The Role of Secondary Cytoreductive Surgery in Primary Platinum-sensitive Recurrent HGSOC Patients With Different BRCA1/2 Mutation Status: a Retrospective Study

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Research

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Abstract

**Background:** The value of secondary cytoreductive surgery (SCS) for platinum-sensitive recurrent high grade serous ovarian cancer (HGSOC) patients and the effects of BRCA1/2 mutation status on the value of surgery are inconclusive.

**Methods:** A retrospective analysis was conducted in HGSOC patients with primary platinum-sensitive recurrence who were admitted to the Department of Obstetrics and Gynecology, Qilu Hospital of Shandong University and Shanghai General Hospital from January 2015 to August 2019. The DESKTOP Trial Score was used to assess whether patients could be included in the study. Relevant medical records were collected, including age at diagnosed, FIGO stage, germline BRCA1/2 mutations status, platinum-free interphase (PFI), recurrence characteristics, progression-free survival (PFS) and overall survival (OS).

**Results:** A total of 195 HGSOC patients were included in the study, including 80 (41.0%) patients with BRCA1/2 germline mutation (BRCAmut) and 115 (59.0%) patients with germline BRCA1/2 wild-type (BRCAwt). SCS improved FPS in patients undergoing secondary cytoreductive surgery, regardless of BRCA1/2 mutation status (BRCAmut, median PFS, 16.3 vs 12.9 months, \( p = 0.003 \); BRCAwt, median PFS, 15.3 vs 11.0 months, \( p = 0.001 \)). There was a significant survival benefit in BRCAwt patients undergoing SCS (median OS, 70.6 vs 52.5 months, \( p = 0.021 \)), however, compared with chemotherapy alone, SCS in BRCAmut patients did not improve overall survival (median OS, 77.5 vs 76.8 months, \( p = 0.827 \)).

**Conclusions:** SCS is recommended for platinum-sensitive recurrent HGSOC patients with BRCAwt. BRCA1/2 genetic test for all HGSOC patients is necessary to specify appropriate post-recurrence treatment strategies.

**Background**

Ovarian cancer is the most lethal gynecological malignancy and the standard initial treatment is maximal tumor cytoreductive surgery followed by platinum-based chemotherapy\(^{(1)}\). After achieving partial or complete response, approximately 70% of patients will relapse within three years\(^{(2)}\). For relapsed patients with platinum-free interval (PFI) more than 6 months, platinum-based chemotherapy can be reused according to the NCCN guidelines, however, whether SCS will benefit, there has been no definitive conclusion. According to previous research, for patients within single solid tumor, the recurrence time more than 12 months, no distant metastasis, no ascites, etc., SCS could be considered to perform, which prolonged the patient's PFS or OS, especially when the complete SCS was achieved\(^{(3–7)}\). Two randomized controlled studies on SCS have been published, but the results are inconsistent. The GOG-0213 study did not show a survival benefit from surgery, but the study was controversial because it did not provide criteria for the choice of surgery or the treatment of bevacizumab\(^{(8)}\). SOC-1 adopted the International Model (IMODEL) score to predict the feasibility of complete resection, and combined with PET-CT imaging to select suitable patients who might benefit from complete resection, resulting in a significant survival benefit\(^{(9)}\). In addition, another study, DESKTOP-III (ClinicalTrials.gov, NCT01166737),
which is being conducted, also suggested the benefit of complete resection of lesions, but the end point of the study has not been reached yet.

Patients with BRCA1/2 mutations usually have longer PFI, and platinum-based chemotherapy after relapse is more effective than patients without BRCA1/2 mutations (10, 11). Whether BRCAmut patients will benefit from SCS is controversial. Although the SOC1 study confirmed the benefit of SCS, less than 5% of patients underwent BRCA1/2 genetic test (9). Marchetti C et al reported that BRCAmut patients did not benefit from SCS, whereas BRCAwt patients received SCS achieved better prognosis (12). However, Gallotta V et al proposed opponent opinion, their study found that resection of the metastases in BRCAmut recurrent ovarian cancer patients with hepatic metastases significantly prolonged 3-year and 5-year survival rates (13). Current conclusions about the correlation between BRCA1/2 mutations and SCS are still confusing due to limited research and sample size, therefore, we conducted this retrospective analysis to investigate the effect of BRCA1/2 mutation status on SCS.

