

Clinical and Treatment Characteristics of Patients Undergoing Cytoreductive Surgery and Hyperthermic Intraperitoneal Chemotherapy for Advanced Ovarian and Primary Peritoneal Cancer: A Retrospective Single-Center Study

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Abstract

In selected patients with advanced or recurrent ovary and primary peritoneal cancer, cytoreductive surgery with hyperthermic intraperitoneal chemotherapy is performed. Institutional data on the clinical features, treatment patterns, and completeness of cytoreduction in patients who have received this treatment, however, are limited. In this study, the disease and treatment characteristics of patients undergoing cytoreductive surgery and hyperthermic intraperitoneal chemotherapy at a single specialist center were described. This is a single-center, retrospective, descriptive study that involved 40 women with epithelial ovarian or primary peritoneal cancer (Stages III-IV) who underwent cytoreductive surgery (CS) and hyperthermic intraperitoneal chemotherapy (HIPEC) from January 2019 to July 2024. Data on age, FIGO stage, tumour location, histopathology, Peritoneal Cancer Index, neoadjuvant chemotherapy, indication of hyperthermic intraperitoneal chemotherapy, and completeness of cytoreduction were obtained. Means and standard deviations were used for continuous variables and frequencies and percentages were used for categorical variables. Mean age was 48.5 ± 11.8 years; mean Peritoneal Cancer Index 10.9 ± 3.7 . The majority of patients (72.5%) had FIGO stage III disease and 11 patients (27.5%) had stage IV disease. The primary tumour was ovarian in 32 patients (80.0%) and primary peritoneal in eight patients (20.0%). Twenty-two patients (55.0%) received neoadjuvant chemotherapy. The most common histological type was high grade serous carcinoma (17 cases, 42.5%). In 16 pa-

tients (40.0%) primary cytoreductive surgery was combined with hyperthermic intraperitoneal chemotherapy. Of the 40 patients, 20 (50.0%) had complete cytoreduction (CC-0), 18 (45.0%) had CC-1 residual disease and two (5.0%) had CC-2 residual disease. This retrospective analysis provides the clinical and treatment characteristics of a subset of patients treated with cytoreductive surgery and hyperthermic intraperitoneal chemotherapy. Complete macroscopic cytoreduction (CC-0) was achieved in 50.0% of patients, while 95.0% had CC-0 or CC-1 residual-disease status and were diagnosed with FIGO stage III disease. Findings are descriptive and do not imply any statements about the safety of treatment, postoperative morbidity, relative effectiveness or survival.

Keywords

Advanced Ovarian Cancer, Primary Peritoneal Carcinoma, Cytoreductive Surgery, Hyperthermic Intraperitoneal Chemotherapy, Peritoneal Cancer Index, Completeness of Cytoreduction

1. Introduction

Ovarian cancer is one of the most malignant gynecological cancers, which is often at later stages (FIGO) with peritoneal dissemination [1]. Ovarian cancer remains one of the leading causes of death from gynecologic cancers in China [2]. Over 70% of patients are FIGO stage III-IV, which have poor long-term survival [3]. This is the reason why late-stage ovarian cancer has high rates of recurrence and poor long-term survival [4]. The most important predictive factor for death in advanced ovarian cancer [5] is cytoreductive surgery for complete macroscopic tumor removal (CC-0). The Peritoneal Cancer Index (PCI) is a system that is widely used to evaluate intraperitoneal tumour burden (scale 0 - 39) and to guide surgical management [6].

Hyperthermic intraperitoneal chemotherapy (HIPEC) combines intraoperative heated chemotherapy and cytoreduction to increase the local distribution of the drugs and may overcome platinum resistance mechanisms by hyperthermia-enhanced drug cytotoxicity [7] [8].

