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Laparoscopic-based score assessment combined with a multiple disciplinary team in management of recurrent ovarian cancer

A single-center prospective study for personalized surgical therapy

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Abstract

The aim of the study was to evaluate the effect of laparoscopic-based score combined with a multiple disciplinary team (MDT) for predicting optimal cytoreduction and perform personalized surgical treatment in recurrent ovarian cancer (ROC).

The study is a single-center, prospective investigation. From March 2013 to May 2015, the consecutive treated patients with platinum-sensitive ROC were collected in Yangpu Hospital. The appropriated patients were enrolled into the study to perform the laparoscopic-based PIV (predictive index value) score assessment with an MDT for predicting optimal cytoreduction. The PIV cutoff value was confirmed to be 8. Patients of PIV <8 received laparoscopic/laparotomy secondary surgery following chemotherapy, and the ones with PIV ≥8 did chemotherapy alone. Sensitivity, specificity, positive predicted value (PPV), negative predicted value (NPV), and overall accuracy for each range of PIV score were calculated. All recruited patients participated in follow-up observation. Overall survival was recorded.

In total, 58 eligible ROC patients received laparoscopy assessment. Forty-one patients of PIV <8 received secondary cytoreductive surgeries. Twenty-three (23/41 56.1%) attained optimal cytoreduction. However, 8 of 23 achieved completed cytoreduction. Also, 17 patients of PIV ≥8 underwent chemotherapy alone. Sensitivity, specificity, PPV, NPV, and overall accuracy for PIV ≥8 were 60%, 100%, 100%, 25%, and 64.7%, respectively. Overall survival in patients performing optimal cytoreduction was significantly higher than in those undergoing suboptimal cytoreduction or chemotherapy alone (45.9±2.5 vs 36.7±4.3 months, $P=.047$; 45.9±2.5 vs 35.8±3.4 months, $P=.027$).

Laparoscopic-based score assessment plus MDT helps to identify the appropriate patients to perform optimal secondary cytoreduction and provide a personalized surgical approach in management of ROC.

Abbreviations: AGO = arbeitsgemeinschaft gynaekologische onkologie, MDT = multiple disciplinary team, NPV = negative predicted value, PIV = predictive index value, PPV = positive predicted value, ROC = recurrent ovarian cancer.

Keywords: laparoscopy assessment, multiple disciplinary team, recurrent ovarian cancer, secondary cytoreduction

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SDC1: PIV score frequency distribution. PIV= predictive index value

SDC2: Procedure of surgery and surgical approach. Forty-one patients with PIV score <8 performed secondary cytoreductive surgeries, among which 23 patients achieved optimal debulking. The performed surgeries involved lesion resection (peritoneal or diaphragmatic carcinoma, omental or mesenteric mass), colectomy, intestinal repairing and bladder repairing. In addition, 17 patients with PIV score ≥8 underwent laparoscopic biopsy and received subsequently secondary platinum-based chemotherapy. RD= residual disease; R0= no visible residual disease

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1. Introduction

Ovarian cancer is the most lethal gynecologic malignancy. Overall prognosis of ovarian cancer remains relatively poor, with the 5-year overall survival of less than 30%. Most of patients with advanced ovarian cancer will develop recurrence within 18 months. Though secondary cytoreduction, chemotherapy, and targeted therapy being regarded as the recent therapeutic improvement are generally considered and present valid options, standard treatments for patients with recurrent ovarian cancer (ROC) has been a subject of debate.[1,2] Several retrospective studies have demonstrated that secondary surgery in the recurrent setting aimed at prolongation survival.[1] The ability to achieve surgery with complete cytoreduction (no visible residual disease, called R0) is associated with significant improvement in overall survival, especially for the platinum-sensitive ROC.[3] A study on the role of secondary surgery for ROC in 2019 patients reported that each 10% increase in optimally cytoreducted patients translated into a 3-month increase of overall survival.[4] DESKTOP III (NCT01166737) is an ongoing randomized, controlled clinical trials in Shanghai, China, which compares tumor debulking surgery versus chemotherapy alone in treatment for recurrent platinum-sensitive ovarian cancer. It aims to detect the role of secondary cytoreduction in management of ROC.

