Research Article
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Assessment of the efficacy of radical surgery and intraperitoneal chemotherapy in ovarian cancer

Abstract

Background: This study aimed to evaluate the overall and disease-free survival in those patients with advanced-stage or recurrent ovarian cancer, and who have undergone cytoreductive surgery according to Sugarbaker technique with hyperthermic intraperitoneal chemotherapy.

Materials and methods: An observational study consisting of 37 patients with ovarian cancer was carried out. These patients underwent peritonectomy at the University Clinical Hospital of Santiago de Compostela between 2000 and 2008. The follow-up period ended in January 2011. 13 of these surgeries were primary cytoreductions, and the rest of them were secondary.

Results: Overall and disease-free survival rates were 56.8% and 43.2% respectively. The only factor which significantly improved the overall survival was the completeness of cytoreduction score (CC score) after surgery. The mortality rate, due to cancer, was 36% in cases in which macroscopic residual tumor did not exist (R0), while in the group of patient in which R0 was not achieved, the mortality reached 100%. Post-surgical morbidity rate was 32.4%.

Conclusion: Radical surgery with peritonectomy and hyperthermic intraperitoneal chemotherapy (HIPEC) in ovarian cancer cases is a surgical procedure with a low morbidity and mortality and which presents a high overall and disease-free survival.

Keywords: ovarian cancer, peritonectomy, survival

Volume 1 Issue 2 - 2018

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Received: November 23, 2017 | **Published:** March 20, 2018

Introduction

Nowadays, ovarian cancer is the fourth cause of death in women being the most frequent cause of death among gynecological malignancies in the developed countries. Peritoneal carcinomatosis is a common characteristic of tumor extension in patients with primary advanced or recurrent ovarian cancer.[1] Although at first it was believed that it constituted a final stage, in which the only therapeutic option was palliative, in 1982 Sugarbaker explained this peritoneal spread as a loco-regional affection of the disease, not as its terminal stage. Sugarbaker considers the peritoneum as the "last margin" which the tumor has. Because of it, he suggests a surgery whose objective is not only to perform a debulking operation but to achieve a complete tumor cytoreduction by a series of peritonectomy procedures developed by him, followed by the treatment of the microscopic residual disease through the direct application of chemotherapy with loco-regional intensification modulated by hyperthermia.

Radical oncological surgery described by Sugarbaker associated with intraperitoneal chemotherapy is presented as a new therapeutic option for advanced-stage ovarian cancer and for recurrent ovarian cancer regardless of its initial stage. Some studies have proved that the survival has significantly improved with this technique.[2,3] This study aimed to analyze the overall and disease-free survival in a cohort of patients with advanced ovarian cancer after peritonectomy by Sugarbaker technique.

Materials and methods

An observational study was carried out. It included the cohort of women with ovarian cancer who underwent the Sugarbaker technique at the University Clinical Hospital of Santiago de Compostela (CHUS) between 2000 and 2008. A primary peritonectomy (PP) was performed without previous oncological surgery, having received chemotherapy or not. Secondary peritonectomy (SP), that is, after a less aggressive gynecologic surgery, with or without later chemotherapy. Indications for secondary peritonectomy are two: scheduled surgery for previous residual disease or relapse (defined by imaging techniques (CAT) or CA-125 rise, which requires starting a chemotherapy treatment). In secondary peritonectomies, cytoreduction achieved after the primary surgery was analyzed, considering the optimal score when the residual tumor was smaller than 2 cm and suboptimal score when it was bigger than or equal to 2cm. According to the removed peritoneum, the type of peritonectomies was divided into subtotal (pelvic peritoneum exeresis), extended (if flanks +/- some upper abdominal quadrants are included too) and total (if it is extended to the whole upper abdominal peritoneum and diaphragmatic surfaces). Likewise, the CC score was determined: R0 when a macroscopic residual tumor did not exist, and no-R0 in the rest. After the hospital discharge, check-ups were performed every six months, including imaging techniques (CAT), tumor markers (CA-125) and the indicated tests according to the clinic and findings in each case. A relapse was considered in the following cases: when the CAT proved the presence of tumor mass; when CA-125 rise required the restart of chemotherapy treatment; and when obstructive clinic improved with chemotherapy or required a new surgery, proving the presence of tumor.he follow-up period of each patient ended on January 31st 2011, or in case of death. In our Hospital, an opening of cavity through xifo-pubic

