

# Results of Primary Cytoreductive Surgery in Advanced-stage Epithelial Ovarian Cancer: A Single-center Experience

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**Abstract.** *Aim: To determine the impact of maximal cytoreductive surgery on overall survival in advanced epithelial ovarian cancer. Patients and Methods: We retrospectively reviewed medical data of patients submitted to primary cytoreductive surgery for advanced epithelial cancer in the Fundeni Clinical Hospital between 1 January 2002 and 1 April 2014. Results: A total of 338 patients were eligible for the study. Complete cytoreduction was achieved in 242 patients and was associated with a significantly improved survival ( $p < 0.001$ ), when compared to patients in whom incomplete debulking surgery was performed. Other prognostic factors associated with an improved survival were stage by the International Federation of Gynecology and Obstetrics and the preoperative biological status of the patient. Conclusion: A more extensive surgical approach is perfectly justified and associated with improved survival in patients with advanced-stage epithelial ovarian cancer. However, patient selection should be performed carefully because the general preoperative status can significantly impact survival.*

Ovarian cancer is one of the most aggressive gynaecological malignancies which still affects a significant number of women around the world; the estimated incidence worldwide is approximately 225,000 cases/year, while almost 140,000 women die annually from this disease (1). Unfortunately, nowadays, the majority of patients are still diagnosed with an advanced stage of the disease, this fact being intimately

correlated with a poor prognosis (2). Although some studies tried to demonstrate the effect of neoadjuvant chemotherapy in order to increase survival (3, 4), the most important benefit in terms of survival seems to be obtained only by performing a complete cytoreductive surgery, with no residual disease (5-8).

## Patients and Methods

We retrospectively reviewed data of patients with advanced epithelial ovarian cancer referred to the Fundeni Clinical Institute between 1 January 2002 and 1 April 2014. For the present study, we excluded all patients who were submitted to neoadjuvant chemotherapy, cases who were initially submitted to surgery for early-stage ovarian cancer and returned with peritoneal recurrence, and those who were diagnosed with advanced-stage disease and who had previously undergone laparotomy in other hospitals but for whom biopsies or incomplete initial cytoreduction were performed. Individual data were reviewed and the following data were collected: age, International Federation of Gynecology and Obstetrics (FIGO) stage, presence of ascites, cancer antigen (CA) 125 level, histological type, differentiation grade, location and size of the largest mass, surgical procedures performed and size of residual disease. Residual disease was classified as: none ( $< 5$  mm), microscopic residual disease ( $< 1$  cm), gross residual disease ( $> 1$  cm). Postoperative data such as hospitalization, postoperative morbidity and mortality according to the Clavien–Dindo scale were also reviewed (9). All patients were submitted to adjuvant chemotherapy.

All these data were collected and statistical analysis was performed using SigmaPlot 12 (<http://www.alfasoft.com/en>) and were considered statistically significant if the  $p$ -value was less than 0.05. The Kaplan–Meier method was used to create survival curves while Cox proportional hazard regression was performed to identify prognostic variables for overall survival by multivariate analyses.

## Results

A total of 338 patients met all inclusion criteria and were considered eligible for this study. At the moment of entering the study, the mean age was 57.9 years (range=18-83 years). The distribution according to FIGO classification revealed

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Table I. The main characteristics of patients in the study.

Characteristic		Value
Age, n	<50 years	75
	≥50 years	263
No. of tumoral ovaries, n	1	29
	2	299
FIGO stage, n	IIIC	300
	IV	38
CA 125, U/ml		
Mean (range)	1160 (47-8073)	
Ascites, n	Yes	233
	No	105

FIGO: International Federation of Gynecology and Obstetrics.

300 patients with stage IIIC and 38 cases with stage IV disease. The mean CA 125 level at the time of diagnosis was 1160 U/ml, while the mean tumor dimension was 6 cm (range=1-30 cm). Ascites was present in 233 cases. The main characteristics are shown in Table I.

Standard surgery was considered to be total hysterectomy with bilateral adnexectomy, omentectomy, pelvic and parietal peritonectomy. In all cases, complete cytoreduction was attempted; however, this was possible only in 242 cases. The most frequently associated resections were bowel resection (40.5%), diaphragmatic peritonectomy (20.7%), splenectomy (15%) and cholecystectomy (8%). The main intraoperative characteristics are shown in Table II.

There were seven resections undertaken for liver metastases. Three out of seven resections were performed for parenchymatous lesions, while four of them were performed for hepatic metastases with peritoneal origin. Hepatic resections consisted of minor hepatectomies in five cases and major hepatectomies (involving more than two segments) in two cases. Splenic resections were associated with standard surgery in 52 cases; 46 patients presented capsular invasion and peritoneal nodules, while parenchymatous lesions were reported in six cases.