High-grade serous carcinoma (HGSC), which is the most common histological type of serous carcinoma, has a fast course, high recurrence rates, and early dissemination in the peritoneum [9]. The standard treatment is cytoreductive surgery (CRS) & chemotherapy (platinum) and the use of neoadjuvant chemotherapy has increased in those with a high disease burden [10] [11]. The combination of cytoreductive surgery and hyperthermic intraperitoneal chemotherapy is a complex combination of treatment that must be carefully planned and patiently decided upon, depending on the patient; it requires specialist surgical skills, standardisation of chemotherapy administration, and multidisciplinary perioperative management. They may differ depending on the stage of the disease, the size of

the tumour, histopathology, platinum sensitivity, past chemotherapy, institutional protocols and the chances of attaining satisfactory cytoreduction [12] [13].

While there have been studies of cytoreductive surgery and hyperthermic intraperitoneal chemotherapy (HIPEC) in other countries, there is limited detail at an institutional level from individual geographic centres. The explanation of patient selection, disease characteristics, chemotherapy use, treatment setting, Peritoneal Cancer Index, and the completeness of cytoreduction can assist in local clinical audit and give the initial evidence for future outcome studies.

The aim of this study was thus to outline the demographic, disease and treatment parameters in patients with advanced ovarian or primary peritoneal carcinoma undergoing hyperthermic intraperitoneal chemotherapy (HIPEC) at a single ovarian cancer specialist centre [14] [15].

2. Methods

2.1. Study Design and Setting

This retrospective, descriptive, single-center study was conducted at the Affiliated Hospital of Xuzhou Medical University, Xuzhou, Jiangsu Province, China. Medical records of patients who underwent cytoreductive surgery with hyperthermic intraperitoneal chemotherapy (HIPEC) between January 2019 and July 2024 were reviewed.

2.2. Study Population

Study subjects were women aged 18 years or older who had histologically confirmed epithelial ovarian or primary peritoneal carcinoma, FIGO stage III or IV, and peritoneal involvement who underwent cytoreductive surgery and who received hyperthermic intraperitoneal chemotherapy while the study was being performed.

2.3. Sampling Strategy

Consecutive sampling was used. During the study period, 64 patients were screened, of whom 40 met the eligibility criteria and were included in the final analysis. The remaining 24 patients were excluded according to the predefined exclusion criteria.

2.3.1. Inclusion Criteria

Eligible patients were women aged ≥ 18 years with histologically confirmed epithelial ovarian or primary peritoneal carcinoma, FIGO stage III or IV disease with peritoneal involvement, who underwent cytoreductive surgery with HIPEC and had adequate documentation of the required study variables.

2.3.2. Exclusion Criteria

Patients were excluded if they did not receive hyperthermic intraperitoneal chemotherapy (HIPEC) at the time of cytoreductive surgery, if cytoreductive surgery was performed for a non-gynecological malignancy, if the disease was judged to be in-

operable after multidisciplinary evaluation, or if the information provided in the records was not sufficient to identify the necessary clinical and treatment features.

2.3.3. Surgical and HIPEC Protocol

Specialist surgeons in gynecological oncology performed cytoreductive surgery with the goal of complete macroscopic cytoreduction, whenever technically and clinically possible. The amount of residual disease was reported based on the Sugarbaker Completeness of Cytoreduction classification:

CC-0 meant that there was no disease seen, CC-1 meant the nodules were 2.5 mm or less, CC-2 meant that the disease measured more than 2.5 mm but not more than 2.5 cm and CC-3 meant that the disease measured more than 2.5 cm.

A Peritoneal Cancer Index was obtained intraoperatively prior to cytoreduction. Hyperthermic intraperitoneal chemotherapy (HIPEC) was once given using the HT-2000 Hyperthermic Perfusion System and closed abdomen technique. The desired perfusate temperature range was 42.0°C - 42.5°C and the perfusion was continued for 60 minutes [16] [17].