Methods

Patients and clinical data

The medical records of HGSOC patients with primary platinum-sensitive recurrence (PFI ≥ 6 months) admitted to the Department of Obstetrics and Gynecology, Qilu Hospital of Shandong University and Shanghai General Hospital from January 2015 to August 2019 were retrospectively analyzed. All patients received cytoreductive surgery at the first-line treatment and received carboplatin/cisplatin-based therapy without specific requirements for the types and doses. All patients had a complete clinical response after at least four cycles of chemotherapy, as assessed by a normal serum cancer antigen 125 (CA-125) value, and negative imaging examinations if obtained.

Patients were followed up regularly after the first-line treatment. The first recurrence was judged by CT, MRI or PET-CT, and there were target lesions that met the RECIST evaluation criteria (14). Patients with biochemical recurrence were not eligible. The second-line treatment was a platinum-containing regimen without any maintenance treatment, and there were no fixed requirements for the types and doses of platinum. The determination of response and PFS were in line with the RECSIT criteria, if the data for the RECIST criteria were not complete, CA-125 was used as an alternative, only if the pretreatment level was at least twice the upper limit of normal (14).

The patient's medical history information was collected including age, FIGO stage, secondary cytoreductive surgery, PFI, number and size of recurrent lesions, ascites, CA-125 level, history of poly (adenosine diphosphate–ribose) polymerase (PARP) inhibitors, PFS and OS. All patients’ informed consents were obtained.

DESKTOP Trial Score
The AGO DESKTOP OVAR trial(4) conformed that variables associated with complete resection were performance status (Eastern Cooperative Oncology Group [ECOG] 0), no macroscopic residual tumor during the first surgery, and ascites less than 500 ml. Positive score predicts resectability of SCS. Patients eligible for this study met the above scoring criteria.

Germline BRCA testing

The BRCA1/2 genetic testing panels covered the entire coding sequences of BRCA1 and BRCA2 including 10–50 bases of adjacent intronic sequence of each exon were used for detection. Sequencing was performed on next generation sequence (NGS) platform according to Illumina's protocol. Sanger DNA sequencing using the specific gene primers was used to confirm all reported variants. Multiplex ligation-dependent probe amplification (MLPA) was used to detect BRCA 1/2 large fragment rearrangement. The variants of mutations were classified according to the 5-class classification standard(15).

Statistical methods

Student's t-test was used to compare the differences in continuous variables. Chi-square test was performed to analyze the differences of clinical characteristics. PFS and OS analysis were performed by Kaplan-Meier. Multivariate proportional odds models were used to identify variables associated with survival outcome of SCS group, and hazard ratio (HR) with 95% confidence interval (CI) was calculated. All the statistical analyses were performed by SPSS version 23.0. Significance levels were *p < 0.05; **p < 0.01.

Results

Patients’ Characteristics

We identified 195 HGSOC patients with primary platinum-sensitive recurrence who met the eligibility criteria. Of these patients, 80 (41.0%) were BRCA1/2 germline mutation carriers (BRCAmut), and 115 (59.0%) were wild-type (BRCAwt). Patient’s characteristics and disease pattern of recurrence were summarized in Table 1 and Table 2. Median age at diagnosis of BRCAmut patients was 51 years (range 34–69), significantly lower than BRCAwt patients (median 54 years, range 26–77; \( p = 0.026 \)). Among BRCAmut patients, the proportion of patients with PFI > 12 months was 65.0%, slightly higher than that of BRCAwt patients (53.0%, \( p = 0.096 \)). Notably, 45 (56.3%) of BRCAmut patients had a history of PARP inhibitors, including rescue and maintenance therapy, compared with 28 (24.3%) of BRCAwt patients (\( p < 0.001 \)). In terms of other clinical characteristics, patients in BRCAmut and BRCAwt groups were comparable. There was no statistical difference in age, FIGO stage, PFI, ascites at recurrence, No. of recurrence sites, maximum size of target lesions, CA-125 level, history of PARP inhibitors between SCS and chemotherapy group in both BRCAmut and BRCAwt patients.