Considering a great survival benefit from optimally cytoreduced, several studies have focused on the search for a

laparoscopic-based predictive score in order to achieve a complete/optimal cytoreduction and select the appropriate patients. The first reported study evaluating laparoscopy prior to cytoreduction was published by Vergote et al[5] in 1998. In total, 173 patients who were surgically evaluated and then assigned to receive primary chemotherapy (43%) or primary debulking surgery (57%) had the higher actuarial 3-year crude survival rate than the ones who did not perform the laparoscopic assessment (42%±4.6% vs 26%±4.3%). Until 2006, Fagotti et al[6] first proposed a predictive index value (PIV) based on objective parameters determined at pre-cytoreduction laparoscopy to estimate the chances of optimal cytoreduction (residual tumor ≤1 cm). The patient with a PIV≥8 was considered to have a suboptimal surgical result with the likelihood of 100%. After that, other authors had also used a PIV score to predict the chance of R0/optimal cytoreductive surgery in management of advanced ovarian cancer. In 2015, M.D. Anderson Cancer Center proposed an algorithm based on laparoscopic PIV evaluation plus multiple disciplinary team (MDT) to predict R0 surgery for advanced ovarian cancer.[7] The Anderson Algorithm identified patients who likely achieved complete resection at primary surgery and aimed to improve overall survival. However, there are few researches that reported laparoscopic PIV score to manage to ROC. In our study, all ROC patients underwent laparoscopy assessment combined with MDT prior to cytoreduction or chemotherapy. The purpose of the present study was to evaluate the effect of laparoscopic-based PIV score combined with MDT for predicting optimal cytoreduction and to perform the personalized surgical treatment for ROC patients.

2. Materials and methods

2.1. Patients

The study was a single-center, prospective investigation. The research was approved by the ethical commitment of Yangpu Hospital, Tongji University School of Medicine. Informed consent was obtained from all individual participants included in the study. From March 2013 to May 2015, the consecutive treated patients with recurrent platinum-sensitive ovarian cancer were collected in our institution. The patients have been performed comprehensive staging surgery or primary/interval cytoreduction and have the treatment-free interval at least 6 months from the completion of first-line chemotherapy (both platinum and taxane). The suspected evidences of recurrence included positive image exams (obtained by pelvic/abdominal ultrasound, CT, PET-CT, or MRI), increasing serum CA125 levels, abnormal symptoms, or physical exams. The eligible patients carried out laparoscopic exploration prior to cytoreduction or chemotherapy. But secondary laparoscopy was inhibited when extra-abdominal relapse had been considered, as well as clinical or image evidences of bowel obstruction, plenty of ascites, and/or any clinical condition contraindicating laparoscopy (such as decline of cardio-pulmonary endurance, abnormal metabolic function in liver or kidney, and so on). The diagnosis of ROC was confirmed depending on histopathology exam of operative resected specimens.

2.2. Combined assessment and personalized treatment

When proceeding secondary laparoscopy, the laparoscopic-based PIV score was introduced to evaluate the condition in pelvic cavity and abdomen.[6,8] The evaluating parameters consisted of peritoneal, diaphragmatic, omental (residual omentum between stomach and transverse colon) mesenteric, intestinal, stomach, and liver lesions. Each positive evaluation received a score of 2. The PIV cutoff value was confirmed to be 8. The patients with PIV≥8 underwent laparoscopic biopsy followed by subsequent chemotherapy. The patients with PIV<8 went on laparoscopic resection or converted to laparotomy cytoreduction (Fig. 1).

