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Feasibility of Secondary debulking surgery for recurrent ovarian cancer

Ryoko OMURA, Fumitoshi TERAUCHI, Yasukazu SAGAWA, Keiichi ISAKA

Department of Obstetrics & Gynecology, Tokyo Medical University

Abstract

Chemotherapy is the main treatment for recurrent ovarian carcinoma ; however, if tumor resection is feasible, secondary debulking surgery (SDS) may improve the prognosis. Complete surgery, in particular, is associated with improved prognosis, although not all patients who undergo complete resection survive long-term. Our objective was to investigate retrospectively candidates for SDS by performing complete resection via aggressive surgery with no limitations on the number of tumors or organs removed.

Data on overall survival (OS), perioperative complications, and prognostic factors were retrospectively investigated in 44 recurrent ovarian carcinoma patients undergoing SDS at Tokyo Medical University between February 2005 and July 2014.

The median OS was 45 months. Total resection was performed in 36 (81.8%) patients. Median OS in the COMPLETE group was significantly longer than that in the NON-COMPLETE group (OPTIMAL and SUBOPTIMAL groups) ($p = 0.027$). Six patients required blood transfusion, but there were no other serious complications. Factors showing a significant effect on OS in the SDS group comprised disease-free interval (DFI) $\geq$ 6 months, complete resection, and $\leq$ 2 tumors resected. Prognostic factors in the COMPLETE group comprised DFI $\geq$ 6 months and $\leq$ 2 tumors resected.

Secondary debulking surgery is now a treatment option for recurrent ovarian carcinoma. With careful eligibility criteria, SDS may improve long-term survival.

Introduction

Although most cases of ovarian carcinoma respond to initial treatment, it recurs within 2 years in at least 50% of patients[1]. Recurrent ovarian carcinoma is difficult to treat. The main treatment is chemotherapy, but if tumor resection is feasible, then secondary debulking surgery (SDS) is reported to improve the prognosis[2-5]. Multiple studies have reported an association between the surgical completion rate and the prognosis[4-12]. Most previous studies have found that complete surgery, in particular, is associated with improved prognosis, although not all patients who have been able to undergo complete resection can be anticipated to survive long-term[8)9)13)14)].

There are no clear criteria to help determine which patients should undergo SDS with the aim of complete resection. Previous studies have identified several prognostic factors, including the time to recurrence, the completion rate of the initial surgery, resection site, number of tumors removed, and tumor diameter[2)3)6-10)15)]. However, restrictions were placed on the subjects of those studies in terms of disease-free interval (DFI), resection site, and number of tumors removed.

The objective of this study was to investigate candidates for SDS by performing aggressive surgery with the aim of complete resection, imposing no limitations on the number of tumors or organs to be removed.

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Key words : ovarian cancer, recurrence, secondary debulking surgery, complete surgery, prognosis

Corresponding author : Ryoko Omura, Department of Obstetrics & Gynecology, Tokyo Medical University, 6-7-1 Nishi-shinjuku, Shinjuku-ku, Tokyo 160-0023, Japan

TEL : +81-3-3342-6111 FAX : +81-3-3348-5918 E-mail : ryokooo@tokyo-med.ac.jp

Methods

Patient selection

The study subjects comprised 103 patients with recurrent epithelial ovarian carcinoma who had achieved clinical complete remission after initial treatment at Tokyo Medical University between February 2005 and July 2014. All had been diagnosed with Stage I–IV epithelial ovarian carcinoma and had undergone initial treatment at the same hospital between 1986 and 2013.

Initial treatment comprised total hysterectomy, bilateral adnexectomy, and omentectomy as the basic surgical procedure, with systematic retroperitoneal lymph node dissection. Patients with Stage II or higher cancer also underwent primary debulking surgery (PDS) to the maximum extent feasible, with the aim of performing complete surgery. All patients other than those with Stage IA or IB disease (according to 2014 FIGO staging system) and a pathological classification of grade 1 underwent at least 6 courses of postoperative chemotherapy with a platinum-based agent (conventional paclitaxel and carboplatin [TC] therapy ; docetaxel and carboplatin [DC] therapy ; or cisplatin and irinotecan [CPT-P] therapy).