Surgical Findings
In BRCAmut and BRCAwt groups, 31 (38.8%) patients and 38 (33.0%) patients received SCS, respectively. The surgical procedures of SCS were shown in table 3. In BRCAmut patients, the top three surgical procedures were peritoneal nodes resection (18, 31.0%), retained omental tissue resection (13, 22.4%) and lymph nodes resection (9, 15.5%). In BRCAwt patients, the top three surgical procedures were peritoneal nodes resection (20, 32.8%), bowel resection (13, 21.3%) and retained omental tissue resection (9, 14.8%).

Regarding the choice of surgical timing, among BRCAmut patients, 25 (80.6%) patients underwent initial reduction surgery followed by postoperative adjuvant chemotherapy, and 27 (71.1%) patients adopted the above regimen among BRCAwt patients. In BRCAmut and BRCAwt patients, the rate of achieving complete resection was 77.4% (24/31) and 68.4% (26/38), respectively, with no significant statistical difference. Two reasons for patients’ failure to achieve complete resection were as follows: the surgeon’s decision to terminate the operation due to the difficulty of surgery and the patient’s rejection of the enterostomy, and no statistical comparison was performed between the two groups due to the small sample size.

### Survival data

After a median follow-up of 50.4 months, 38 (47.5%) BRCAmut patients were alive, compared with 48 (41.7%) patients in the BRCAwt group (p = 0.43). At Kaplan–Meier analysis, SCS improved FPS in patients undergoing secondary cytoreductive surgery (Fig. 1, BRCAmut, median PFS, 16.3 vs 12.9 months, p = 0.003; BRCAwt, median PFS, 15.3 vs 11.0 months, p = 0.001). There was a significant survival benefit in BRCAwt patients receiving SCS (Fig. 2B, median OS, 70.6 vs 52.5 months, p = 0.021), however, there was no significant difference in terms of OS among BRCAmut patients, regardless of SCS (Fig. 2A, median OS, 77.5 vs 76.8 months, p = 0.827).

At multivariate analysis, complete SCS at recurrence (Table 4, HR 0.311, 95%CI 0.121–0.75, p = 0.015) was the unique independent prognostic variable for OS. BRCA1/2 mutation status, PFI, FIGO stage, ascites at recurrence, No. of recurrence sites, maximum size of target lesions, CA-125 level, surgery time of SCS and history of PARP inhibitors were not found to be prognostic.

### Discussion

For the treatment of sensitive recurrent ovarian cancer, platinum-containing chemotherapy is widely recognized, however, as for the feasibility of SCS, there are still obvious controversies as mentioned before. Currently, there are at least two ongoing clinical trials exploring the advantages of SCS in sensitive recurrent ovarian cancer, including DESKTOP-III (ClinicalTrials.gov, NCT01166737) and SOCceR (Netherlands Trial Register number, NL3137). The previous study of DESKTOP-III confirmed the scoring model for predicting complete resection of lesions, and it was verified by the clinical trial of DESKTOP-II (16), so this scoring model was also adopted in this retrospective analysis. In our study, the complete removal rates of BRCAmut and BRCAwt patients were comparable (77.4% vs 68.4%, p = 0.51), suggesting that the DESKTOP Trial Score model was not affected by the mutation status of BRCA1/2. To the best of our knowledge, this is the first study to adopt DESKTOP Trial Score model to discuss the effect of BRCA1/2 mutation status on secondary cytoreductive surgery.
Our study found that BRCAmut patients had a better prognosis, regardless of whether SCS was performed. Even though there was a significant prolongation of median PFS in patients receiving SCS, the overall survival benefit was comparable (77.5 vs 76.8 months, \( p = 0.827 \)). However, it was worth noting that our study confirmed the effectiveness of SCS in BRCAwt patients. SCS could prolong the median FPS of BRCAwt patients by 4.3 months, and the median OS was extended by 17.4 months. Therefore, we only recommend SCS for BRCAwt patients. Further analysis revealed that complete resection was an independent risk factor affecting overall survival of patients underwent SCS, which was consistent with the reports in the literature\(^\text{4, 17–21}\). Therefore, complete resection of the tumor should be achieved, which is inseparable from adequate preoperative evaluation.

