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Laparoscopic Cytoreduction of Locally Advanced Epithelial Ovarian Cancer Post Neoadjuvant Chemotherapy, A Feasibility Study

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Abstract:

Background:

Ovarian cancer is the most lethal gynecologic malignancy and is usually diagnosed after becomes locally advanced, Over the last few decades, the use of interval surgery after a few cycles of neoadjuvant chemotherapy in patients with irresectable disease (stage IIIC/IV) has been proposed to increase the rate of the optimal debulking and reduce the complications. Until the beginning of this century, ovarian cancer surgery was strictly conducted via an exploratory laparotomy. As the laparoscopic approach gained acceptance in gynecology and its utility expanded to ovarian cancer surgery as well. Initially this was limited to management of early-stage disease and assessment of resectability in advanced disease, but now expanded to cytoreduction of locally advanced ovarian cancer, we conducted a prospective cohort study to evaluate the feasibility and operative safety of laparoscopic cytoreduction in locally advanced epithelial ovarian cancer post neoadjuvant chemotherapy. **AIM OF THE WORK:** This work aims to evaluate the feasibility and operative safety of laparoscopic cytoreduction in locally advanced epithelial ovarian cancer post neoadjuvant chemotherapy. **Patients and Methods:** All patients diagnosed with locally advanced epithelial ovarian cancer who received Neoadjuvant chemotherapy and showed complete or partial clinical response, followed by laparoscopic cytoreduction in the National Cancer Institute (NCI), Cairo University (CU), during the period from august 2019 to august 2021. **Results:** During the study period, 23 patients met the inclusion criteria and were included in the study, after exclusion of 2 patients who underwent open cytoreduction, the 23 patients underwent complete laparoscopic cytoreduction, and with Conversion rate of 8 %. (2 patients underwent open cytoreduction). **Conclusion:** Our study suggests that laparoscopic cytoreduction for advanced ovarian cancer post neoadjuvant CTH is feasible and safe in term of perioperative outcomes.

Key Words: Laparoscopy, advanced ovarian cancer, neoadjuvant chemotherapy.

Introduction:

Ovarian cancer is the most lethal gynecologic malignancy and is usually diagnosed after the cancer has spread within the peritoneal cavity (**Cannistra SA. Cancer of the ovary, 2014**).

Although the conventional treatment of advanced ovarian cancer is based on associating surgery and chemotherapy, the residual of disease after surgery seems to be the most important factor affecting survival (**Carney et al., 2012**).

Over the last few decades, the use of surgery (interval surgery) after a few cycles of neoadjuvant chemotherapy in patients with irresectable disease (stage IIIc/IV) or in patients with poor general conditions has been proposed to increase the rate of the optimal debulking and reduce the number of complications (**Vergote et al., 2010**).

Complete surgery, whether performed as primary surgery or after NACT (neoadjuvant chemotherapy), without macroscopic residual tumor, was the aim of the surgical management of advanced epithelial ovarian cancer. Traditionally, extended vertical midline abdominal incision was the recommended approach, but with the advance of minimally invasive surgical techniques, surgeons are able to perform all procedures for comprehensive surgical staging using laparoscopic and robotic surgery (**Liu et al., 2009**).

While minimally invasive surgery has gained an important role in the comprehensive surgical staging of early-stage ovarian cancer, (**Ghezzi et al., 2012**), the use of laparoscopy for advanced forms is usually limited to the preoperative evaluation of resectability of the disease, in order to discriminate those patients in whom an extensive surgical effort may lead to optimal cytoreduction from those who may benefit more from neoadjuvant chemotherapy, followed by interval debulking and then completion of cytotoxic treatment (**Fagotti et al., 2013**). In recent years, laparoscopy has been further applied to as advanced epithelial ovarian cancer successful tool for secondary cytoreduction in case of limited recurrent disease (**Gallotta et al., 2014**). Although only retrospective series have been published on this type of approach, results appear promising and deserve further investigation. (**Fagotti et al., 2013**).