A total of 44 patients underwent SDS ; 53 patients received chemotherapy ; and the remaining 6 chose to receive palliative care beginning immediately following recurrence. The patients who underwent CPT-P therapy were participants in the GCIC/JGOG3017 trial[16].

The site of recurrence was assessed by means of positron emission tomography/computed tomography.

Recurrence therapy was not initiated on the basis of elevated tumor markers alone.

Surgical procedures

All surgical procedures were performed with the aim of complete resection. These were classified as follows depending on the maximum diameter of residual tumors : complete debulking surgery (to remove all macroscopic recurrent tumors) ; optimal debulking surgery (when the maximum diameter of the residual tumors was less than 1cm ; and suboptimal debulking surgery (when diameter was 1 cm or more). The number is irrelevant.

The exclusion criteria for SDS were as follows : malignant pleuritis or peritonitis ; multiple lymph node metastasis ; mediastinal tumor or mediastinal lymph node metastasis ; elevated tumor markers alone with no identifiable recurrence on images ; or the patient choosing not to undergo surgery. All patients other than those listed above, for whom it was suggested preoperatively that complete resection would be difficult, were included in the study.

Ethical considerations

Informed consent was obtained from all patients prior to surgery or other treatment.

Chemotherapy

Chemotherapy was administered in all 44 patients after SDS. The duration of postoperative chemotherapy was determined by the outcome of SDS. Those patients for whom complete surgery was possible (COMPLETE group) and those who underwent optimal surgery (OPTIMAL group) were administered a total of 6 courses. However, those who underwent suboptimal surgery (SUBOPTIMAL group) were administered chemotherapy with the aim of radiographic complete elimination of the tumor. This goal was achieved in half of the patients in the SUBOPTIMAL group (tumor disappearance was achieved after a maximum of 11 courses). In the other half of this group, symptoms progressed rapidly during chemotherapy, and remission was not achieved.

Postoperative chemotherapy consisted of a regimen including a platinum-based agent (conventional TC therapy, DC therapy, or CPT-P therapy). The regimen was normally similar to that used for initial therapy, but was changed for patients who developed recurrence after a DFI of < 6 months and those who had experienced serious side effects during initial treatment.

Conventional TC therapy regimen consisted of paclitaxel (175 mg/m^2) and carboplatin (AUC 5–6). The DC therapy regimen consisted of docetaxel (75 mg/m^2) and carboplatin (AUC 5). The CPT-P therapy regimen comprised irinotecan (60 mg/m^2) on days 1, 8, and 15 and cisplatin on day 1 (60 mg/m^2).

The response to treatment was evaluated from imaging findings based on the Response Evaluation Criteria in Solid Tumors (RECIST ver. 1.1)[17].

Overall survival (OS), perioperative complications, and prognostic factors according to the methods described above were retrospectively investigated.

Statistical methods

Overall survival was measured from the first day of treatment for recurrence (the day on which SDS was performed). Survival curves were created using the Kaplan-Meier method. Factors influencing survival were investigated via a univariate analysis using the log-rank test. Prognostic factors were investigated via a multivariate analysis using a Cox proportional hazard model. In the multivariate analysis, we used factors with a p-value of < 0.05 in the univariate analysis. Statistical significance was defined as a p-value of < 0.05. The statistical calculations were performed with SPSS statistics version 22.0 IBM Corp.

Results

Patient characteristics

Median age at the time of SDS was 56 years. Performance status (PS) was 0–1 in all patients, and histological type was serous adenocarcinoma in 84.6% of cases, accounting for the majority of all cancers. The time to

Table 1 Attributes of secondary debulking surgery patients

	n = 44
Median age	56 years (36-87 years)
Median follow-up period	24.5 months (2-143 months)
FIGO stage I	3
II	8
III	28
IV	5
Histological type	
Serous adenocarcinoma	38
Endometrioid adenocarcinoma	3
Clear cell adenocarcinoma	2
Mucinous adenocarcinoma	1
Other	0
Time to recurrence	
Disease-free interval < 6 months	5
6-11 months	8
≥ 12 months	31
Primary debulking surgery	
Complete surgery	13
Optimal surgery	13
Suboptimal surgery	18

Median age at time of SDS was 56 years. Median follow-up after SDS was 24.5 months.
Histological type was serous adenocarcinoma in 84.6% of cases.
Surgical completion rate in 44 patients undergoing primary debulking surgery was complete surgery in 13 cases, optimal surgery in 13, and suboptimal surgery in 18.

recurrence was 12 months or more, indicating platinum sensitivity, in 64.1% of patients, but was less than 6 months in 12.8%. Median follow-up after SDS was 24.5 months. The PS was assessed according to the criteria of the Eastern Cooperative Oncology Group (Table 1).