Cisplatin 100 mg/m² was given to 10 patients, paclitaxel 175 mg/m² plus cisplatin 100 mg/m² to 20 patients and mitomycin 15 mg/m² plus cisplatin 100 mg/m² to 10 patients. HIPEC regimen selection was based on available treatment records; however, the rationale for regimen choice, its variation by treatment setting, histology, or time period, and details regarding carrier solution, perfusate volume/flow, and renal-protection protocol were not consistently available.

2.4. Data Collection

Information was retrieved from electronic medical records, surgical records, pathology records, oncology records and available treatment records. The variables involved were age, FIGO stage, tumour location, histopathological subtype, neoadjuvant chemotherapy status, Peritoneal Cancer Index, treatment category, chemotherapy regimen and completeness of cytoreduction score. FIGO stage and histology were recorded at Xuzhou Affiliated Hospital that was affiliated with confirmed HIPEC program, whereas PCI was recorded intraoperatively before cytoreduction. Primary disease referred to upfront CRS-HIPEC, and interval disease to CRS-HIPEC following neoadjuvant chemotherapy. Recurrent disease was classified as platinum-sensitive or platinum-resistant using a platinum-free interval of January 2019 & July 2024 months.

Available analytical information lacked standardisation at the patient level with regard to the type of postoperative complication, the Clavien-Dindo grade, the use of the intensive-care unit, reoperation, readmission, postoperative death, renal toxicity, haematological toxicity or hospital stay. As a result, a morbidity rate and predictors of morbidity could not be calculated after the surgery.

2.5. Data Quality and Missing Data

The data set was checked for completeness, inconsistent terminology and duplicate patient identifiers. All patients were represented only once. Labels of histo-

pathological, tumour-location, treatment-category, and FIGO stage were standardized prior to the analysis. No imputation of statistics was done.

2.6. Statistical Analysis

IBM SPSS Statistics 27 was used for analyzing the data. Means and standard deviations were used to summarise continuous variables. Frequencies and percentages were used to summarize categorical variables. Given the small sample size and descriptive nature of the study, no multivariable analysis was done. Inferential analyses that did not directly address the main description goal were excluded because of possible unstable estimates, sparse cell bias and over-interpretation of comparisons with fewer than 40 observations of these variables.

2.7. Ethical Considerations

The study was approved by the Ethics Committee of Xuzhou Second Affiliated Hospital, China (XYFY2023-KL107-01), which is the Affiliated Hospital of Xuzhou Medical University. Patient records were reviewed anonymously, and informed consent was waived because of the retrospective study design.

3. Results

Most patients presented with advanced FIGO stage III disease, predominantly stage IIIC, and ovarian origin was the most common tumor site **Table 1**.

Table 1. Disease characteristics of the study population.

Characteristic	Frequency	Percentage
FIGO stage IIIA	7	17.5
FIGO stage IIIB	8	20
FIGO stage IIIC	14	35
FIGO stage IVA	6	15
FIGO stage IVB	5	12.5
Ovarian primary tumour	32	80
Primary peritoneal tumour	8	20

The continuous clinical characteristics were also analysed in order to describe the age distribution and extent of the disease in the peritoneum in the cohort. The mean, standard deviation, and observed range is used to summarise patients age and the Peritoneal Cancer Index. Histopathological and treatment characteristics are represented in **Table 2**. These are measures to give more background information about the demography profile and intra-abdominal tumour burden of patients who were chosen for CRS-HIPEC. Continuous clinical characteristics shown in **Table 3**.

Table 2. Histopathological and treatment characteristics.

Characteristic	Frequency	Percentage
High-grade serous carcinoma	17	42.5
Clear-cell carcinoma	5	12.5
Low-grade serous carcinoma	5	12.5
Mucinous carcinoma	5	12.5
Undifferentiated carcinoma	5	12.5
Endometrioid carcinoma	3	7.5
Neoadjuvant chemotherapy: Yes	22	55.0
Neoadjuvant chemotherapy: No	18	45.0
Primary CRS-HIPEC	16	40.0
Platinum-sensitive recurrence	10	25.0
Platinum-resistant recurrence	7	17.5
Interval CRS-HIPEC after neoadjuvant treatment	7	17.5
CC-0	20	50.0
CC-1	18	45.0
CC-2	2	5.0
High-grade serous carcinoma	17	42.5
Clear-cell carcinoma	5	12.5
Low-grade serous carcinoma	5	12.5

Table 3. Continuous clinical characteristics.

