to have a representative from a patient organisation at the meeting.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).