Secondary debulking surgery

Secondary debulking surgery was performed in 44 cases. The mean volume of hemorrhage was 953 ± 376 mL, and 6 patients required blood transfusion. The volume of ascites was ≤ 200 mL in all cases. A single tumor was removed in 22 cases (50.0%), and multiple tumors in 22 cases (50.0%). The mean tumor diameter was 42 mm (range : 14-70 mm). The site of resection was most commonly the gastrointestinal tract (20 cases). The tumor location was in the sigmoid colon or rectum in 7 cases, with one requiring stoma creation. The next most common site was the diaphragm ; disseminated lesions that did not exhibit muscle-layer infiltration were removed by stripping of the diaphragm, whereas if muscle-layer infiltration was present, then full-thickness resection was performed. In cases of infiltration of the liver surface (capsule) by disseminated lesions on the diaphragm, the area of infiltration of the liver surface was resected at the same time.

Lymph nodes were the third-most common site of removal, with tumors removed not only from regional lymph nodes, but also from axillary nodes. Partial hepatectomy, splenectomy, and total cystectomy were also subsequently performed. Other procedures were also carried out to remove extraperitoneal lesions, including partial hepatectomy and the resection of a subcutaneous tumor in the navel region. These resections were carried out in collaboration with departments other than the gynecology department with the aim of performing complete surgery as far as possible.

Tumor resection was performed at a single site in 22 cases, at 2 sites in 8 cases, and at 3 sites in 4 cases, with 10 patients requiring tumor removal at 4 or more sites.

The surgical completion rate in these 44 patients was high, with complete surgery performed in 36 cases (81.8%), optimal surgery in 1 (2.3%), and suboptimal surgery in 7 (15.9%) (Table 2).

The main reason for the inability to perform complete surgery in the 8 cases of optimal or suboptimal surgery was the presence of minute malignant peritonitis that had not been identified on preoperative imaging. In those patients, widespread dissemination in the gastrointestinal tract and mesentery meant that complete resection would have required the removal of a large part of the small intestine and was therefore unfeasible. Other reasons included strong adhesions between blood vessels and tumors, as well as the presence of multiple hepatic metastases.

Perioperative complications

Blood transfusions were required in 6 patients (15.3%),

Table 2 Surgical operation in secondary debulking surgery patient

		n (%)
Mean volume of hemorrhage	953 ± 376 mL	44 (100)
Number of tumors resected	Single tumor	22 (50.0)
	Multiple tumors	22 (50.0)
Mean number of tumors resected	2.3±0.4	44 (100)
Mean resected tumor diameter	42±28 mm	44 (100)
Ascites volume	< 200 mL	44 (100)
Main site of recurrent tumor resection	Small intestine/colon	20 (45.5)
	Diaphragm	10 (22.7)
	Lymph nodes	7 (15.9)
	Liver	3 (6.8)
	Spleen	2 (4.5)
	Bladder	2 (4.5)
	Other	4 (9.1)
Surgical completion	Complete surgery	36 (81.8)
	Optimal surgery	1 (2.3)
	Suboptimal surgery	7 (15.9)
Perioperative complications	Wound dehiscence	1[a] (2.3)
	Blood transfusion	6 (13.6)
	Intestinal obstruction	1 (2.3)
	Vesicovaginal fistula	0 (0.00)
	Pelvic abscess	0 (0.00)
	Hepatic abscess	0 (0.00)
	Bladder/ureter damage	0 (0.00)
	Intestinal damage	0 (0.00)

[a]Conservative therapy only

Mean volume of hemorrhage was 953 ± 376 mL, and 6 patients required blood transfusion, but there were no other serious complications. Volume of ascites was ≤ 200 mL in all cases, which was small. Surgical completion rate in these 44 patients was high, with complete surgery performed in 36 cases, optimal surgery in 1, and suboptimal surgery in 7.

but there were no other serious complications (Table 2). No patient died within 1 month after SDS.

