Efficiency of Laparoscopic Interval Cytoreductive Surgery After Neoadjuvant Chemotherapy in Patients with Stage III and IV Epithelial Ovarian Cancer

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Abstract

Purpose: Laparoscopic surgery may have the benefits of minimally invasive surgery (MIS). Laparoscopic interval cytoreduction may be effective for eradication of tumor implants in advanced ovarian cancer after NACT and similar complications.

Methods: It was a prospective single-arm phase II clinical trial study. The efficacy and complications of laparoscopic interval cytoreduction in patients with COEA after NCT were evaluated. Patients diagnosed with advanced ovarian carcinoma who received NCT of 3 to 4 cycles of carboplatin/paclitaxel with or without bevacizumab were included. Interval cytoreductive laparoscopic surgery was performed.

Results: 18 of 40 patients were included, with a median age of 45.5 years (range: 38-72). The most common histological type was high-grade serous carcinoma 14 (77.77%). 6 (33.33%) were stage IIIC, 9 (50%) IVB and 3 (16.67%) IVA. 14 patients (77.78%) received 4 cycles of chemotherapy. 1 (5.56%) received standard surgery, 5 (27.78%) radical surgery, 10 (55.56%) supraradical surgery and 2 (11.11%) were non-cytoreducible. 16 (88.89%) had optimal R0 = no residual, and 2 (11.11%) were not resected. In complications, the median blood loss was 50 ml (range: 10 - 600 ml), 13 (72.2%) patients had no complications, and 1 patient had a grade III complication.

Conclusion: The primary objective was achieved, 88.89% of patients were cytoreduced. 4 (22.22%) patients presented mild complications while 1 (5.56%) patient presented moderate grade IIIa complications.

Keywords: Laparoscopy, Cytoreduction Surgical Procedures, Ovarian Neoplasm

INTRODUCTION

Epithelial Ovarian Cancer (EOC) is the eighth cause of cancer worldwide in women according to the Global Cancer Observatory, World Health Organization (WHO), and the International Agency for Research on Cancer. The global incidence of ovarian cancer was 7.8 cases per 100,000 inhabitants in

2022. In Mexico, ovarian cancer has an incidence of 7.7 per 100,000 women. [1]

Primary cytoreduction surgery (PCS) is the regular course of treatment for EOC. Cytoreduction can be categorized as “optimal” (residual disease <1cm), “suboptimal” (residual disease >1cm), or “complete” (with no macroscopic evidence of residual disease), this last one being considered the ultimate goal of cytoreduction surgery due to its impact on survival prognosis. [2]

The use of neoadjuvant chemotherapy (NACT) has increased substantially in the last decade, four phase III non-inferiority trials randomly assigned women with advanced stage EOC to receive NACT followed by Interval Cytoreduction Surgery (ICS). They demonstrated similar percentages of optimal cytoreduction (most between 70 and 80%) and had the same survival outcomes as the women assigned to PCS and adjuvant chemotherapy; the results were consistent and demonstrated no inferiority. [3-6]

The prognostic factor for survival is complete cytoreduction, so the objective of surgery should be laparotomy vs CMI.

The use of CMI in the staging of EOC is feasible and safe in patients with suspected early-stage tumors without extraovarian involvement, with the benefits of CMI including: less bleeding, shorter hospital stays, and quick recovery to usual activities. (7-11)

Some studies demonstrated that women who underwent ICS via Minimally Invasive Surgery (MIS) after NACT reported a high rate of complete cytoreduction, good perioperative reports, and excellent rates of disease-free survival. [12-15]

Due to 70% of EOC being diagnosed in advanced stages, the majority of patients receive the standard course of treatment: initial NACT followed by ICS via laparotomy. However, this procedure can present high morbidity rates. A laparoscopic procedure allows for smaller incision sites and improved recovery; it also has similar oncological control and rates trans- and post-operative complications to laparotomies.