During the early postoperative period, complications occurred in 91 cases (27%), while the early postoperative mortality (30-day mortality) was 5%. The complications classified according to the Clavien–Dindo scale are shown in Table III. It can be seen that complications of all grades for those with stage IV disease were more often seen; we consider that this can be explained by a more advanced stage of the disease which necessitated a more extensive surgical procedure on the one hand, while on the other hand, this can be explained by a poorer biological status for patients diagnosed with FIGO stage IV disease.

Table II. Intraoperative characteristics of the patients submitted to primary cytoreduction.

Intraoperative characteristic		No. of cases
Associated resection	Diaphragmatic peritoneum resection	70
	Diaphragmatic muscle resection	22
	Total colectomy	14
	Subtotal colectomy	2
	Right colectomy	19
	Left colectomy and rectosigmoidectomy	94
	Transverse colectomy	1
	Subtotal gastrectomy	6
	Segmental enterectomy	7
	Appendectomy	31
	Cholecystectomy	30
	Hepatectomy	7
	Splenectomy	52
	Distal pancreatectomy	1
	Urinary bladder resection	6
CHIP		78
Fulguration of the peritoneal nodules		80
Type of resection	R0	242
	R1	34
	R2	36
	Palliation	3
	Biopsy	23
Tumor histology	Serous	306
	Endometrioid	4
	Mucinous	20
	Other histological types	8
Differentiation grade	G1	51
	G2	134
	G3	152

CHIP: Intraperitoneal chemotherapy.

Table III. Postoperative complications classified according to the Clavien–Dindo scale.

Clavien–Dindo scale	Cases (%) Initial stage IIIC	Cases (%) Initial stage IV
I	7.6	18.0
II	8.0	13.0
III	2.0	3.3
IV	2.3	0
V	5.3	10.0

When estimating the impact of preoperative parameters on overall survival, the biological status of patients according to the American Society of Anaesthesiology (ASA) score and FIGO stage proved to have statistical significance: patients with an ASA score of 1-2 and FIGO stage IIIC disease

Table IV. Preoperative parameters-effect on overall survival.

Factor	Value	No. of patients (%)	Hazard ratio (95% CI)	p-Value	Median survival (months)
Age	<60 years	191 (56.5%)	1 (ref)	0.158	40
	≥60 years	147 (43.5%)	0.810 (0.605-1.085)		27
ASA	1-2	211 (62.4%)	1 (ref)	<0.001	48
	3-4	127 (37.6%)	0.469 (0.347-0.635)		21
Stage	IIIC	300 (88.7%)	1 (ref)	0.03	36
	IV	38 (11.3%)	0.768 (0.677-0.898)		16
No of affected ovaries 2	1	29 (8.5%)	1 (ref)	0.136	61
	2	299 (91.5%)	0.817 (0.467-1.429)		34
Ascites	Yes	233 (68.9%)	1 (ref)	0.778	35
	No	105 (31.1%)	1.185 (0.877-1.600)		38
Tumor histology	Serous	306 (90.5%)	1 (ref)	0.874	36
	Non-serous	32 (9.5%)	0.961 (0.588-1.571)		27
Grade of differentiation	G1/G2	185 (54.7%)	1 (ref)	0.458	37
	G3	153 (45.3%)	1.117 (0.834-1.495)		35
Location of the largest mass	Pelvis	285 (84.3%)	1 (ref)	0.561	36
	Upper	53 (15.7%)	0.875 (0.557-1.347)		33
	Abdomen				
Dimension of the largest mass	<10 cm	253 (74.8%)	1 (ref)	0.126	37
	≥10 cm	85 (25.2%)	1.313 (0.926-1.861)		27

ASA: American Society of Anaesthesiology; CI: confidence interval; ref: reference.

reported improved outcomes (48 months *versus* 21 months,  $p<0.001$ ; 36 months *versus* 16 months,  $p=0.031$ ). Other studied preoperative parameters are shown in Table IV.

Although not statistically significant, younger age was associated with an improved outcome, probably due to a better biological condition. The serous histological type, pelvic localization of the largest mass and a maximal tumor diameter were also associated with improved outcomes (36 *versus* 27 months, 36 *versus* 33 months and 37 *versus* 27 months, respectively).

Complete R0 resection was obtained in 242 cases, while incomplete resections were performed in 70 cases. In 26

Table V. Median survival (months) according to the type of resection performed.

Type of resection	No. of cases (%)	p-Value	Median survival (months)
R0	242 (78%)	<0.001	46
R1	34 (10%)	<0.001	19
R2	36 (10.6%)	0.808	9
Palliation/biopsy	26 (7.6%)	0.848	6

cases, surgery was limited to palliation or biopsy and the patients were referred to the Oncology Clinic for palliative chemotherapy. The reported median overall survival was of only 6 months. Five-year overall survival rate on the entire cohort was 20% (Table V).