Survival among all 44 patients undergoing SDS

First, an analysis was performed of all the patients undergoing SDS. Median OS in the SDS group as a whole was 45 months (95% CI : 27.68-62.32). Five-year OS was 51.0% (Fig. 1).

Secondary debulking surgery improved long-term survival. Median OS after recurrence is reportedly approximately 24 months[18], but here this was greatly exceeded.

Figure 2 shows the post-recurrence survival rates for each SDS completion rate. In the COMPLETE group, median OS was not reached, but was significantly longer than that in the NON-COMPLETE group (OPTIMAL group and SUBOPTIMAL group, 13 months (95% CI : 5.42-20.58) ($p = 0.027$).

Factors influencing overall survival after SDS in univariate and multivariate analyses

Univariate and multivariate analyses were used to identify prognostic factors associated with OS. Univariate analysis identified 3 significant factors : DFI ≥ 6 months ; ≤ 2 tumor resection sites ; and complete resection.

As a result, the only one of these factors found to be significant in the multivariate analysis was DFI ≥ 6 months (platinum-sensitive) (Table 3).

Discussion

In the present study, no restrictions were placed on patient selection similar to those used in previous studies, such as the number of tumors or organs to be removed. This design was adopted in the hope that we could both confirm the prognostic factors previously reported and identify new ones, thus drawing closer to the appropriate indication criteria. For example, the National Comprehensive Cancer Network 2013 guidelines indicate a DFI of at least 6 months as a condition for performing SDS. Almost no previous study has included patients with a DFI of < 6 months. In the present study, however, we also included platinum-resistant patients with a DFI of < 6 months.

Other studies have also shown that surgery has achieved a good prognosis in patients with recurrence in organs such as the intestinal tract, liver, spleen, and dia-

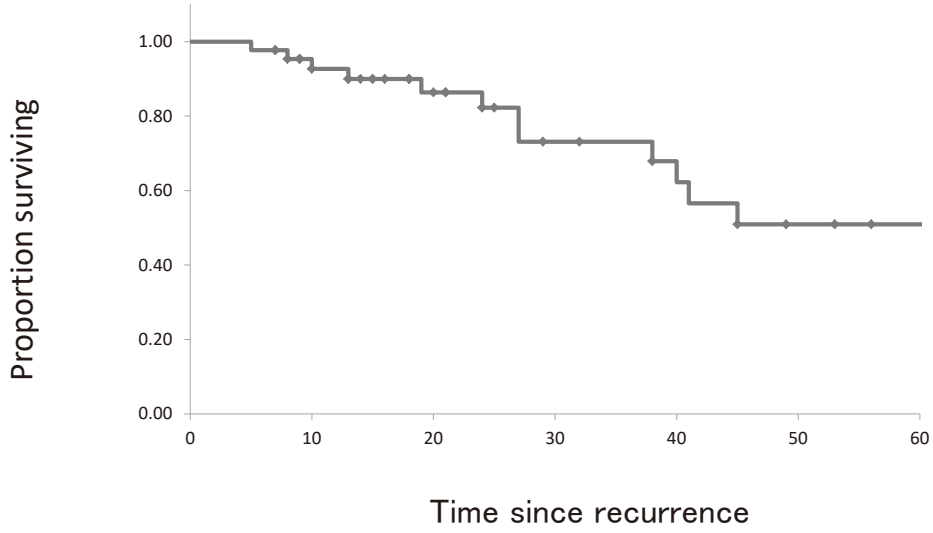

Fig. 1 Overall survival in 44 patients undergoing secondary debulking surgery.
Median OS was 45.0 months and 5-year OS was 51.0%.