Variable	Mean	Standard deviation	Range
Age, years	48.50	11.77	27 - 70
Peritoneal Cancer Index	10.90	3.66	4 - 20

3.1. Patient and Disease Characteristics

Total number of patients included in the study were 40. The mean age was 48.5 ± 11.8 years, with ages ranging from 27 to 70 years. The mean Peritoneal Cancer Index was 10.9 ± 3.7 , and ranged from 4 to 20 values.

Twenty-nine patients (72.5%) were with the FIGO stage III disease. Seven (17.5%) had stage IIIA, eight (20.0%) had stage IIIB and 14 (35.0%) had stage IIIC disease. Eleven patients (27.5%) had stage IV disease and 6 of them (15.0%) had stage IVA and 5 of them (12.5%) had stage IVB disease.

Thirty-two patients (80.0%) had a primary tumour found in the ovary, and eight patients (20.0%) in the primary peritoneal tumour. The most common histological type was high grade serous carcinoma (17 patients, 42.5%). Clear-cell, low-grade serous, mucinous and undifferentiated carcinomas were all found in five patients each (12.5%) and endometrioid carcinoma in three patients (7.5%).

3.2. Treatment Characteristics

Amongst the 22 patients (55.0%) who received neoadjuvant chemotherapy, 18 patients (45.0%) did not. Of the 22 patients who received neoadjuvant chemotherapy, seven subsequently underwent interval CRS-HIPEC; detailed information on chemotherapy regimen, number of cycles, and timing before surgery was not consistently available in the retrospective records. For 16 patients (40.0%) primary cytoreductive surgery and hyperthermic intraperitoneal chemotherapy was performed. Ten patients received treatment for platinum-sensitive recurrence (25.0%), seven for platinum-resistant recurrence (17.5%) and seven had interval cytoreductive surgery and hyperthermic intraperitoneal chemotherapy after neoadjuvant treatment.

In 20 patients (50.0%) complete cytoreduction (CC-0 score) was obtained. The number of patients who achieved CC-1 cytoreduction was 18 (45.0%) and 2 (5.0%) the number of patients who had a CC-2 score. Complete macroscopic cytoreduction (CC-0) was achieved in 20 patients (50.0%), while 38 patients (95.0%) had CC-0 or CC-1 residual-disease status.

None of the patient-level postoperative complication variables were available in the analytical data set. As a result, postoperative morbidity rates, the distributions of Clavien-Dindo grades, mortality rates and any parameters that could be assessed regarding the relationship between clinical parameters and postoperative morbidity were not calculated.

4. Discussion

This is a retrospective, single center study that characterizes the disease and treatment of 40 patients with advanced ovarian or primary peritoneal cancer receiving cytoreductive surgery and hyperthermic intraperitoneal chemotherapy. The majority of patients presented with FIGO stage III disease, ovarian primary tumours and serous histology. Over a half of the patients were treated with neoadjuvant chemotherapy, the most common treatment category was primary cytoreductive surgery plus hyperthermic intraperitoneal chemotherapy [18] [19].

The most common high grade histopathological subgroup was serous carcinoma (42.5%). However, the study population was diverse and included both clear-cell and endometrioid, low-grade serous, mucinous and undifferentiated carcinomas. The histological heterogeneity should be taken into account when interpreting the cohort as there may be differences in the biological behaviour, platinum-based chemotherapy response and treatment pathways.