medium laparotomy is performed. In primary peritonectomies, total hysterectomy with bilateral salpingoophorectomy and omontectomy is performed; in secondary peritonectomies such hysterectomy is completed if it has not been performed previously. The number of necessary viscera according to the tumor extension is removed and then the removal of the peritoneum is performed. Hyperthermic intraperitoneal chemotherapy is administered at the end of the visceral removal and before anastomoses, if necessary. Chemotherapeutic drugs are administered at temperatures ranging from 40 to 42ºC, extending them throughout the abdominal cavity in order to reach any area affected by the tumor. The average time with each chemotherapeutic drug is approximately one hour. Then, a peritoneal cavity washing is performed. The characteristics of the patients are expressed as the median (interquartile range) or in percentages. For categorical variables, cross-tabulation significance levels were based on Pearson's chi-square test with Yate's correction as appropriate, and Fisher's exact test. For continuous variables the non-parametric Mann-Whitney test was used. Kaplan-Meier was used for survival curves, and the log-rank test was used for differences between curves. Statistical significance was defined as $P < 0.05$. SPSS 15.0 statistical package was used for all the analysis (SPSS, Inc, Chicago, IL.)

Results

A total of 37 peritonectomy cases were studied, with a median age of 56 years. Table 1 shows the clinical and follow-up characteristics for both the global sample and cases with secondary and primary peritonectomy. Peritonectomy was total in 40.5% of cases (41.7% in SP and 38.5% in PP); in 32.4% of cases it was subtotal (25% in SP and 46.2% in PP) and in 27% of cases it was extended (33.3% in SP and 15.4% in PP). During surgery, the median of removed viscera were 2 (range from one to six), anastomoses was performed in 43.2%, that is 16 cases (45.8%, 11, in SP). Postoperative complications appeared in 12 cases, 32.4%. A higher number of complications were detected in patients with positive histological study (Table 2). Surgical wound infection and development of hemoperitoneum were the most frequent ones. Only one patient died of sepsis. Chemotherapy regimens and complications are detailed in Table 1. The median hospital stay was 17.5 (13.2, 27.5) days (17 (14, 30) days in SP and 18 (13.22) days in PP). As regards CC score, it was total (R0) in 33 cases, 89.2% (21 cases, 87.5%, in SP and 12 cases, 92.3%, in PP). The follow-up period presented a median of 61.1 (46.1, 86.1) months in global sample (63.8 (46.5, 88.2) months in SP and 53.1 (42.2, 61.9) in PP). In the global sample, a relapse was observed in 21 cases, 56.8%, and 16, 43.2%, cases died. In SP, a relapse was observed in 14, 58.3%, cases, and 10, 41.7%, cases died. In PP, a relapse was observed in 7, 53.8%, cases and 6, 46.2%, cases died. Before the study of overall and disease-free survival, different characteristics of the patients included in this study were compared between groups. The considered groups were: R0 versus no R0; primary indication versus secondary indication; and positive histological study versus negative. Likewise, and within the subgroup of women who underwent a secondary peritonectomy, the following groups were compared: optimal cytoreduction versus suboptimal; relapse versus scheduled; and histological study. Results are shown in Table 2. Relative to the survival study, the overall survival rate was 56.8%, with an average survival time of 69.8 months. In the case of disease-free survival, survival rate was 43.2%, with an average time without relapse after surgery of 52.6 months (Table 1) (Table 3) & (Figures 1) (Figure 2). However, in those women who had macroscopic residual tumor after surgery, average survival time decreased to 20.9 months, versus 77.6 of R0 group (Table 3, Figure 3; P-value: 0.001). This descent in the survival time might explain why only one woman in no-R0 group had a relapse. However, in overall and free-disease survival comparative analysis, according to other factors, such as the type of peritonectomy, primary versus secondary, or the pathology, no statistically significant differences (Table 3) were found in any case.

