

Ultra-radical (extensive) surgery for advanced ovarian cancer

Interventional procedures guidance

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[nice.org.uk/guidance/ipg470](https://www.nice.org.uk/guidance/ipg470)

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. However, 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.

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.

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.

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of ultra-radical (extensive) surgery for advanced ovarian cancer is inadequate. Therefore this procedure should not be done except with special arrangements for clinical governance, consent and

audit or research (with the objective of publishing outcomes for all patients having this procedure – see recommendation 1.5).

- 1.2 Clinicians wishing to undertake ultra-radical surgery for advanced ovarian cancer should take the following actions:
- Inform the clinical governance leads in their NHS trusts.
 - During the consent process, inform patients clearly about alternative treatment options, and about their benefits and risks compared with ultra-radical surgery for advanced ovarian cancer. Clinicians should provide patients with clear written information. In addition, the use of NICE's [information for the public](#) is recommended.
 - Clinicians should submit data on all patients having this procedure to the national register when it becomes available and review clinical outcomes locally.
- 1.3 Selection of patients should be done by a specialist gynaecological cancer multidisciplinary team.
- 1.4 Ultra-radical surgery for advanced ovarian cancer should be done by collaboration between surgeons with appropriate expertise (such as specialists in gastrointestinal and hepatobiliary surgery) and/or by specialists in gynaecological cancer surgery with specific training in such extensive surgery. The procedure should only be done in specialised units with a regular practice in this type of surgery.
- 1.5 NICE encourages further research on this procedure, either in the form of research trials or in audits intended for publication (ideally by collaboration between units). Clinicians should ensure that details of patient selection and the precise extent of surgery are fully documented. Reported outcomes should include all complications, survival, and quality of life. Trials comparing complication rates, survival and quality of life against those of standard surgery and chemotherapy would be especially useful.

2 Indications and current treatments

- 2.1 Ovarian cancer is the leading cause of death from gynaecological cancer in the UK, and its incidence is rising. It is the fifth most common cancer in women, with a lifetime risk of about 2% for women in England and Wales.

- 2.2 Early symptoms of ovarian cancer are non-specific and include persistent bloating, pain in the pelvis and lower abdomen, and urinary frequency and/or urgency. Most women who have ovarian cancer are diagnosed with advanced disease and the outcome is generally poor, with an overall 5-year survival rate of less than 35%. The stage of the disease at diagnosis is the most important factor affecting outcome.
- 2.3 The main treatments for advanced ovarian cancer are surgery and chemotherapy. 'Standard' (sometimes referred to as 'radical') surgery involves bilateral salpingo-oophorectomy, total abdominal hysterectomy, omentectomy and lymphadenectomy. Potentially curative surgery requires resection of all macroscopic disease. More commonly, the goal is to remove all areas of tumour tissue greater than 1 cm in diameter (optimal cytoreduction, also known as optimal debulking).

3 The procedure

- 3.1 The aim of ultra-radical surgery for advanced ovarian cancer is to remove all visible disease, with a view to improving survival compared with standard (radical) surgery.
- 3.2 Extensive or ultra-radical surgery for advanced ovarian cancer is a development and extension of standard (radical) surgery. The precise differences between these procedures are not well defined, but some typical features of ultra-radical surgery include:
- stripping of the diaphragm
 - extensive stripping of the peritoneum
 - multiple resections of the bowel (excluding localised colonic resection)
 - liver resection
 - partial gastrectomy
 - cholecystectomy
 - splenectomy.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 4.1 A non-randomised comparative study of 267 patients treated by ultra-radical or standard surgery reported no statistically significant difference in overall survival between the 2 groups in patients with optimal cytoreduction (hazard ratio 1.37, 95% confidence interval 0.70 to 2.69, $p=0.36$). A non-randomised comparative study of 168 patients treated before and 210 patients treated after the introduction of ultra-radical surgery reported 5-year overall survival rates of 35% and 47% respectively ($p=0.03$). Median overall survival was 43 months in patients treated before ultra-radical surgery was introduced and 54 months in patients treated after ($p=0.03$).
- 4.2 The non-randomised comparative study of 262 patients treated by ultra-radical or standard surgery reported median progression-free survival of 24 months for patients with optimal cytoreduction by ultra-radical surgery, 23 months for patients with optimal cytoreduction by standard surgery and 11 months for patients with suboptimal cytoreduction ($p<0.001$). The non-randomised comparative study of 378 patients treated either before or after ultra-radical surgery was introduced reported 5-year progression-free survival rates of 14% and 31% respectively ($p=0.01$).
- 4.3 The specialist advisers listed the key efficacy outcomes as disease-free survival, progression-free survival and overall survival.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the [overview](#).

- 5.1 Major complications were reported in 19% (16/85) of patients treated by ultra-radical surgery and 5% (5/95) of patients treated by standard surgery in a non-randomised comparative study of 180 patients ($p=0.013$). Major complications were reported in 12% (7) of patients with optimal cytoreduction by ultra-radical

surgery, 7% (5) of patients with optimal cytoreduction by standard surgery and 8% (4) of patients with suboptimal cytoreduction, in the non-randomised comparative study of 262 patients (denominators not reported). The rate of major perioperative complications was significantly higher in patients treated after the introduction of ultra-radical surgery than patients treated before this period in the non-randomised comparative study of 378 patients ($p=0.015$). This included higher rates of infectious, gastrointestinal and haematological complications (10% compared with 4%, 4% compared with 2%, and 2% compared with 0% respectively).

- 5.2 Perioperative mortality was reported as 1% (2/210) for patients treated after the introduction of ultra-radical surgery and less than 1% (1/168) for patients treated before the introduction of ultra-radical surgery in the non-randomised comparative study of 378 patients. Sixty-day mortality was 3% (3/88) for patients with complete cytoreduction by ultra-radical surgery, 0% (0/38) for patients with complete cytoreduction by standard surgery and 6% (8/141) for patients with incomplete cytoreduction in the non-randomised comparative study of 267 patients. Thirty-day mortality was 1% (2/141) in a case series of 141 patients.
- 5.3 Bleeding that required reoperation was reported in 2% (3/141) of patients in the case series of 141 patients.
- 5.4 Postoperative temperature over 38°C for more than 3 days was reported in 17% (15/88) of patients treated by ultra-radical surgery and 5% (2/38) of patients treated by standard surgery in the non-randomised comparative study of 267 patients.
- 5.5 Symptomatic pleural effusion needing drainage was reported in 9% (12/141) of patients in the case series of 141 patients.
- 5.6 Pancreatic leak needing drainage was reported in 3% (4/141) of patients in the case series of 141 patients.
- 5.7 Additional anecdotal adverse events listed by the specialist advisers included pneumothorax, and injury to large blood vessels, the bowel, the urinary tract and nerves. They stated that theoretical adverse events were anastomotic leak

and fistulae. The specialist advisers stated that delay in starting chemotherapy was an additional adverse event reported in the literature.

6 Committee comments

6.1 The Committee noted that apparently complete resection of ovarian cancer, together with all intra-abdominal metastases, is the best prognostic factor for improving survival. However, this potential survival advantage needs to be weighed against the morbidity and risks of very extensive surgery when considering the balance of quality of life and survival.

7 Further information

7.1 For related NICE guidance see the [NICE website](#).

Information for patients

NICE has produced information on this procedure for patients and carers ([Information for the public](#)). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedures guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedures guidance process](#).

We have produced a [summary of this guidance for patients and carers](#).

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responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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Endorsing organisation

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

Accreditation

