# Consensus on Treatment for Inoperable and Peroperatively Unresectable Ovarian Cancer: A Modified Delphi Study

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Running title: Consensus on Treatment for Advanced Inoperable Ovarian Cancer

Abstract

*Objective*

To achieve consensus on treatment strategies for patients with inoperable or peroperatively unresectable epithelial ovarian cancer.

*Design*

A modified Delphi method was employed.

*Setting*

The study was conducted in academic and regional hospitals across the Netherlands specializing in the treatment of ovarian cancer.

*Population or Sample*

Participants included gynaecologists, gynaecologic-oncologists and medical oncologists.

*Methods*

Three survey rounds were conducted with a structured questionnaire featuring clinical case-scenarios, with anonymized feedback and aggregated responses after each round to refine consensus (defined as ≥80% agreement).

*Main Outcome Measures*

Consensus on treatment strategies for inoperable or peroperatively unresectable epithelial ovarian cancer.

*Results*

Seventeen clinicians representing all academic centres in the Netherlands completed all three rounds of survey. Consensus was achieved on 9 statements. Agreement was reached on the continuation of systemic therapy for patients in good clinical condition following neoadjuvant chemotherapy and on transitioning to best supportive care for those in suboptimal condition after futile laparotomy (peroperatively unresectable disease). Variability was observed in the choice of systemic therapy regimens. During the study, clinicians identified a strong preference for shared decision-making and highlighted the need for decision-aids to facilitate patient-clinician discussions.

*Conclusions*

This study provides consensus for the management of inoperable and peroperatively unresectable epithelial ovarian cancer. However, lack of agreement on systemic therapy regimens underscores the urgent need for further research.

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*Keywords*

Carcinoma, Ovarian Epithelial; Unresectable; Systemic Therapy; Inoperable; Modified Delphi Technique; Consensus

*List of abbreviations*

FIGO: International Federation of Gynaecology and Obstetrics; EOC: epithelial ovarian cancer; CRS: cytoreductive surgery; NACT: neoadjuvant chemotherapy; WMO: Dutch Medical Research Involving Human Subjects Act ; NVOG: Dutch Society of Obstetrics and Gynaecology ; WHO: World Health Organization; HRD: homologous recombination deficiency; RESIST: Response Evaluation Criteria in Solid Tumours ; CT: computed tomography; HGS: high grade serous; PARPi: poly ADP-ribose polymerase inhibitors; LGS: low-grade serous; OS: overall survival; PFS: progression free survival

## Introduction

The most important prognostic factor for survival in FIGO stage III-IV (International Federation of Gynaecology and Obstetrics 2021) epithelial ovarian cancer (EOC) is the surgical outcome of cytoreductive surgery (CRS) (1), with a significant survival benefit when there is no macroscopic residual disease (2). When faced with primarily unresectable EOC, neoadjuvant chemotherapy (NACT) has proven to be a feasible option after which interval CRS can still be performed (3). In some cases clinicians decide to refrain from surgery when the disease shows an unfavourable response to NACT. In other cases the patient may be unfit for surgery or the patient decides not to undergo CRS. Furthermore in some cases the disease proves to be unresectable peroperatively due to extensive disease, leading to a futile laparotomy. Further treatment of these inoperable and peroperatively unresectable patients presents a significant clinical challenge, as there are no clear guidelines available.

The management of inoperable or peroperatively unresectable ovarian cancer requires a multidisciplinary approach, incorporating various treatment modalities to improve patient outcomes and quality of life. This group of patients seems underreported in the literature, as many studies focus either on curative treatment, or end of life treatment, effectively excluding the patient with unresectable cancer who can still be treated for extension of life with good quality of life. Furthermore, the outcomes of the inoperable or peroperatively unresectable EOC patients are often grouped together with patients with suboptimal CRS ( >1cm residual disease) or excluded from studies (4).

In such cases, the modified Delphi method can serve as an effective approach to gather insights on questions that are challenging to answer using available data. This is a structured communication technique used to gather expert opinions and achieve consensus through multiple rounds of surveys. It is particularly useful in medical research in small and underreported patient groups for developing guidelines and treatment strategies, as it allows for the systematic collection and refinement of expert input. By presenting literature based questionnaires and iteratively refining responses, the modified Delphi method helps build a consensus on best practices, ultimately guiding clinical decision-making in cases lacking clinical evidence (5).

To address this knowledge gap in the preferred treatment strategies for inoperable or peroperatively unresectable EOC patients, we aimed to conduct a modified Delphi study to gain insights into expert opinions on treatment strategies.