Table 3 Analysis of prognostic factors for overall survival in patients undergoing secondary debulking surgery

		Univariate		Multivariate	
	n	HR (95% CI)	*p*-value	HR (95% CI)	*p*-value
Disease-free interval ≥ 6 months	39	1.00	0.002	1.00	0.030
< 6 months	5	17.03 (2.70-107.29)		8.55 (1.24-59.16)	
Number of tumors resected ≤ 2	26	1.00	0.004	1.00	0.120
> 2	18	6.87 (1.85-25.58)		3.05 (0.75-12.44)	
Secondary debulking surgery					
COMPLETE Group	36	1.00	0.038	1.00	0.578
NON-COMPLETE Group	8	3.42 (1.07-10.92)		1.46 (0.39-5.52)	
Primary debulking surgery				—	—
COMPLETE Group	13	1.00	0.690		
NON-COMPLETE Group	13	1.31 (0.35-4.86)			
Resected tumor diameter < 42 mm	22	1.00		—	
≧42 mm	22	2.17 (0.64-7.35)	0.211		—
FIGO stage I-II	11	1.00	0.628	—	—
III-IV	33	1.46 (0.32-6.68)			

Univariate and multivariate analyses were used to identify prognostic factors associated with OS after SDS. Six factors were analyzed : disease-free interval ≥ 6 months or < 6 months ; number of tumors resected ≤ 2 or > 2 ; surgical resection rate in SDS ; surgical resection rate in PDS ; resected tumor diameter < 42 mm or >42 mm ; and FIGO stage.
Univariate analysis identified 3 significant factors : DFI ≥ 6 months ; ≤ 2 tumor resection sites, and complete resection in SDS. Multivariate analysis involved 3 factors, of which only one, a DFI of ≥ 6 months (platinum-sensitive) was found to be significant.

phragm[13]. No limitations were placed on resected organs in the present study, however, and aggressive surgery was performed in patients with recurrence at sites not usually dealt with by gynecologists with the aim of carrying out complete surgery.

First, candidates for SDS comprised those with a DFI of ≥ 6 months (platinum-sensitive). The results of the multivariate analysis revealed that a DFI of ≥ 6 months was the only factor significantly influencing OS. Patients with a DFI of ≥ 6 months or longer have a good prognosis after SDS[4)6-8)11)15)21)]. Many previous studies have therefore excluded patients with a DFI of < 6 months. As described above, here, SDS was also performed in platinum-resistant patients. However, the results reconfirmed that platinum sensitivity and a DFI of at least 6 months is a strong factor influencing survival.

The goal of SDS in this study was complete debulking surgery, not optimal debulking surgery. Overall survival was significantly longer in the COMPLETE group

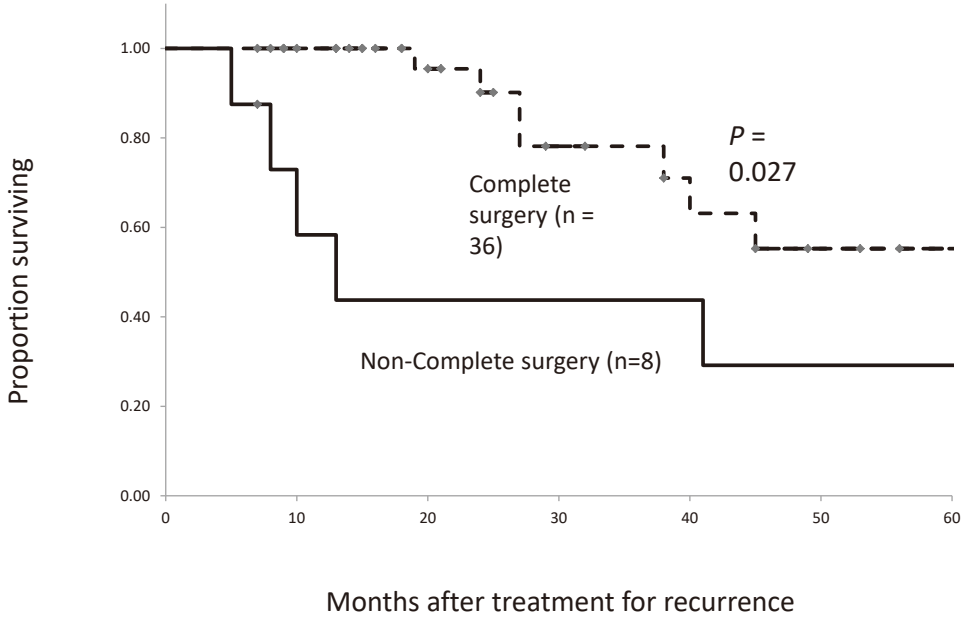

Fig. 2 Outcome as function of whether or not surgery was complete.
Median OS in COMPLETE group was significantly longer than in OTHERS group (OPTIMAL and SUBOPTIMAL groups) ($p = 0.027$).

than in the NON-COMPLETE group (Fig. 2). This was therefore also included as a factor significantly influencing OS in the univariate analysis (Table 3).