In the last decade, improvements in operators' skills, surgical technique, and minimally invasive instrumentation have allowed the accomplishment of highly complex procedures in gynecologic surgery such as laparoscopic pelvic exenteration (**Martínez et al., 2011**), (**Puntambekar et al., 2011**) and upper abdominal debulking (**Menderes et al., 2016**).

As a logical consequence, some authors have recently suggested a possible role of laparoscopic debulking surgery in secondary cytoreduction after neoadjuvant chemotherapy (**Corrado et al., 2015**). However, primary laparoscopic cytoreduction for AOC (advanced ovarian cancer) has been reported only in limited retrospective series with a low number of patients included and a short follow-up (**Nezhat et al., 2010**), (**Fanning J et al., 2011**). It is well known that open debulking is associated with an inevitably high rate of threatening intra- and post-operative complications and long-lasting hospital admissions. The expectable advantages of applying minimally invasive surgery to primary cytoreduction for advanced epithelial ovarian cancer include better quality of life, earlier initiation of adjuvant therapy, and lower overall morbidity. (**Tozzi et al., 2016**).

This prospective study will evaluate the feasibility, operative safety of laparoscopic cytoreduction in locally advanced epithelial ovarian cancer post neoadjuvant chemotherapy.

AIM OF THE WORK :

This is a prospective cohort study to evaluate the feasibility and operative safety of laparoscopic cytoreduction in locally advanced epithelial ovarian cancer post neoadjuvant chemotherapy

Patients and Methods:

This is a prospective cohort study including all patients diagnosed with locally advanced epithelial ovarian cancer who received Neoadjuvant chemotherapy and showed complete or partial clinical response, followed by laparoscopic cytoreduction in the National Cancer Institute (NCI), Cairo University (CU), during the period from august 2019 to august 2021.

Inclusion criteria:

- Locally advanced epithelial ovarian cancer.
- Received Neoadjuvant chemotherapy
- Complete or partial clinical response
- Normalization of CA125.

Exclusion criteria:

- Cardiopulmonary disease.
- Bleeding tendency and coagulopathy.
- Morbid obesity.
- Previous abdominal surgery.
- Performance status III, IV.

Data were collected from the following sources:

1. Archive and the outpatient clinics of surgical oncology department, NCI.
2. Archive of medical oncology department, NCI.
3. Archive of biostatistics department, NCI.
4. Archive of pathology department, NCI.

Patients' data included:

- Patient demographics, body mass index.
- Preoperative laboratory and radiological investigation.
- Neoadjuvant chemotherapy received.
- Clinical response after neoadjuvant chemotherapy.
- Operative procedures including time, the extent of resection, blood loss, operative and postoperative complication, the rate of convergence to open procedures, length of hospitalization, risk of readmission.
- Final pathological report

Sample size (number of participants included):

The aim of the present study is to evaluate the feasibility and operative safety of laparoscopic cytoreduction in locally advanced epithelial ovarian cancer post neoadjuvant chemotherapy. Based on previous study by (**Huamao Liang et al., 2017**), the conversion rate from laparoscopic technique to the open one is 3.1%. A total sample size of 18 cases will be needed to provide a two-sided 95% confidence interval for a single proportion using the large sample normal approximation and will extend 8% from the observed proportion for an expected proportion of 0.031. This sample will be increased to be 25 cases to compensate for losses. Sample size estimation was performed by Epi info statistical package .

Statistical methods

Data will be analyzed using IBM SPSS advanced statistics (Statistical Package f Sciences), version 24 (SPSS Inc., Chicago, IL). Numerical data will be described as m standard deviation or median, interquartile range or range, as appropriate. Chi-square exact) test will be used to examine the relation between qualitative variables, as appropriate.

P-value ≤ 0.05 will be considered significant and all tests were 2 tailed.