## Methods

*Study design*

A comprehensive questionnaire containing two realistic clinical cases was developed, based on the findings from a scoping literature review and group discussions within the research team. These cases were designed to reflect common scenarios encountered in the treatment of unresectable ovarian cancer. The Delphi process consisted of three rounds; in the first round, participants were asked to provide their preferred treatment strategies for the presented cases. The responses were anonymised, summarized and analysed. In the second round, the summarized responses were shared with the participants, who were asked to reconsider their initial answers in light of the group’s feedback. The third and final round aimed to achieve consensus, with participants refining their responses based on the feedback from the previous rounds, after which findings were analysed for the final results. All results were shared with the participant group anonymously. *Figure 1* presents an overview of the study design. Patients were not involved in the study process. This study was conducted without the need for approval under the Dutch Medical Research Involving Human Subjects Act (WMO), as confirmed by the institutional review board of Erasmus MC. The study was registered under protocol number MEC-2024-0320.

*Expert recruitment*

Expert clinicians from the Netherlands were invited to participate in the study via the Dutch Society of Obstetrics and Gynaecology (NVOG). Invitations were extended to gynaecologic oncologists, gynaecologists and medical oncologists, as these specialists play a crucial role in the decision-making process and treatment of patients with unresectable ovarian cancer. Efforts were made to ensure representation from a diverse range of clinical centres, recognizing that treatment policies often vary between institutions. This distribution was intended to enhance the reliability and generalizability of the study results.

*Survey*

The survey was divided into three sections: demographic questions, clinical cases, and participants’ opinions on the need for further research in this patient group as well, as the necessity of a decision aid. The clinical cases involved two hypothetical patients: one representing a patient with EOC in good clinical condition (75 years old, World Health Organization [WHO] performance status 1) and the second representing a patient in suboptimal clinical condition (85 years old, WHO performance status 3). Homologous recombination deficiency (HRD) status also varied between the cases, with the first patient being HRD-positive and the second HRD-negative, allowing this factor to be taken into account. Participants were asked to answer seven questions regarding treatment options, with variations in tumour characteristics based on response to NACT, assessed according to RECIST 1.1 (Response Evaluation Criteria in Solid Tumours)(6) on computed tomography (CT) scans, and surgical outcomes (either not operated or futile laparotomy). As previously mentioned, a futile laparotomy was defined as an intention to perform CRS that could not be completed due to extensive disease. After each question, participants had the opportunity to provide comments, which were considered in subsequent rounds. Additionally, six open-ended questions per clinical case addressed treatment strategies for ovarian cancers of other histological types, including clear cell, mucinous, and low-grade serous. A translated version of the complete survey is presented in *supplement 1*.

*Data analysis*

Consensus can be defined in different ways, ranging from percentages 75-80% and interquartile ranges (7, 8). As options in this Delphi study were non-inferior multiple choice options without ranking, consensus was defined as more than 80% unanimity in results. Surveys were conducted in Castor EDC/CDMS and data was analysed using descriptive statistics in Microsoft Excel 2016.

## Results

*Response rate and demographics*

The study was conducted from September to November 2024 in which three Delphi rounds were sent out. The 23 participants in the first round consisted of 14 (60%) gynaecologic oncologists, 6 (27%) gynaecologists and 3 (13%) medical oncologists. The response rate in round two was 82% and 74% (17 clinicians) in round three. Participants were from 18 centres treating patients with advanced ovarian cancer, of which representatives from 13 centres completed all three rounds (72%). A least one participant from each academic centre in the Netherlands completed all three rounds. *Table 1* outlines the demographic characteristics of the participants.

*Case-based questions – high grade serous EOC*

The seven case-based multiple-choice questions were divided into 13 statements *(table 2),* on which consensus was reached for 9 statements (69%). For a primary high-grade serous (HGS) type EOC patient with stable disease following NACT, all clinicians would continue with 3-weekly platinum-based chemotherapy for patients in good clinical condition (WHO 1) who declined surgery. However, for patients in suboptimal clinical condition (WHO 3), 50% would continue with 3-weekly platinum-based chemotherapy, 31% would switch to a weekly regimen, and 13% would stop all systemic therapy and initiate best supportive care. If the patient was willing to consider surgery, 6% would consider CRS for patients in suboptimal clinical condition *(figure 2)*.

Regarding the use of poly ADP-ribose polymerase inhibitors (PARPi) in patients who are HRD-positive, opinions were divided among participants: 56% would deem the patient eligible for PARP inhibitors, while 44% would not.