The existing observational studies and case series suggest that laparoscopic surgery apports the benefits of MIS, such as: reduced bleeding, better vision, decreased length of hospital stay, and improved recovery from surgery. The finality of this study is to demonstrate the efficiency of laparoscopic cytoreduction in the eradication of tumoral implants in advanced stage ovarian cancer after NACT and

the similarity in rates of laparotomy complications by the surgical teams at the Instituto Nacional de Cancerología (INCan) and ABC Medical Center (ABCMC).

MATERIALS AND METHODS

Design

This is phase two of a prospective clinical trial. The purpose is to evaluate the efficiency and complications of optimal laparoscopic cytoreduction in patients with advanced ovarian cancer after receiving NACT; the investigators will be comparing the results with those of open cytoreduction surgery as reported in the literature: interval cytoreduction of 70 to 80% and a 7% complication rate.

The investigators included patients from the ABCMC and INCan, who were diagnosed with stage III-IV FIGO (16) classification for cancer of the ovary, fallopian tube and peritoneum. Had received 3 to 4 cycles of NACT, and were then evaluated by CT imaging or PET-CT. The investigators excluded patients who had partial response to chemotherapy with persistent ascites or pleural drainage, and those who met any criteria for unresectable tumors. The selection of patients for the study is presented in Figure 1.

Patients who received 3-4 cycles of NACT with carboplatin/paclitaxel were assessed with CT imaging or 18 FDG PET-CT 2-3 weeks after the last cycle of chemotherapy.

The patient was introduced to the operating room, the anesthesia technique used was at the discretion of the anesthesiology team. Using a V-care type uterine manipulator that was placed prior to surgery, a trocar was introduced at a 12mm supraumbilical port for direct vision or open technique (as directed by the surgeon). The abdominal cavity is inflated with 12 to 14 mmHg of CO2 gas at a flow of 3-6 L/min, 4 trocars were placed in 5mm ports in the lower quadrants and one was placed in a 5 or 12 mm supraumbilical port at the midline. If necessary, additional trocars were placed in the superior quadrants to ensure the comfort of the surgeon and obtain the greatest possible cytoreduction. (Fig 2)

The procedure started with the cytoreduction of highest complexity (determined at the time of initial inspection), after which, if necessary, the patient underwent a complete hysterectomy, bilateral salpingo-oophorectomy, omentectomy, or partial peritonectomy and excision of any peritoneal implants

present. The magnitude of the surgical procedures will be classified as:

1. Standard surgery: minimal hysterectomy, adnexectomy y omentectomy
2. Radical Surgery: included resection of the ovaries, of the rectouterine excavation (pouch of Douglas) and or the peritoneum between the bladder and uterus, hysterectomy, rectosigmoid colectomy, and complete omentectomy (Fig 3)
3. Supra-radical Surgery: included other procedures such as splenectomy, diaphragm resection, or other intestinal resection.

Any complications that arise will be documented at 30 days postop and measured according to Clavien Dindo score (17) (class III - V). The investigators did not include class 0 - II. Definition of Clavien Dindo scores as they relate to postoperative complications is presented in Table 2.

Evaluation of the Cytoreduction will be done via surgical findings, the video of the laparoscopic surgery, and through imaging techniques. A second CT or PET-CT was realized 4 weeks after the conclusion of the laparoscopic cytoreduction surgery in order to evaluate the level of tumor eradication realized by the surgery; and prior to complementary chemotherapy. This was conducted by the imaging and nuclear medicine departments.

Statistical Analysis

The investigators conducted a descriptive analysis to determine the clinical and demographic characteristics of the patients included in the study. Qualitative variables will be presented as frequencies and proportions. For quantitative variables, the investigators will analyze the distribution as well as evaluate the asymmetry and kurtosis with critical values of ±0.5 and ±1 respectively. The investigators will also employ the Kolmogorov Smirnov or Shapiro Wilk tests to determine normal distribution; considering the data to be normal if the significance of the test is greater than 0.05. Variables with normal distribution will be represented by the mean and standard distribution. Variables with non-normal distribution will be represented by the median and interquartile range. Survival curves will be calculated according to Kaplan-Meier global survival curves and compared using log rank tests.