Complete macroscopic cytoreduction (CC-0) was achieved in 50.0% of patients,

while 95.0% had CC-0 or CC-1 residual-disease status. The CC-score distribution is an important operative characteristic in advanced ovarian cancer; however, its association with progression-free or overall survival was not assessed in this study, and thus could not be related to progression-free or overall survival. Low mean Peritoneal Cancer Index and the high combined rate of CC-0 and CC-1 cytoreduction may also be due to careful patient selection for the extensive cytoreduction surgery [20].

There were various types of treatment settings represented, such as primary disease, interval surgery following neoadjuvant chemotherapy, platinum-sensitive recurrence, and platinum-resistant recurrence. All of the various clinical settings extend the descriptive range of the study, but they also make for treatment heterogeneity. The three reported hyperthermic intraperitoneal chemotherapy (HIPEC) regimens were also found, suggesting that there was not a standard approach throughout the cohort. The differences do not permit direct comparisons to be made between treatment categories.

The study offers institution-specific data in a regional centre where there are only limited published data on patient selection and operative characteristics. But there was no standardized information about surgical complications in the available analytical data. Thus, the study is unable to measure the incidence or severity of postoperative morbidity, nor is it able to determine the safety or feasibility of cytoreductive surgery and hyperthermic intraperitoneal chemotherapy or to determine comparative effectiveness.

The results should therefore be considered as descriptive rather than confirmatory, and hypothesis generating. The collection of standardized postoperative outcomes, such as Clavien-Dindo grade, the type of complication, acute kidney injury, hematological toxicity, intensive-care admission, reoperation, readmission, length of hospital stay, and mortality at 30 and 90 days, should be collected in future studies in a prospective manner. Additional multicentre study cohorts would also allow for adjustment for age, comorbidity, Peritoneal Cancer Index, complexity of operation, chemotherapy regimen and completeness of cytoreduction.

5. Conclusions

This is a retrospective, single-center study of 40 patients who received cytoreductive surgery and hyperthermic intraperitoneal chemotherapy (HIPEC) for advanced ovarian or primary peritoneal cancer (PP). The majority of patients presented with FIGO stage III disease and high-grade serous carcinoma was the most common histological type. Cytoreduction was successful (CC-0 or CC-1) in 95.0% of the patients. Due to lack of standardized patient-level postoperative complication data, no conclusions can be drawn about postoperative morbidity, safety, comparative effectiveness or survival. Standardization of the collection of outcomes and larger multicenter samples are needed for prospective studies.

There are a number of significant limitations to this study. This was a retro-

spective study and thus suffered from incomplete documentation, inconsistent documentation, information bias and residual selection bias. The study was limited to a single centre, with a small number of patients (only 40), which reduced the generalisability and statistical power of the study. Several treatment settings and hyperthermic intraperitoneal chemotherapy regimens as well as histological subtypes were included in the cohort, leading to high clinical heterogeneity. A comparison group for non-HIPEC was not available. Most importantly, the analytical dataset was not standardized to provide information on patient level post-operative complications, which would allow estimation of morbidity, Clavien-Dindo grade, treatment-related toxicity, reoperation, readmission, postoperative mortality, and factors associated with adverse outcomes. Not evaluated: Recurrence-free survival and overall survival.

Ethics Approval and Consent to Participate

The study received approval from the Ethics Committee of Xuzhou Second Affiliated Hospital, China (XYFY2023-KL107-01). Subjects were reviewed anonymously for research purposes, and informed consent was waived per institutional policy, due to the retrospective design of this study.

Author Contributions

Ishfaq Beenish conceptualized, curated data, performed formal analysis and undertook writing: original draft. Chen Buze participated in the supervision, validation and writing: review & editing. The manuscript was read and approved by all authors.

Data Availability Statement

Patient privacy concerns mean that the datasets analyzed and/or generated during the current study are not publicly available, but they may be made available to the corresponding author on reasonable request.

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Conflicts of Interest

The authors have declared that there are no conflicts of interest.

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