Results:

During the study period, 23 patients met the inclusion criteria and were included in the study, after exclusion of 2 cases, underwent open cytoreduction.

Patients' characteristics (23 patients):

Our included patients had median age of 57 year old, median BMI of 26, 19 patients had medical comorbidity (DM, HTN, IHD, HCV), diagnosed with stage III serous ovarian caner, with median CA-125 before CTH of 656(UI/ml), received 3 to 6 NACT cycles (platinum-taxane based), with reduction of CA-125 to median of 16(UI/ml) and 10 patients showed complete response.

Table (3): patient characteristics:

variables	Laparoscopic(n =23)
Age	57 year (48-79 year)
BMI	26 Kg/m ² (23-31 Kg/m ²)
Medical comorbidity	19(82.6%)
Tumor type(serous)	23(100%)
CA-125 before CTH	656 UI/ml (180-3264 UI/ml)
CA-125 after CTH	16 UI/ml (8-32 UI/ml)
NO. of NACT cycles	6 cycles (3-6 cycles)
CT before CTH(stage III)	23(100%)
CT after CTH (CR to CTH)	10(43.5%)

Operative outcome:

After laparoscopic assessment, 5 patient had extraovarian affection (pelvic peritoneal nodules), with median PCI of 6.

Eighteen patients underwent TAH, BSO, and omentectomy, 5 patients underwent TAH, BSO, omentectomy, and pelvic peritonectomy with 100% achieved complete cytoreduction.

One patient complicated with urinary bladder injury during pelvic peritonectomy, which primary repaired.

The median operative time was 4hours, the median estimated blood loss was 400 ml, and 8 patients received blood transfusion.

Two patients (not included in our study) underwent open cytoreduction, due to severe intraabdominal adhesions, with Conversion rate 8%.

Table (4): operative outcome:

variables	Laparoscopic(n =23)
lap (extraovarian affection)	5(21.7%)
lap(PCI)	6(0-6)
surgical procedure:	
TAH, BSO, omentectomy	18(78.3%)
TAH, BSO, omentectomy, peritonectomy	5(21.7%)
complete cytoreduction	23(100%)
Conversion	2(8%)
intraoperative complication	1(4.3%)

operative time	4 hrs. (3-6 hrs.)
estimated blood loss	400 ml (300-600 ml)
Intraoperative blood transfusion	8(34.8%)

Postoperative outcome:

Three patients had postoperative complication, 2 with prolonged ileus for 5 days, one with chest infection, which managed medically, the 3 patient were morbid obese.

The median duration of return of intestinal sound was 2 days, the median duration of hospital stay was 3days, without hospital readmission.

The pathology report showed marked pathological response in 9 cases, moderate in 10 cases, mild in 4 cases.

The median time for first CTH cycle after operation was 19 days.

Table (5): postoperative outcome:

variables	Laparoscopic(n =23)
postoperative complication	3(13%)
Return of intestinal sound	2days(2-5days)
Hospital stay	3days(3-7days)
Hospital readmission	0(0%)
CTH response(PATHOLOGY)	
Marked	9(39.1%)
Moderate	10(43.5%)
mild	4(17.4%)
Time for first CTH cycle after operation	19days(16-24days)

Discussion:

From the time Joseph V. Meigs, a gynecologic surgeon at Massachusetts General Hospital, described ovarian tumor debulking surgery in 1934, (**Meigs JV Tumors of the Female Pelvic Organs, 1934**) until the beginning of this century, ovarian cancer surgery was strictly conducted via an exploratory laparotomy. As the minimally invasive approach gained acceptance in gynecology, (**Melamed A et al., 2017**), (**Walker JL et al., 2009**) its utility expanded to ovarian cancer surgery as well. Initially this was limited to management of early-stage disease and assessment of resectability in advanced disease, but now the National Cancer Network Guidelines endorse the minimally invasive technique as an approach for interval debulking surgery in “select patients”. (**Armstrong DK et al., 2020**) While there is no clear guidance defining the ideal candidate for minimally invasive interval debulking surgery, approximately 1 in 4 women will undergo this procedure after neoadjuvant chemotherapy. (**Ramirez PT et al., 2018**).