IRB/IACUC approval & informed consent

The investigators conducted this study in compliance with the principles in the Declaration of Helsinki. This study's protocol was reviewed and approved by the Institutional Review Board of (022/014/GII) (CEI/022/22). Written informed consent was obtained from all the patients included in this study.

RESULTS

The investigators evaluated 40 patients diagnosed with advanced stage III or IV ovarian cancer who had received 3 to 4 cycles of NACT. Of these, only 18 met the inclusion criteria and subsequently underwent laparoscopic surgery. One patient was excluded because she had advanced stage endometrial cancer.

The median age of participants was 45.5 years (range: 38-72). The most common histological type was high-grade serous carcinoma in 14 (77.77%) patients. Among the participants, 6 (33.33%) were in stage IIIC, 9 (50%) were in stage IVB, and 3 (16.67%) in stage IVA (Table 3). 14 (77.78%) participants received 4 cycles of chemotherapy; 16 (88.89%) participants had a partial response to treatment and 1 (5.56%) had a complete response to treatment. (Table 4) All patients underwent laparoscopic surgery, of which 1 (5.56%) was standard surgery, 5 (27.78%) were radical surgery, 10 (55.56%) were supraradical surgery, and 2 (11.11%) were not cytoreducible. None of the procedures were converted to open surgery. Regarding the type of residual tumor after cytoreduction, 16 (88.89%) were classified as optimal R0 = no residual. (Table 5)

Regarding trans and postoperative complications, the median blood loss was 50 ml (range: 10-600 ml) and there were no readmissions during the first 30 postoperative days. (Table 6) At 30 days postoperatively, 13 (72.22%) patients had no complications, 4 (22.22%) had grade I complications, and 1 (5.56%) had a grade III complication: bleeding and vaginal opening, which required closure in the operating room with regional anesthesia.

DISCUSSION

EOC continues to be a world-wide health issue due to 75 – 80% of cases being diagnosed in advanced stages (III and IV) resulting in the deterioration of the patient´s functional state prior to reception of medical attention. A total of 40 patients were recruited at the INCan and ABCMC with the diagnosis of

stage III and IV EOC, who due to their functional and nutritional status received chemotherapy and were followed throughout their treatment. Of these, only 18 patients met the inclusion criteria, and were subsequently operated on by laparoscopy; 1 was excluded for having advanced endometrial cancer.

As reported in the literature, the investigators identified that the most frequent histological type in our study was high-grade serous carcinoma in 14 patients (77.77%), stage FIGO IIIC in 6 (33.33%) and IVB in 9 (50%) patients, followed by IVA in 3 (16.67%).

Though primary cytoreductive surgery remains the traditional treatment for EOC, the use of NCT has increased substantially for patients with either poor functional or nutritional status or for unresectable disease by imaging.

Laparoscopy offers lower postoperative complication rates, shorter postoperative hospital stay, and less blood loss (7). However, intraoperative tumor rupture has been reported to occur more frequently in patients undergoing laparoscopy compared to laparotomy in retrospective cohort studies (8). There is no randomized data comparing laparotomy and laparoscopy staging for ovarian cancer (9-10), and there probably never will be.

The use of laparoscopy for cytoreduction in advanced ovarian cancer is questionable. Nehzat et al. suggested that total or interval laparoscopic primary cytoreduction is technically feasible in a well-selected population of patients with suspected stage IIC or higher ovarian cancer (11). Other authors have also suggested that laparoscopy may benefit select patients with recurrent ovarian cancer without compromising survival, but laparotomy is recommended for patients with widespread peritoneal implants, multiple sites of recurrence, and/or extensive adhesions (18-19).