Typically, many studies have found that optimal debulking surgery is associated with improved prognosis[2-5]. However, many studies have also found that only complete tumor resection was associated with improved prognosis, as in this study[6-9)11)].

One meta-analysis of 2,109 patients, in particular, also found that only complete resection was associated with improved prognosis[12)], and that surgery should be performed with the goal of complete resection. Recent studies have found that complete surgery significantly improved prognosis after PDS compared with optimal surgery[19)20)]. Complete surgery may improve prognosis after SDS as well.

Finally, it is not the case that all patients who have been able to undergo complete resection can be anticipated to survive long-term.

It has been repeatedly reported that predictors for complete tumor removal are a recurrence in stageI/IIpatients, complete debulking surgery in PDS, a PS of 0-1, 500 ml or less of ascites in SDS, a single recurrent tumor, and recurrent tumor size[2)6-10)].

However, it remains unclear as to which combination of these factors makes it possible to predict accurately complete tumor resection. Although the above factors were also analyzed in the present study, none was identified as an independent prognostic factor.

A high recurrence rate is characteristic of advanced ovarian carcinoma. A chemotherapy regimen that is effective in the majority of patients with recurrent ovarian carcinoma has yet to be developed. If chemotherapy is ineffective, the regimen is repeatedly changed, but this has its limitations, and when chemotherapy alone is used, the options become restricted. In this study, we found that with careful patient selection, SDS may improve long-term survival.

Here, aggressive surgery was performed with the aim of complete resection. As a result, good long-term survival was obtained. These results suggest that complete surgery in patients with a DFI of ≥ 6 months and ≤ 2 tumors resected may lead to further improvements in prognosis.

However, this study had a number of limitations, including the small sample size and its retrospective design. This meant that we were unable to investigate prognostic factors in the COMPLETE group.

Further multicenter studies on the effects of SDS on prognosis are planned.

著者の COI 開示：本論文発表内容に関して特に申告なし

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再発卵巣癌に対する SDS (secondary debulking surgery) の feasibility に関する検討

大村涼子　寺内文敏　佐川泰一
井坂惠一

東京医科大学産科婦人科学分野

【要旨】 再発卵巣癌は化学療法が主たる治療法であるが、腫瘍摘出が可能な症例では secondary debulking surgery（SDS）が予後を改善する可能性があり、選択肢の一つとなってきている。過去の報告の中で、手術完遂度その中でも特に complete surgery が予後と相関するという報告は多いが、完全摘出可能だった症例が全て長期生存を望めるわけではない。

本研究の目的は、再発卵巣癌に対し、摘出個数や摘出臓器などを限定せず完全摘出を目指し積極的に手術を行うことで、SDS の適応について後方視的に検討することである。

2005 年 2 月～ 2014 年 7 月に当院で再発卵巣癌 44 症例に SDS を施行し、SDS 症例全体の再発後 Overall Survival（OS）、周術期合併症そして予後因子について後方視的検討を行った。

SDS 症例全体の OS 中央値は 45 ヶ月だった。44 症例のうち 36 症例（81.8%）は完全摘出できた。COMPLETE 群の OS は、NON-COMPLETE 群（OPTIMAL 群と SUBOPTIMAL 群）に比べ優位に延長した（p 値 =0.027）。

合併症は、6 症例に輸血を行ったが、その他重篤な合併症はなかった。再発後 OS に影響を及ぼす予後因子解析で有意差が認められたのは、DFI 6 か月以上、完全摘出、摘出個数 2 個以下だった。

DFI 6 か月以上、摘出個数 2 個以下を満たす症例に compelte surgery をすれば、さらに予後改善が期待できる可能性が示唆された。SDS は治療の一つであり、慎重に症例を選択すれば長期生存をもたらす可能性がある。

〈キーワード〉卵巣癌、再発、secondary debulking surgery（再発卵巣癌に対する腫瘍減量術）、完全摘出、予後因子