The adoption of minimally invasive interval debulking surgery is based on limited observational studies. Gueli Alletti et al. (**Gueli Alletti S et al., 2016**) performed this procedure in 30 women with clinical response to neoadjuvant chemotherapy and achieved resection of all visible disease in 29 women. All patients were alive with a median follow up of 10.5 months. Similarly, in a retrospective study, Corrado et al. (**Corrado G et al., 2015**) found that interval minimally invasive cytoreduction was associated with low rates of intra- and postoperative complications, and at a median follow-up of 15 months, 26 of 30 patients were alive without recurrence. Recently, the INTERNATIONAL MISSION trial, a multi-center retrospective study of 127 women who underwent minimally invasive surgery after neoadjuvant chemotherapy for ovarian cancer, demonstrated a median progression-free survival of 23 months and a

5-year overall survival rate of 52%. (**Fagotti A et al., 2019**) Finally, Melamed et al. (**Melamed A et al., 2017**) utilized the National Cancer Database to compare 450 women who underwent minimally invasive cytoreduction with 2,621 women who underwent laparotomy and found no difference in overall survival or surgical outcomes between these groups, even after adjusting for numerous potential confounders.

While these findings are promising, results demonstrating impaired survival in patients undergoing minimally invasive radical hysterectomy for cervical cancer (**Ramirez PT et al., 2018**) should caution against the acceptance of minimally invasive interval debulking surgery in the absence of prospective randomized data. The LANCE trial will provide an assessment of the oncologic efficacy of this approach. By controlling for known and unknown confounders via randomization, this trial will produce unbiased comparative estimates of disease-free survival, as well as overall survival, intra- and post-operative complication rates, and post-surgical quality of life associated with each surgical modality.

Here we aimed to evaluate the feasibility and operative safety of laparoscopic cytoreduction in locally advanced epithelial ovarian cancer post neoadjuvant chemotherapy by conducting our prospective cohort study that included 23 patients who met the inclusion criteria after exclusion of 2 patients who underwent open cytoreduction, in the National Cancer Institute (NCI), Cairo University (CU), during the period from August 2019 to August 2021.

We compared the results of our prospective study with the results of other relevant studies in this field.

In our study, the median age of our patients was 57 years (range 48-79 years), the median body mass index of our patients was 26 kg/m² (range 23-31 kg/m²). Upon comparing our results, the demographic characteristics are quite similar to that reported in the study conducted by (**Fagotti A et al., 2019**).

In our study, all of our patients diagnosed with stage III serous ovarian cancer. Our patients received a median number of 6 NACT cycles (range 3-6 NACT cycles), with median serum CA-125 at the time of operation was 16 UI/ml (range 8-32 UI/ml) and complete clinical response occurred in 10 patients (43.5%). Upon comparing our results, our patients had single stage category, single pathology type, unlike studies like (**Corrado G et al., 2015**) and (**Fagotti A et al., 2019**), in which the patients diagnosed with stage III to IV serous, endometrioid, mucinous and clear cell ovarian cancer, the median number of NACT cycles is similar to that reported in the study conducted by (**Favero et al., 2015**), the median serum CA-125 at the time of operation was less than that reported in the study conducted by (**Morton et al., 2021**) which was 18.8 UI/ml (range 12-28 UI/ml), and our patients had more complete clinical response when compared to the study conducted by (**Gueli Alletti et al., 2016**) in which complete clinical response occurred in 6 patients (20%).