The studies have demonstrated a high rate of complete cytoreduction, good perioperative outcomes, and excellent disease-free survival in women who underwent interval cytoreduction for CMI, after a good response to NACT (12-15). In our series of cases, all patients underwent laparoscopic surgery, of which 1 (5.56%) was standard surgery, 5 (27.78%) were radical surgery, 10 (55.56%) were supraradical surgery and 2 (14, 3%) were not cytoreducible. None of the procedures were converted to open surgery. Regarding the type of residual tumor after cytoreduction, 16 (88.89%) were classified as optimal R0 =

no residual, and the 2 (11.11%) patients who could not be resected due to unresectable carcinomatosis were classified as R2 = with residual.

Gueli Alletti et al. performed cytoreduction by CMI in 30 women with a clinical response to NCT, achieving complete cytoreduction in 29 of them. At a mean follow-up of 10.5 months, all patients were alive. (12)

Corrado et al. found that interval cytoreduction by CMI was associated with lower percentages of intra- and postoperative complications (3.3% and 6.6%, respectively). In a completed study, 26 of 30 patients were alive without recurrence with a median follow-up of 15 months. In a controlled study, in which 10 women underwent interval cytoreduction by CMI and 11 women underwent laparotomy (13). In our study the median blood loss was 50 ml (range: 10-600 ml) and there were no readmissions during the first 30 postoperative days. At 30 postoperative days, 13 (72.22%) patients had no complications, 4 (22.22%) had grade I complications, and 1 patient had a grade III complication, which was bleeding and vaginal opening, which required closure in the operating room with regional anesthesia.

Favero et al., found a non-significant decrease in cancer-specific survival and a non-significant reduction in the chemotherapy-free interval in women undergoing CMI (14).

Melamed et al. performed a retrospective cohort using the National Cancer Database to evaluate the use and effectiveness of laparoscopic cytoreductive surgery in patients with advanced EOC who have received NCT. This study also suggested that the CMI approach may be reasonable and effective in well-selected patients. Importantly, there was a significant increase in the frequency of interval cytoreduction by CMI in the United States from 2010 to 2012 (11-16%, $P<0.001$) (15)

Therefore, the investigators consider that laparoscopic surgery in interval cytoreduction to be safe when performed by highly experienced surgeons; and in hospitals with high volume of ovarian cancer care and treatment, this procedure can be performed with high success rates and low complications.

The Laparoscopic Cytoreduction After Neoadjuvant Chemotherapy (LANCE) trial is an international, prospective, randomized, multicenter, non-inferiority Phase III trial that compares minimally invasive surgery to laparotomy in women with high-risk epithelial ovarian cancer. These women had advanced stage grades, had complete or partial surgery and response to three or four cycles of neoadjuvant

chemotherapy with normalization of CA-125. The first 100 participants were enrolled in a pilot test and Phase III was determined to be feasible and currently ongoing. (20)

Therefore, the results of this phase III trial will be of utmost importance to determine if minimally invasive surgery is not inferior to laparotomy.

CONCLUSIONS

The main objective of the study was met, optimal cytoreduction in 88.89% of the patients, without intraoperative complications and at 30 days, 4 patients (22.22%) had grade I complications and 1 patient presented a grade III complication: bleeding and vaginal opening, which required closure in the operating room with regional anesthesia. The median blood loss was 50 ml (range: 10-600 ml) and there were no readmissions during the first 30 postoperative days.

The selection of post-chemotherapy advanced ovarian cancer patients to perform cytoreduction by interval laparoscopy was the most important part to achieve it successfully, the objective in the effectiveness of the procedure was met.

The investigators consider up to this point that laparoscopic surgery in interval cytoreduction to be safe. When performed by experienced surgeons this procedure can be performed with high success rates and low complications.

A phase III study is needed to confirm the previously issued results

Limitations.

It was a study has selection bias of patients to be operated by interval laparoscopy. Although it does not reflect the generality of patients with advanced ovarian cancer, since it identifies those who best respond to neoadjuvant chemotherapy, they are the best candidates to receive laparoscopic surgery.