Standard surgery was considered to be total hysterectomy with bilateral adnexectomy, omentectomy, pelvic and parietal peritonectomy and was performed in 145 cases.

In cases presenting disseminated but resectable lesions, a maximal cytoreductive effort was made with the aim of R0 resection. This was achieved by the combination of multiple visceral resections involving the upper abdominal viscera, bowel and diaphragmatic resections. In all these cases, an R0 resection was finally achieved (Table VI). The results showed that R0 resection including multivisceral resection was associated with a significantly improved outcome when compared to patients with residual disease ( $p=0.001$ ).

In order to evaluate whether associated resections also significantly increase the postoperative mortality, complications related to every type of surgery were studied. In cases in which upper abdominal resections were performed, the most frequently seen complications were pancreatic fistula (3.7%) and abdominal abscess (3.7%); re-operation was necessary in one case (1.8%), while death occurred in two cases. In cases in which bowel resection was undertaken, anastomotic fistula was seen in four out of the 104 cases (3.8%), while intra-abdominal abscess was encountered in another four cases (3.8%). Wound infection was seen in six cases (5.7%). Cardiopulmonary complications occurred in another five cases: one pulmonary thromboembolism (0.9%), one acute coronary syndrome (0.9%), while pneumonia occurred in three cases (2.7%). Death occurred in two patients and was related to an enteral fistula in one case and to a pelvic abscess with secondary generalised peritonitis and septic shock in the second case. In cases submitted to diaphragmatic resections, the most severe complications were bronchopneumonia associated with respiratory insufficiency and death in three cases and cardiac arrest and death in one case (Table VII).

These results sustain the idea that associated visceral resection provides a survival benefit without significantly

Table VI. The impact of associated resections on overall survival in multivariate analysis.

Associated resection		No. of cases with R0 resection	p-Value	Median survival (months)
Association of intestinal resection	Yes	102	0.911	41
	No	140		50
Upper abdominal resection	Yes	53	0.629	40
	No	189		50
Diaphragmatic surgery	Yes	64	0.446	41
	No	178		50

Table VII. Correlation between the type of associated resections and postoperative complications according to the Clavien–Dindo scale in patients submitted to R0 resection.

Clavien–Dindo scale	Standard surgery	Associated with		
		Upper abdominal resections	Bowel resections	Diaphragmatic surgery
I	5 (3.40%)	4 (7.50%)	6 (5.70%)	3 (4.60%)
II	7 (4.80%)	4 (7.50%)	6 (5.70%)	3 (4.60%)
III	2 (1.30%)	1 (1.80%)	2 (1.90%)	2 (3.10%)
IV	0	0	4 (3.80%)	1 (1.55%)
V	5 (3.40%)	2 (3.70%)	2 (1.90%)	4 (6.20%)

increasing the postoperative complications. As suggested by our results, the association of various types of resection leads to a higher rate of complete cytoreduction and raises the median overall survival to values comparable with cases who had pelvic-confined disease and benefited from standard surgery. Although patients with R0 resection and standard surgery had a median overall survival of 50 months while that for cases with associated visceral resection was 7-10 months shorter, this has no statistical significance for any of the groups described.

## Discussion

It has been more than eight decades since Meigs first described the principles of debulking surgery in ovarian cancer: “as much tumor as possible should be removed to enhance the effectiveness of postoperative radiation therapy” (10). Four decades later, in 1975, Griffiths *et al.* reported the first series of patients operated on according to these principles (11). Since then, numerous studies have been conducted on this subject in an attempt to establish the rules that should be applied in advanced ovarian cancer in order to improve outcome. Firstly, it was the dimension of the minimum residual disease which was modified: although historically, residual disease less than 2 cm was considered acceptable, in time, this dimension decreased to 1 cm and even 0.5 cm since better survival seemed to correlate inversely to residual tissue (5-8). Early studies from our Centre by Setlacec *et al.* (12) at the beginning of the 1980s tackled different aspects, some still under discussion, such as the extent of resection to the superior abdomen, surgical procedures required for proper staging of early ovarian cancer, extent of lymph node dissection, secondary cytoreductive surgery. A study from the same institution by Popescu *et al.* (13) on 59 patients concluded on the importance of the first intervention performed for ovarian

cancer; patients with sub-optimal debulking lived for a shorter period than patients in whom appropriate R0 cytoreduction was obtained by complex procedures, including gynaecological, visceral, urological and even thoracic surgery. A recent study from our Institution emphasized the survival benefit of intra-peritoneal chemotherapy associated with R0 resection *versus* R0 resection alone (14). In 1992 and 1994, Hoskins *et al.* conducted two studies in which they included 349 patients with advanced epithelial ovarian cancer submitted to debulking surgery with residual disease less than 1 cm and 294 patients with residual disease greater than 1 cm. The overall survival incrementally improved as the maximum residual disease decreased from 2 cm to no macroscopic residual disease (5-year overall survival was 60% for patients with no macroscopic residual disease, 35% for cases with residual disease less than 2 cm, and only 20% for patients with residual disease larger than 2 cm (7,15).