Two gynecologic oncologists were demanded to take part in the assessment for each case and give the PIV score, respectively. When the evaluating result was not consistent, MDT as the

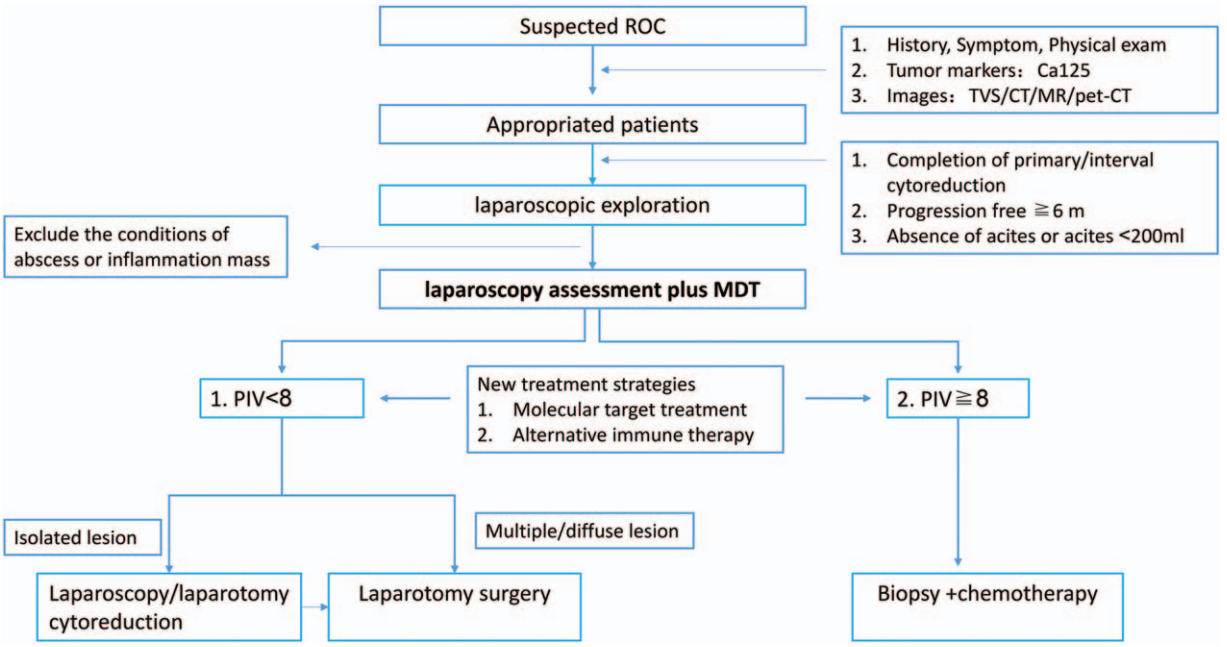

Figure 1. Flow diagram for patients how to be enrolled into the study and how to perform the treatment. MDT = multiple disciplinary team, PIV = predictive index value, ROC = recurrent ovarian cancer.

consultant group was invited to discuss together. In our institution, the members of MDT contained hepatobiliary, gastrointestinal, urologic and thoracic surgical oncologist, and chemotherapy physician. The final PIV score depended on the value from most majority. PIV score plus MDT assessment aimed to predict which patients were the suitable candidates for optimal cytoreduction and to provide personalized surgical treatment for each one. Optimal cytoreduction are defined as residual tumor <1 cm at the end of surgery. The number of case with different PIV scores was recorded. The sensitivity, specificity, positive predicted value (PPV), negative predicted value (NPV), and overall accuracy for each range of PIV score were calculated.

The predicted appropriated patient with PIV <8 performed secondary cytoreduction. Considering the single, localized lesion located in peritoneum, diaphragm, and mesentery, with the diameter of ≦4 cm, our team tried to carry out laparoscopic resection. Of course, laparotomy surgery was adopted when minimal invasive approach did not achieve R0 or optimal cytoreduction. The surgical approach was recorded and the operative time was accumulated.

2.3. Follow-up

The patients who completed secondary laparoscopy were required to participate in follow-up observation with the interval of 3 to 6 months. The patient's status of death or survival was recorded. Similar to the exams in primary OC patients, the follow-up in ROC patients included physical exam, image review, and level measure of tumor serum marker CA125. The overall survival was defined from initial diagnosis to death or the end of follow-up. Overall survival was compared between the patients with optimal cytoreduction and the ones with suboptimal surgery or chemotherapy.