Strengths

Being a prospective study, this patient selection bias means that the investigators have the best responders to chemotherapy and a low tumor burden, which makes laparoscopic surgery feasible, therefore making it a strength of the study.

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Table 1. Review of Literature

Author	N	Cytoreduction	Follow-up	Complications	Survival
Gueli Alletti et al. (12)	N=30	Complete cytoreduction in 29 patients	10.5 months	Most patients were discharged one the second day postop (range 2-3). There were no early postop complications registered.	All survived at follow-up
Corrado et al. (13)	N=30	Complete debulking surgery with no residua disease	15 months	3.3% had intraoperative complications and 6.6% had postoperative complications	26 of 30 patients had recurrence free survival at follow-up
Favero et al. (14)	N=21	Complete resection of macroscopic and microscopic disease	24.2 months	No observed oncological differences between groups, no intraoperative complications were present in each group	Non-significant reduction in cancer specific survival during the chemotherapy free interval
Melamed at al. (15)	N=450	Suboptimal cytoreduction in 20.6% in patients who had a laparoscopic procedure compared to 22.6% in patients who had a laparotomy.	3 years	Shorter hospital stays in laparoscopy group (median 4 days, $p<0.001$), hospital readmission rate 5.3% versus 3.7% for laparotomy group.	No significant difference in overall survival. 90-day mortality at 2.8% for laparoscopy group compared to 2.9% for laparotomy

Table 2. Clavien Dindo Classification of postoperative complications

Grade	Definition
I	Any deviation from the normal postoperative course without need for pharmacological treatment (with the exception of antipyretics, antidiarrheics, and antiemetics) or radioscopic or surgical intervention.
II	Any complication that may require pharmacological treatment or that may requires blood transfusion or parenteral nutrition.
III	Any complication that requires endoscopic, radiologic, or surgical intervention. Without the need of general anesthesia (IIIA) and with the use of general anesthesia (IIIB).
IV	Any potentially fatal complication that requires management in the ICU. Dysfunction of a single organ (IVA) or that involves multiple organs (IVB).
V	Death

Table 3. Demographic and Epidemiological Characteristics

Characteristic	Total*
Age	45.5 (43 – 53)
BMI	25.85 (23.5 – 27.9)
Papillary Serous Carcinoma	3 (16.67%)
High Grade Serous Carcinoma	14 (77.77%)
Endometrioid Carcinoma	4 (22.22%)
FIGO Stage	
IIIC	6 (33.33%)
IVA	3 (16.67%)
IVB	9 (50%)
Number of Chemotherapy Cycles	
3 Cycles	4 (22.22%)
4 Cycles	14 (77.78%)
Response to Chemotherapy	
Partial	16 (88.89%)
Complete	1 (5.56%)
Not quantifiable	1 (5.56%)
CA-125 <200 after chemotherapy	16 (88.89%)

*Data expressed as number (%) for categorical variables or median (interquartile range) for continuous variables

BMI: body mass index, FIGO: International Federation of Gynecology and Obstetrics

Table 4. Descriptive analysis of patients included in the study

Patient	Age	BMI	FIGO Stage	Histological type	Chemotherapy cycles	Type of Chemotherapy	Response to Chemotherapy as defined by imaging
1	45	20.7	IVB	HGSC	4/4	CBP/TXL	Partial
2	42	25	IIIC	HGSC	4/4	CBP/TXL/BVZ	Partial
3	43	27.2	IVB	HGSC	4/4	CBP/TXL	Partial
4	43	35.6	IIIC	Poorly differentiated EC	3/3	CBP/TXL	Partial
5	44	25.4	IVA	HGSC	3/3	CBP/TXL/BVZ	Partial
6	46	23.5	IVB	HGSC	4/4	CBP/TXL	Partial
7	72	23.7	IVB	HGSC	4/4	CBP/TXL	Partial
8	50	27.9	IIIC	HGSC	3/3	CBP/TXL	Partial
9	38	21.4	IIIC	Well differentiated EC	4/4	CBP/TXL	Partial
10	42	22.2	IIIC	Well differentiated EC	4/4	CBP/TXL	Complete
11	53	25.2	IVA	HGSC	4/4	CBP/TXL	Partial
12	57	26.4	IIIC	HGSC	4/4	CBP/TXL	Partial
13	47	32.4	IVB	HGSC	4/4	CBP/TXL	Partial
14	45	22.6	IVB	HGSC	4/4	CBP/TXL	Partial
15	60	26.4	IVB	Poorly differentiated EC	4/4	CBP/TXL	Not quantifiable
16	45	32	IVA	HGSC	3/3	CBP/TXL	Partial
17	61	26.3	IVB	HGSC	4/4	CBP/TXL	Partial
18	52	29	IVB	HGSC	4/4	CBP/TXL	Partial