In previous literature reports, the mutation rate of BRCA1/2 in Chinese ovarian cancer patients was between 16.7–28.5\%\(^{11, 22, 23}\), while in our study, the proportion of patients with BRCA1/2 mutation was as high as 42.0\%. In addition, BRCAmut patients have a lower age of onset and a higher proportion of fully sensitive patients (PFI > 12 months). This could be explained by that patients with BRCA1/2 mutations have a longer relapse interval and higher platinum sensitivity\(^{22, 24, 25}\). There was no detection of somatic BRCA1/2 mutation in the study, which might lead to some deviation in the results, however, the clinical characteristics of the SCS group and the chemotherapy group were similar, which could avoid the bias of the study to some extent and make the conclusion more scientific and reliable.

Among the BRCAmut patients, the median OS of the SCS group and the chemotherapy group was up to 77.5 and 76.8 months, respectively, which was significantly higher than previous literature reports\(^{4, 7, 18}\). There were several possible reasons. First of all, the patients included in the study were all patients with platinum sensitive recurrence with a better prognosis than platinum-resistant patients. Secondly, 56.2\% of the BRCAmut patients were treated with PARP inhibitors, which could improve the therapeutic effect of BRCAmut patients by synthetic lethality\(^{26, 27}\). In recent years, a large number of studies have confirmed the significant survival benefit of BRCAmut patients with PARP inhibitors\(^{28–31}\), therefore, the use of PARP inhibitors might conceal the benefit of SCS. In addition, the benefit of PARP inhibitors in BRCAwt patients was relatively limited\(^{28, 32}\), so the benefit of SCS was still remained. The occurrence of this situation was similar to the GOG-0213\(^{8}\). Compared with chemotherapy alone, the PFS and OS of GOG-0213 patients underwent SCS were not significantly improved. As the authors discussed, more than 80\% of patients in the study received bevacizumab combined therapy, but it was not possible to assess the effect of bevacizumab. In our study, due to the limited number of patients and the inconsistency of the medication regimen for PARP inhibitors, the subgroup analysis was not conducted. In general, the survival benefits of secondary cytoreductive surgery may be concealed by certain effective therapeutic measures.

In conclusion, secondary surgical cytoreduction in platinum-sensitive recurrent HGSOC patients with BRCAwt could result in longer overall survival than no surgery. In contrast, patients with BRCAmut had no obvious survival benefit. We recommend that BRCA testing in all HGSOC patients for individualized treatment.
Declarations

Ethics approval and consent to participate:

Ethical approval was obtained from the Ethics Committee of Shandong University. Informed consent was obtained from all individual participants included in the study.

Consent for publication:

Not applicable.

Availability of data and materials:

Not applicable.

Competing interests:

The authors declare that they have no conflict of interest.

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Authors' contributions:

Hualei Bu and Xia Wang: Data curation, formal analysis and original draft.

Jin Peng: Funding acquisition.

Yana Ma, Shuai Feng, Mengdi Fu, Jingying Chen and Lekai Nie: Data curation.

Chengjuan Jin: Formal analysis, review and editing.

Youzhong Zhang: Conceptualization, supervision and project administration.

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**Tables**

Due to technical limitations, tables 1 to 4 xlsx are only available as a download in the Supplemental Files section.

**Figures**

**Figure 1**

The progression-free survival of primary platinum-sensitive recurrent HGSOC patients of different BRCA1/2 mutation status with SCS performed or not.
Figure 2

The overall survival of primary platinum-sensitive recurrent HGSOC patients of different BRCA1/2 mutation status with SCS performed or not.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- Table1.xlsx
- Table2.xlsx
- Table3.xlsx
- Table4.xlsx