In the case of a primary HGS type EOC with stable disease following NACT and a futile laparotomy, 94% of clinicians would continue systemic therapy for a patient in good clinical condition (WHO 1). Of these, 63% would opt for platinum-based chemotherapy (57% 3-weekly and 6% weekly), 25% would consider clinical trials, and 6% would switch to an entirely different regimen. For patients in suboptimal clinical condition (WHO 3), 81% would continue platinum-based systemic therapy (50% 3-weekly and 31% weekly), while 19% would stop treatment and switch to best supportive care *(figure 2).*

In the case of progressive disease after NACT, 100% of clinicians would continue systemic therapy in patients in good clinical condition (WHO 1), with varying regimens: 13% would continue 3-weekly platinum-based chemotherapy, 13% would switch to weekly platinum-based chemotherapy, 18% would add the monoclonal antibody bevacizumab, 25% would choose a completely different regimen and 31% would consider clinical trials. In contrast, for a patient in suboptimal clinical condition (WHO 3), 90% of clinicians would stop all systemic therapy and initiate best supportive care *(figure 2).* Due to the high level of consensus, this statement was not repeated in round three.

However, when progression of disease is observed in a patient in suboptimal clinical condition (WHO 3) who has undergone a futile laparotomy, 84% of clinicians would stop treatment and initiate best supportive care. This contrasts with the earlier scenario, where 80% would continue systemic therapy for the same patient based on CT findings alone. Due to the high level of consensus, this statement was not repeated in round three.

*Histological subtypes*

Different histological subtypes were explored in both patients with good and suboptimal clinical conditions, presented with stable disease after NACT and following a futile laparotomy. These were open-ended questions and were not included in the Delphi rounds, thus not contributing to official consensus. There was a trend toward continuing systemic therapy in patients with mucinous and clear cell ovarian cancer in good clinical condition (WHO 1), whereas most clinicians opted to stop systemic treatment and start best supportive care for patients in suboptimal clinical condition (WHO 3). For low-grade serous (LGS) EOC, nearly all clinicians recommended initiating hormonal therapy regardless of the patient’s clinical condition.

*Assessing research needs and decision aid*

Participants expressed a higher need for research focused on inoperable or peroperatively unresectable patients with EOC (84%) compared to those who decline CRS (65%). Nearly all clinicians emphasized the importance of shared decision-making, highlighting that patient preferences play a critical role in the treatment process, thereby adding nuance to these findings. Additionally, 65% of respondents indicated that a decision aid would be helpful in simplifying the decision-making process for patients.

## Discussion

*Main findings*

In this study, the modified Delphi method was employed to collect insights from gynaecologists and oncologists across the country regarding treatment strategies for a significantly underreported patient group. Seventeen clinicians completed all three rounds of structured questionnaires representing all academic hospitals in the Netherlands. Consensus (≥80%) was achieved on 9 out of 13 statements. For the patient in good clinical condition (WHO 1) who either presented with stable disease after NACT and declined surgery, or presented with progressive disease after NACT, most clinicians recommended continuing systemic therapy. For the patient in suboptimal condition (WHO 3) who either presented with progressive disease following NACT, or with stable disease following NACT and a futile laparotomy, the vast majority opted to initiate best supportive care. Opinions on the use of PARPi in HRD-positive patients were divided. This study concludes that though treatment protocol for patients with inoperable or peroperatively unresectable EOC is similar among clinicians, systemic therapy regimens demonstrate considerable variability.

*Strengths and Limitations*

Strengths: This study utilized multidisciplinary teams and a modified Delphi method, which proved effective in addressing an underreported patient population with limited available data. The approach allowed for the collection of anonymized opinions from clinicians across all participating centres, minimizing peer pressure and the influence of dominant voices during discussions. Anonymity ensured unbiased responses, while the repetitive rounds of the Delphi process enabled participants to refine their answers after reviewing aggregated feedback from peers. The inclusion of representatives from all academic hospitals in the Netherlands, and some regional hospitals, strengthened the validity of the findings, as several centres reported consistent protocols within their institutions.

Limitations: The study faced a small sample size of clinicians completing all rounds and a limited number of medical oncologists, which may have introduced bias and contributed to the lack of consensus on certain treatment regimens, particularly those requiring more specialized oncological expertise. However, the inclusion of representatives from all academic hospitals and feedback that centres nominated a single clinician due to standardized protocols and discussion within their multidisciplinary tumour boards, suggests the findings are still broadly representative whilst also avoiding disproportionate weighting from centers with more respondents. There was also participant dropout between Delphi rounds, which could introduce bias, as it is not clear why they opted out of subsequent rounds. Open-ended questions addressing other histological subtypes were excluded from the Delphi process to prevent overly long questionnaires, though further research on these topics is necessary. Finally, while this study reflects opinions within the Netherlands, expanding to incorporate international perspectives would provide a more comprehensive understanding of global practices.