BMI: body mass index, FIGO: international Federation of Gynecology and Obstetrics, HGSC: High Grade Serous Carcinoma, EC: Endometrioid Carcinoma, CBP: Carboplatin, TXL: Taxol, BVZ: Bevacizumab

Table 5. Descriptive Characteristics of the Surgical Procedures

Characteristic	**Total***
Classification of Laparoscopic Surgeries	
Standard	1 (5.56%)
Radical	5 (27.78%)
Supra-radical	10 (55.56%)
Non-cytoreductable	2 (11.11%)
Conversion to open surgery	0 (0%)
Type of residual	
R0	16 (88.89%)
R2	2 (11.11%)
Complications (Clavien-Dindo Score)	
None	13 (72.22%)
I-II	4 (22.22%)
III-V	1 (5.56%)
Intraoperative hemorrhage (mL)	50 (50 – 100)
Hospital Readmission	1 (5.56%)

*Data expressed as number (%) for categorical variables or median (interquartile range) for continuous variables

R0: no residual, R2: with residual

Table 6. Descriptive analysis of Performed Surgeries

Patient	Type of Surgery	Residual Tumor	Reason for not completing cytoreduction	Hemmorhage (mL)	Type of complication	Complication Grade: Clavien Dindo
1	Radical	R0	N/A	150 mL	Pain at incision site	I
2	Radical	R0	N/A	50 mL	No	No
3	Not cytoreductable	R2	Fagotti score 10	20 mL	No	No
4	Radical	R0	N/A	50 mL	No	No
5	Radical	R0	N/A	100 mL	No	No
6	Radical	R0	N/A	20 mL	No	No
7	Not cytoreductable	R2	Fagotti score 12	10 mL	No	No
8	Supra-radical	R0	N/A	50 mL	Pain at drainage site	I
9	Standard	R0	N/A	150 mL	No	No
10	Supra-radical	R0	N/A	50 mL	No	No
11	Supra-radical	R0	N/A	100 mL	No	No
12	Supra-radical	R0	N/A	100 mL	No	No
13	Supra-radical	R0	N/A	50 mL	No	No
14	Supra-radical	R0	N/A	50 mL	3 cm vaginal dehiscence	III
15	Supra-radical	R0	N/A	600 mL	Haematuria	I
16	Supra-radical	R0	N/A	100 mL	No	No
17	Supra-radical	R0	N/A	50 mL	Vaginal dehiscence	I
18	Supra-radical	R0	N/A	50 mL	No	No

R0: no residual, R2: with residual, N/A: not applicable

Figure Legends

Fig. 1. Flowchart describing the selection of patients to be included in the study. Initially 40 patients identified and subjected to neoadjuvant chemotherapy. 29 patients excluded due to having no response to chemotherapy. 17 patients included in protocol and underwent laparoscopic cytoreduction. 1 patient excluded due to advanced endometrial cancer diagnosis.

Fig 2. Image of final phase of laparoscopic cytoreduction for patient with ovarian cancer whom had been treated with neoadjuvant chemotherapy (pelvis).

Fig 3. Image of resected tumors from ovary, uterus, and peritoneum from patient with ovarian cancer treated with neoadjuvant chemotherapy.