Table 1 Clinical and follow-up characteristics of peritonectomy cases studied for the global sample (n=37) and for primary and secondary peritonectomy (n = 13 and n= 24 respectively)

Characteristic	Global(37)	Primary(13)	Secondary(24)
Age *	56.0 (50.0, 51.0)	57 (53.5, 63.5)	55.5 (50.0, 60.0)
Comorbidities	18 (51.4%)	6 (46.2%)	12 (50%)
CA-125 pre *	27.0 (12.0, 45.0)	13.0 (9.2, 32.5)	28.0 (17.0, 48.0)
CA-125 post # *	25.0 (14.75, 55.5)	21.0 (12.0, 39.0)	26.0 (15.0, 96.0)
Stage			
I	2 (5.4%)	-	2 (8.3%)
II	6 (16.2%)	-	6 (25%)
III	26 (70.2%)	11 (84.6%)	15 (66.7%)
IV	2 (5.4%)	2 (15.4%)	-
Peritonectomy			
Primary	13 (35.1%)		
Secondary	24 (64.9%)		
Cytoreduction (secondary cases)			
Optimal			8 (33%)
Suboptimal			12 (50%)

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Table Continued

Characteristic	Global(37)	Primary(13)	Secondary(24)
Unknown			4 (17%)
Peritonectomy indications (secondary cases)			
Relapse			9 (37.5%)
Scheduled			15 (62.5%)
Type of peritonectomy			
Total	15 (40.5%)	5 (38.5%)	10 (41.7%)
Subtotal	12 (32.4%)	6 (46.2%)	6 (25.0%)
Extended	10 (27%)	2 (15.4%)	8 (33.3%)
Intraoperative chemotherapy	34 (94.5%)	12 (92%)	22 (91.7%)
Type: Paclitaxel	22 (57.9%)		
Cisplatin and Paclitaxel	4 (10.5%)		
Carboplatin and Paclitaxel	3 (7.9%)		
5-Fluouracile	2 (5.3%)		
Mitomycin C and Cisplatin	2 (5.3%)		
Unknown	2 (5.3%)		
Number of viscera *	2.0 (2.0, 3.0)	2 (2.0, 4.0)	2.0 (2.0, 3.0)
Type: Gallbladder	27 (72.9 %)		
Spleen	18 (48.6%)		
Appendix	10 (27.2%)		
Recto-sigma	10 (27.2%)		
Small intestine extract	8 (21.6%)		
Colon	7 (18.9%)		
Cecum	2 (5.4%)		
Liver segment	2 (5.4%)		
Kidney	1 (2.7%)		
Pancreatic extract	1 (2.7%)		
Anastomoses	16 (43.2%)	5 (38.5%)	11 (45.8%)
Complications	12 (32.4%)	1 (7.7%)	11 (45.8%)
Type: Surgical wound infection	3 (8.1%)		
Hemoperitoneum	3 (8.1%)		
Pleural effusion	2 (5.4%)		
Confusional syndrome	2 (5.4%)		
Lung edema	1 (2.7%)		
Respiratory failure	1 (2.7%)		
Pneumony	1 (2.7%)		
Kidney failure	1 (2.7%)		
Surgical wound seroma	1 (2.7%)		
Fever	1 (2.7%)		
Colostomy stenosis	1 (2.7%)		

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Table Continued

Characteristic	Global(37)	Primary(13)	Secondary(24)
Sepsis	1 (2.7%)		
Positive histological study	27 (72.9%)	8 (61.5%)	19 (79.2%)
Hospital stay (days) *	17.5 (13.25, 27.5)	18.0 (13.0, 22.0)	17.0 (14.0, 30.0)
CC score : R0	33 (89.2%)	12 (92.3%)	21 (87.5%)
Death	16 (43.2%)	6 (46.2%)	10 (41.7%)
Relapse	21 (56.8%)	7 (53.8%)	14 (58.3%)
Monitoring time (months) *	61.13 (46.1, 86.1)	53.1 (42.2, 61.9)	63.8 (46.5, 88.2)

#, First postoperative determination; *, median (interquartile range, IQ)

Table 2 Comparison of clinical and follow-up characteristics of peritonectomy cases studied in the global sample (n=37) and in secondary peritonectomy cases (n=24)