Bristow *et al.* reported a meta-analysis conducted on 6,885 cases with advanced ovarian cancer (FIGO stages III-IV) submitted to cytoreductive surgery and concluded that each 10% increase in the proportion of cases undergoing maximal debulking surgery was associated with a 5.5% increase in the median survival time of the cohort (16).

Once the efficacy of complete debulking surgery was widely demonstrated, a similar aggressive surgical approach was also proposed for cases with upper abdominal disseminations. Chi *et al.* conducted a study on two different groups: the first consisted of 168 patients submitted to primary cytoreductive surgery during a period in which debulking surgery did not include extensive upper abdominal resections, while in the second group, 210 patients who also benefited from upper abdomen resections were included. The authors defined upper abdominal resections as partial phrenectomy, diaphragmatic peritonectomy, splenectomy, distal pancreatectomy, chole-

cystectomy atypical hepatectomy or tumor resection from the *porta hepatis*. The 5-year progression-free survival rates for the second group *versus* the first were 31% *versus* 14%, respectively ( $p=0.01$ ), while the five-year overall survival rates were 47% *versus* 35%, respectively ( $p=0.03$ ). The same study concluded that the median overall survival for the second group was 54 months, which was significantly longer than that of 43 months for the first group ( $p=0.03$ ) (17).

Another study conducted on this theme at the Memorial Sloan Kettering Hospital involved patients with stage IIIC ovarian cancer organized into two groups: the first group presented disease in the upper abdominal cephalad to the great omentum, while the second group had no signs of disease in the upper abdomen. Although complete resection was performed in both groups, patients with no upper abdominal burden had a progression-free survival of 33 months, while for those with upper abdominal tumoral disseminations it was 22 months ( $p=0.003$ ) (18). We report on similar results, with a median overall survival of 40 months for cases submitted to upper abdominal resection compared to 50 months for cases with pelvic-confined disease, although all the patients had been submitted to R0 resection. We consider that this difference in terms of survival can be explained by a more aggressive biological behaviour or a longer period of evolution of the disease for cases with upper abdominal disease.

Association of diaphragmatic resection is another widely discussed topic when evaluating the possibility of achieving complete resection. Studies have shown that diaphragmatic surgery can be safely performed in patients with advanced ovarian cancer presenting diaphragmatic involvement and it can also provide a benefit in terms of survival (19, 20). In our case, diaphragmatic surgery as part of complete R0 cytoreduction was performed in 64 cases and consisted of diaphragmatic peritonectomy and partial phrenectomy; diaphragmatic surgery was associated with a median overall survival of 41 months, while in cases with no diaphragmatic involvement it was 50 months. The survival difference between the two groups was not statistically significant ( $p=0.446$ ) and we consider that it was associated with there being more advanced disease.

Another frequently performed visceral resection during primary cytoreduction was bowel resection. In our study, more than 40% of the patients were submitted to bowel resection in order to achieve complete R0 resection. Large studies have already demonstrated that bowel resection is one of the most frequently performed procedures in order to remove bulky tumoral masses (21, 22) and estimated that this kind of surgery is required in almost 50% of optimal debulking operations. Multiple studies have demonstrated that bowel resection can significantly increase the percentage of complete cytoreduction and is associated with similar survival rates when compared to patients submitted to R0 resection, but who did not require intestinal surgery (21-23).

Gillette-Cloven *et al.* demonstrated that association of bowel resection in order to obtain complete resection was associated with a median overall survival of 35 months compared to a median survival of 18 months for cases with no bowel resection but with residual disease (22). In their study of 48 cases diagnosed with FIGO stage III-IV epithelial cancer submitted to bowel resection as part of complete cytoreduction surgery, Estes *et al.* demonstrated that bowel resection can provide a benefit in survival outcomes by increasing the rate of R0 resection; bowel resection was performed with acceptable perioperative morbidity; anastomotic leak was encountered in 2% of cases, while postoperative mortality rate was 4% (23).

## Conclusion

Total debulking to achieve no residual tumoral tissue is the best chance of long-term survival for patients with advanced ovarian cancer. Maximal upper abdominal surgery including liver resection will bring survival for this category of patients with more advanced disease closer to that of patients with a lower extent of disease. The effort of complete cytoreduction also seems to be perfectly justified in cases presenting upper abdominal involvement including diaphragmatic disease or bowel involvement, while association of multiple resections at these levels seems to be safely performed, with acceptable postoperative rates of morbidity.

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