In our study, after laparoscopic assessment, 5 patients (21.7%) had extraovarian affection (pelvic peritoneal nodules), with median PCI of 6 (range 0-6). Upon comparing our results, our patients had less extraovarian affection and only in the form of pelvic peritoneal nodules when compared to study conducted by (**Fagotti A et al., 2019**) in which 67 patients (52.8%) had extraovarian affection (abdominal, pelvic peritoneal nodules, appendix and bowel nodules).

In our study 18 patients (78.3%) underwent TAH, BSO, and omentectomy, 5 patients (21.7%) underwent TAH, BSO, omentectomy, and pelvic peritonectomy with 100% achieved complete cytoreduction, with Conversion rate 8% due to severe intraabdominal adhesions. Upon comparing our results, apart of TAH, BSO, and

omentectomy, our patients underwent only pelvic peritonectomy, unlike study conducted by (Fagotti A et al., 2019) in which 127 patients (100%) underwent TAH, BSO, omentectomy, 56 patients (44.1%) underwent abdominal and pelvic peritonectomy, 8 patients (6.3%) underwent appendectomy and 3 patients (2.4%) underwent bowel resection, our complete cytoreduction rate was similar to that reported in the study conducted by (Corrado G et al., 2015) in which with 100% achieved complete cytoreduction our Conversion rate was less than that reported in the study conducted by (Melamed et al., 2017) in which Conversion rate was 16%.

In our study the median operative time was 4 hours (range 3-6 hrs.), the median estimated blood loss was 400 ml (300-600ml), 1 patient (4.3%) complicated with urinary bladder injury during pelvic peritonectomy, which primary repaired. Upon comparing our results, we had slight higher median operative time than that reported in the study conducted by (Fagotti A et al., 2019) in which the median operative time was 3.75 hours (range 1-10 hrs.), and less than that reported in the study conducted by (Morton et al., 2021) in which the median operative time was 5.4 hours, higher median estimated blood loss than that reported in the study conducted by (Fagotti A et al., 2019) in which the median estimated blood loss was 100 ml (70-1320ml), our operative complication rate was less and more milder than that reported in the study conducted by (Fagotti A et al., 2019) in which 7 patient (5.5 %) complicated with bowel, bladder and vascular injury.

In our study 3 patients (13%) had postoperative complication, 2 with prolonged ileus for 5 days, 1 with chest infection, which managed medically, the 3 patient were morbid obese, The median duration of return of intestinal sound was 2 days, the median duration of hospital stay was 3 days (3-7 days), without hospital readmission, The median time for first CTH cycle after operation was 19 days (range 16-24 days). upon comparing our results, we had more postoperative complication but more milder than that reported in the study conducted by (Fagotti A et al., 2019) in which 6 patients (4.7%) had postoperative complication, in the form of intestinal fistula and pleural effusion, the median duration of hospital stay was similar to that reported in the study conducted by (Morton et al., 2021) and the median time for first CTH cycle after operation was less than that reported in the studies conducted by (Gueli Allettiet et al., 2016) and (Fagotti A et al., 2019) in both studies was 20 days.

Based on our study and other current studies, we suggest that laparoscopic cytoreduction for advanced ovarian cancer post neoadjuvant CTH is feasible and safe in term of perioperative outcomes.

Conclusion:

Our study suggests that laparoscopic cytoreduction for advanced ovarian cancer post neoadjuvant CTH is feasible and safe in term of perioperative outcomes.

Conflict of interest statement:

The authors declare no competing interests.

Authors contributions:

Mohmed Abdelfattah Elzohairy, Ziad Samir Gad, Hala Aziz Shokrallah designed the research study.

Alaa Mohamed Mahfouz, Wael Abdelwahab, Amr Kamal, Mohamed mostafa performed the research.

Rasha Mahmoud Allam analyzed the data.

Alaa Mohamed Mahfouz wrote the manuscript.

All authors contributed to editorial changes in the manuscript.

All authors read and approved the final manuscript.

Ethical approval and consent to participate :

Approval of Institutional Review Board (IRB) at NCI was obtained.

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