	Global (n = 37)								
	CC score			**Peritonectomy**			**Histological study**		
Characteristic	R0 n=33	No R0 n=4	p-valor	Primary n=13	Secondary n=24	p-valor	Negative n=10	Positive n = 27	p-valor
Death	12 (36%)	4 (100%)	0.028	6 (46%)	10 (42%)	0.932	2 (20%)	14 (52%)	0.173
Relapse	20 (61%)	1 (25%)	0.617	7 (54%)	14 (67%)	0.701	4 (40%)	17 (71%)	0.194
Comorbidities	15 (45%)	3 (75%)	0.34	6 (46%)	12 (50%)	0.903	6 (60%)	12 (44%)	0.638
Complications	10 (30%)	2 (50%)	0.582	1 (7.6%)	11 (46%)	0.027	0 (0%)	12 (44%)	0.015
Age (years)	55	60	0.25	57	55	0.499	55	57	0.431
	(50.00, 60.00)	(55.75, 64.25)		(55.00, 63.00)	(50.00, 60.00)		(51.5, 56.75)	(50.5, 62.50)	
Monitoring time (months) *	60.3	82.8	0.127	53.1	63.9	0.095	57.9	61.4	0.371
	(44.57, 80.70)	(60.78, 110.10)		(47.60, 60.33)	(50.27, 87.52)		(43.82, 67.53)	(48.90, 87.87)	
CA-125 pre*	26	46.5	0.171	13	28	0.077	13	31	0.004
	(12.00, 34.00)	(45.75, 47.25)		(9.75, 29.50)	(19.50, 48.00)		(10.50, 16.25)	(26.0, 48.0)	
CA-125 post *	24	219	0.045	21	26	0.395	15	30.5	0.056
	(14.50, 39.00)	(124.50, 940.00)		(14.00, 32.00)	(15.00, 84.00)		(11.00, 24.25)	(15.75, 85.00)	
	Secondary (n=24)								
	Cytoreduction			**Indication**			**Histological study**		
Characteristic	Optimal	Suboptimal	p-valor	Relapse	Scheduled	p-valor	Negative	Positive	p-valor
	n=8	n=12		n = 9	n=15		n = 5	n = 19	
Death	3 (38%)	6 (50%)	0.67	4 (44%)	6 (40%)	0.831	1 (20%)	9 (47%)	0.552
Relapse	6 (86%)	8 (73%)	1	6 (86%)	8 (57%)	0.337	2 (40%)	12 (75%)	0.365
Comorbidities	4 (50%)	6 (50%)	1	5 (56%)	7 (47%)	1	3 (60%)	9 (47%)	1

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Table Continued

	Global (n = 37)								
	CC score			**Peritonectomy**			**Histological study**		
Complications	1 (13%)	8 (67%)	0.028	3 (33%)	8 (53%)	0.597	0 (0%)	11 (58%)	0.041
Age (years)	55.5	54.5	0.69	56	51	0.654	51	57	0.165
	(49.75, 59.00)	(47.75, 59.25)		(55.00, 60.00)	(49.50, 60.50)		(50.00, 53.00)	(50.50, 61.00)	
Monitoring time (months) *	63.4	70.9	0.531	61.4	80.7	0.45	61.1	64.3	0.235
	(55.01, 69.61)	(44.45, 89.22)		(59.03, 64.30)	(48.37, 87.87)		(40.73, 68.83)	(55.60, 89.88)	
CA-125 pre *	24	28.5	0.253	28	28.5	0.375	17	38	0.012
	(16.00, 29.75)	(27.25, 51.75)		(26.50, 38.00)	(13.25, 55.50)		(14.00, 22.00)	(27.25, 51.75)	
CA-125 post *	26	31.5	0.85	28.5	25	0.726	22	28.5	0.508
	(19.00, 114.50)	(21.75, 57.00)		(23.00, 31.75)	(13.00, 96.00)		(15.00, 32.00)	(15.75, 90.00)	

*, Median (IQ range)