*PARP inhibitors*

The role of PARPi in patients with HRD-positive tumours as primary maintenance treatment remains a topic of active debate. In the ESMO/ESGO/ASCO guidelines PARPi have been recommended for this subgroup (9, 10). However, recent findings challenge this paradigm. Overall survival (OS) data from the PRIMA study demonstrated no benefit in OS with the use of the PARPi niraparib in the subgroups with a BRCA-mutation and homologous recombination deficient or proficient EOC. These results are nuanced by the fact that part of the placebo group did receive PARPi at a later moment. Furthermore it showed a twofold improvement in progression-free survival (PFS) in patients with HRD EOC receiving first-line niraparib (11). In contrast, the PAOLA-1/ENGOT-ov25 previously did show both PFS and OS benefit with maintenance treatment with olaparib and bevacizumab compared to bevacizumab alone in the HRD group. Overall survival data from the SOLO1 trial seem to show OS benefit with olaparib in patients with BRCA-mutant EOC, but these data are not yet fully mature (12, 13). The ATHENA-MONO/GOG-3020/ENGOT-ov45 trial also showed significant improvements in PFS with maintenance treatment with rucaparib in patients with EOC, but OS outcomes are not yet mature (14). Other first-line PARPi studies have yet to be published. Given that PFS cannot be considered a surrogate endpoint for OS in EOC (15), these findings raise critical questions when PARPi in HRD EOC patients should best be used and underscore the need for updated guidelines informed by robust, long-term data. However a critical note is that a prerequisite for the use of PARPi is the achievement of response to treatment. Many respondents cited the aforementioned studies as the rationale for not using PARPi in HRD-positive patients. The variability in responses may also be attributed to the publication timing of the updated OS results of the PRIMA study (11), which occurred during the questionnaire period.

*Trends in surgical decision making*

There is a noticeable trend in clinical decision-making towards greater reliance on intraoperative findings compared to imaging results. Clinicians in this study are more likely to discontinue systemic therapy when faced with evidence of extensive disease during surgery than when confronted with similar findings on imaging. This underscores the human element in medical decision-making, as direct visualization of disease may have a stronger psychological impact than imaging results. Furthermore, the findings of this study highlight the tendency of clinicians to persist with treatment, particularly in patients who remain in good clinical condition, despite a lack of supporting evidence. For instance, in cases where a patient exhibits progressive disease following NACT, many clinicians opt to continue chemotherapy. The literature on cognitive biases and decision-making in healthcare (16, 17) highlights the importance of understanding these dynamics in human decision making to ensure that decisions are both evidence-based and patient-centred. Training on bias awareness and debiasing strategies could reduce these differences (18). Furthermore, concrete evidence-based guidelines in this patient population are needed to make unbiased opinions, highlighting the pressing need for additional studies on treatment and survival in the inoperable and peroperatively unresectable EOC patient group to clarify these uncertainties.

*Shared decision making and decision aids*

Given the complexity involved in treating unresectable ovarian cancer, shared decision-making plays a pivotal role in oncological clinical care (19) and is not always sufficiently discussed according to patients (20). Many clinicians in this study emphasized the importance of shared decision-making in practice, irrespective of findings in research. The integration of shared decision-making tools, such as decision aids, can enhance communication between patients and clinicians, ensuring that patients are fully informed about their options and the potential risks and benefits of each approach (21, 22). These tools not only support patient autonomy but also help clinicians navigate difficult conversations and align treatment decisions with patients' values and preferences. To be able to design these tools, further research is needed to assess the survival and quality of life differences between treatment modalities.

## Conclusion

## This study shows that consensus exists among clinicians on the overall treatment strategies for patients with inoperable or peroperatively unresectable EOC. Agreement was reached on the continuation of systemic therapy for patients in good clinical condition following NACT and on transitioning to best supportive care for those in suboptimal condition following a futile laparotomy. However, significant variability remains regarding the choice of systemic therapy regimens, reflecting the lack of evidence to guide these decisions

## While this study provides a framework for consensus-based management, future research is crucial to establish evidence-based treatment protocols and quantify outcomes in this underreported patient group. Addressing these gaps will further refine care strategies, facilitate the development of a decision aid and improve quality of life in this patient group.

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## Disclosure of interests

Nothing to declare.

## Contribution to authorship

PG (P. Garkhail), GN (G.M. Nieuwenhuyzen-de Boer), and HB (H.J. van Beekhuizen) contributed to the conception of the study. PG, GN and IB (I. Boere) were involved in the planning of the work. PG was responsible for carrying out the study, as well as analyzing the data and drafting the manuscript. All authors reviewed and provided critical revisions to the manuscript, and approved the final version for submission.

## Details of Ethics Approval

This study was conducted without the need for approval under the Dutch Medical Research Involving Human Subjects Act (WMO), as confirmed by the institutional review board of Erasmus MC. The study was registered under protocol number MEC-2024-0320.

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