Table 3 Survival endpoints, in the global sample and by groups

	Months of overall survival		**Months of disease-free survival**	
	Mean (95% CI)	**p-value (log-rank)**	**Mean (95% CI)**	**p-value (log-rank)**
Global simple	69.787 (55.159, 84.415)	-	52.624 (37.204, 68.043)	-
CC score				-
R0	77.599 (63.180, 92.018)	0.001	53.653 (37.898, 69.407)	
No R0	20.892 (0, 51.832)		18.667*	
Histological study (global sample)				
Positive		0.102		0.11
Negative	61.926 (44.622, 79.230)		44.024 (26.691, 61.357)	
	73.614 (59.653, 87.576)		58.580 (37.756, 79.404)	
Peritonectomy				
Primary	50.535 (35.941, 65.130)	0.866	35.249 (20.847, 49.651)	0.741
Secondary	71.571 (53.453, 89.599)		50.111 (31.587, 68.634)	
Cytoreduction				
Optimal	59.923 (36.884, 82.962)	0.634	28.319 (8.109, 48.529)	0.444
Suboptimal	64.740 (39.960, 89.530)		44.907 (21.170, 68.644)	
Indication				
Relapse	63.333 (33.116, 93.550)	0.681	33.371 (8.308, 58.435)	0.21
Scheduled	75.393 (54.164, 96.622)		59.260 (35.941, 82.587)	

*, Only one patient had a relapse; CI, Confidence Interval

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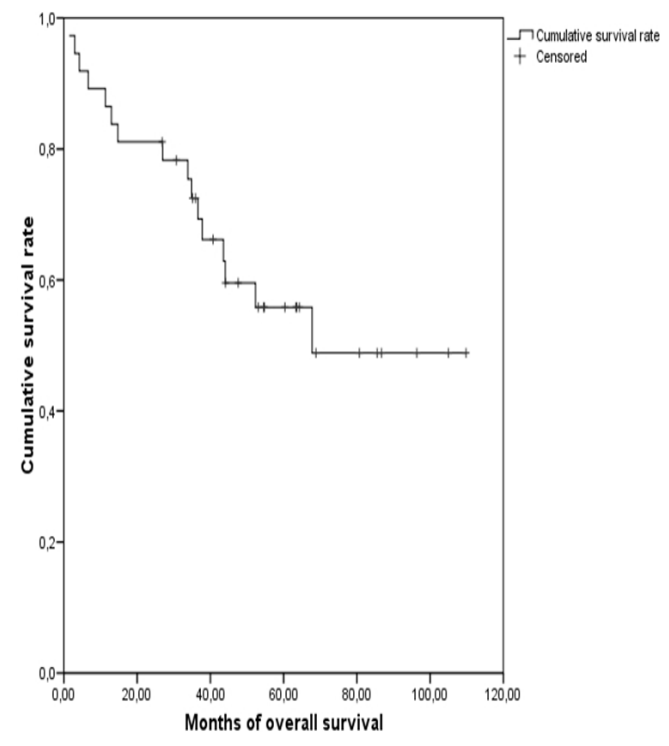

Figure 1 Overall survival in months.

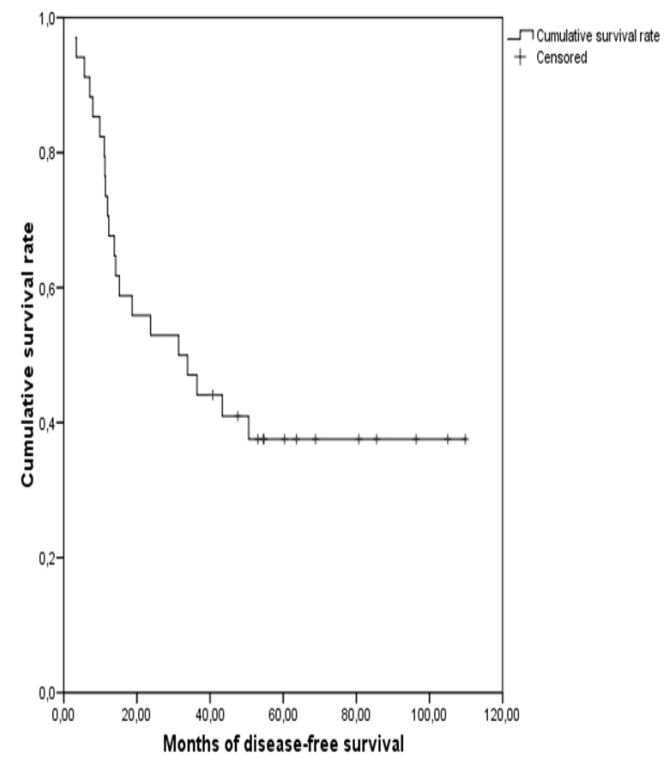

Figure 2 Disease-free survival in months.

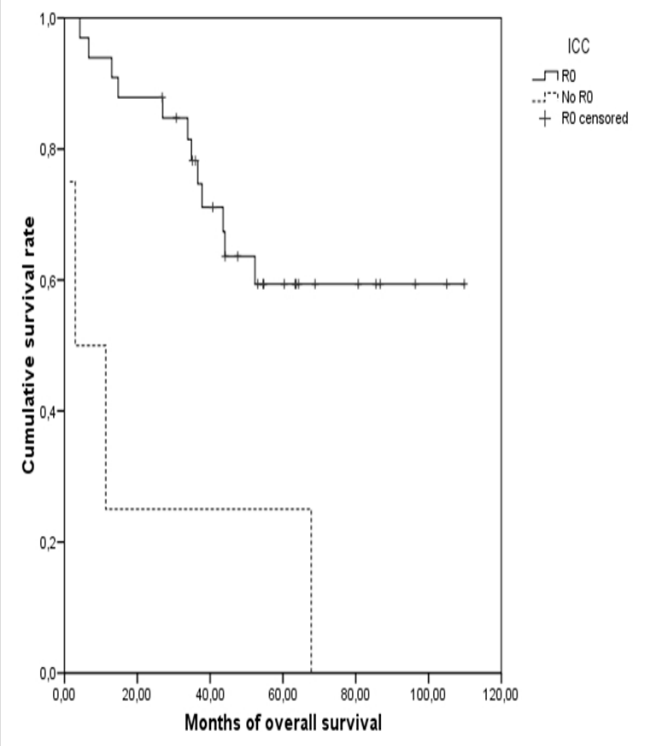

Figure 3 Overall survival in months by cytoreduction.

Discussion

Our results in women with primary advanced or recurrent ovarian cancer, with diffuse peritoneal carcinomatosis in whom Sugarbaker technique was performed, support this therapeutic alternative as a reasonable option. Overall and free-disease survival rates in these women are 56.8% and 43.2% respectively, data in keeping with other studies.[4] It is observed that when the surgery is more cytoreductive, better results are obtained in terms of survival rate, detecting significant statistical differences in favor of R0 group. This trend has also been shown in other studies.[5,6] Regarding advanced ovarian cancer, a lot of studies have been published that, add various and contradictory information. A study concludes that a second cytoreductive surgery, after three cycles of fosfamide, improved the prognosis.[7] A later study examined the same question but a different chemotherapy was used, based on paclitaxel plus cisplatin; in these cases, benefits in survival did not exist, choosing secondary cytoreductive surgery or not.[8] An alternative to conventional surgery followed by chemotherapy is neoadjuvant chemotherapy followed by surgery whose benefits might be a lower surgical morbidity and better chemotherapy tolerability.[9] In order to decide_the best option, to determine women to whom a complete cytoreduction can be achieved might be basic. However, nowadays, a reliable imaging technique does not exist. Peritonectomy described by Sugarbaker clarifies some aspects of this dilemma, since it is effective regardless of the moment in which it is performed. Differences between primary and secondary peritonectomies are not observed as regards overall and disease-free survival, in agreement with other studies[1] and corroborated by our findings. Its usefulness lies in the capacity to completely eliminate the tumor. However, we can find significant statistical differences in our study as regards

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postoperative complications: secondary peritonectomies presented 46% of complications compared to 7.6% in primary peritonectomies. We have to bear in mind this information because although primary or secondary peritonectomy indication does not affect survival, a higher postoperative morbidity is observed when a previous surgery exists. In our study, we can find four pseudomyxoma peritonei cases which show a 75% survival rate at the end of the study. All of this is according to data obtained by other authors, where the average survival of this tumor varies from 70 to 90% within five years.[10] This study has some limitations; the sample size is small, due to the fact that this technique is not standard practice in patients with ovarian cancer. We could not include the Peritoneal Cancer Index (PCI) nor the CC score (R0/R1/R2) since the size of macroscopic tumor is not reported in surgical descriptions, neither before nor after the completion of Sugarbaker technique. Results of this study support that Sugarbaker technique in advanced ovarian cancer treatment can be considered in cases selected by the high survival reached in studies up to now and the low morbidity and mortality which it entails, despite, in principle, it is an aggressive technique.

Acknowledgments

None.

Conflict of interest

The authors declare no Conflict of interest.

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