2.4. Statistics

Data were presented as mean ± SD or number/percentages (%). Commercial software (SPSS 19.0, Inc., an IBM Company, Chicago, IL) was used for statistical analysis. Mean and life tables were computed using the product-limit estimate by the Kaplan–Meier method, and analyzed by the log rank test. A P value of <.05 was considered statistically significant.

3. Results

From March 2013 to May 2015, 72 ROC patients were treated in our hospital. Ten patients were excluded, of which 6 patients were with suspected extra-abdominal relapse and 4 patients with plenty of ascites plus decline of cardio-pulmonary endurance. Sixty-two eligible patients completed secondary laparoscopy. However, there were 4 cases whose explored outcomes showed pelvic abscess or inflammatory mass. Finally, 58 ROC patients were enrolled into the study and received laparoscopic-based PIV score assessment. The general clinic characteristics and the evidences of relapse (abnormal symptoms, serum CA125, and image exams) are listed in Table 1.

PIV scores were obtained from 2 gynecologic oncologists. Due to inconsistent score results, 21 patients (36.2%) further performed MDT assessment. Finally, 8 cases were evaluated with PIV < 8 and 13 cases with PIV ≥8. The frequency distribution of PIV score was shown in SDC1 (supplemental digital content 1, SDC1, http://links.lww.com/MD/B816). Forty-one patients of PIV score <8 went on performing secondary cytoreductive surgeries and 17 patients of PIV score ≥8 received secondary platinum-based chemotherapy. The performed surgeries covered lesion resection (peritoneal or diaphragmatic carcinoma, omental or mesenteric mass), colectomy, intestinal repairing, and bladder repairing (Fig. 2) (SDC2, http://links.lww.com/MD/B816). In total, 23 of 41 cases of secondary surgeries obtained optimal cytoreduction, and 8 cases achieved R0 resection. Eight patient with PIV ≦2 achieved laparoscopic secondary cytoreduction. The evaluating results for each PIV scores are shown in Table 2. When PIV was of ≥8, specificity and PPV got to 100%.

All the 58 patients undergoing secondary laparoscopy have participated in the follow-up study. The mean time of follow-up was 35.2 ± 14.3 m (range: 13–58 months). Eighteen patients died due to the nature of ovarian cancer and 40 survived. The overall survival in groups of optimal cytoreduction, suboptimal cytoreduction, and chemotherapy were 45.9 ± 2.5 m, 36.7 ± 4.3 m, 35.8 ± 3.4 m, respectively. Overall survival was significantly higher in the optimal cytoreduction group than that in the suboptimal cytoreduction group and the chemotherapy group ($x^2 = 3.95$, $P < .05$; $x^2 = 4.87$, $P < .05$, respectively). The survival curves of 3 various treatments group are described in Fig. 3.

Table 1

General characteristics.

Characteristics	Data, %
Age, years	53.9 ± 8.9 (range 36–69)
BMI, kg/m^2	24.3 ± 3.7
FIGO stage	
I	14 (24.1)
II	2 (3.4)
III	34 (58.6)
IV	8 (13.8)
Grade	
I	4 (6.9)
II	18 (31)
III	36 (62.1)
Histology	
Serous	48 (82.8)
Endometrioid	2 (3.4)
Clear cell	4 (6.9)
Mucous	4 (6.9)
Primary surgery	
Comprehensive staging/primary cytoreduction	46 (79.3)
Interval cytoreduction	12 (20.7)
Progression free, m	12.7 ± 6.4
6–12 m	28 (48.3)
12–18 m	14 (24.1)
18–24 m	12 (20.7)
>24 m	4 (6.9)
Symptoms	
Yes*	42 (72.4)
No†	16 (27.6)
Serum CA125	
Normal	14 (24.1)
Raise	44 (75.9)
Image review	
Positive	40 (69.0)
Negative	18 (31.0)

BMI = body mass index, FIGO = International Federation of Gynecology and Obstetrics.
* Yes: accompanying abnormal symptoms including abdominal pain, abdominal distension, irregular bleeding, nausea, and constipation.
† No: without uncomfortable complaints.

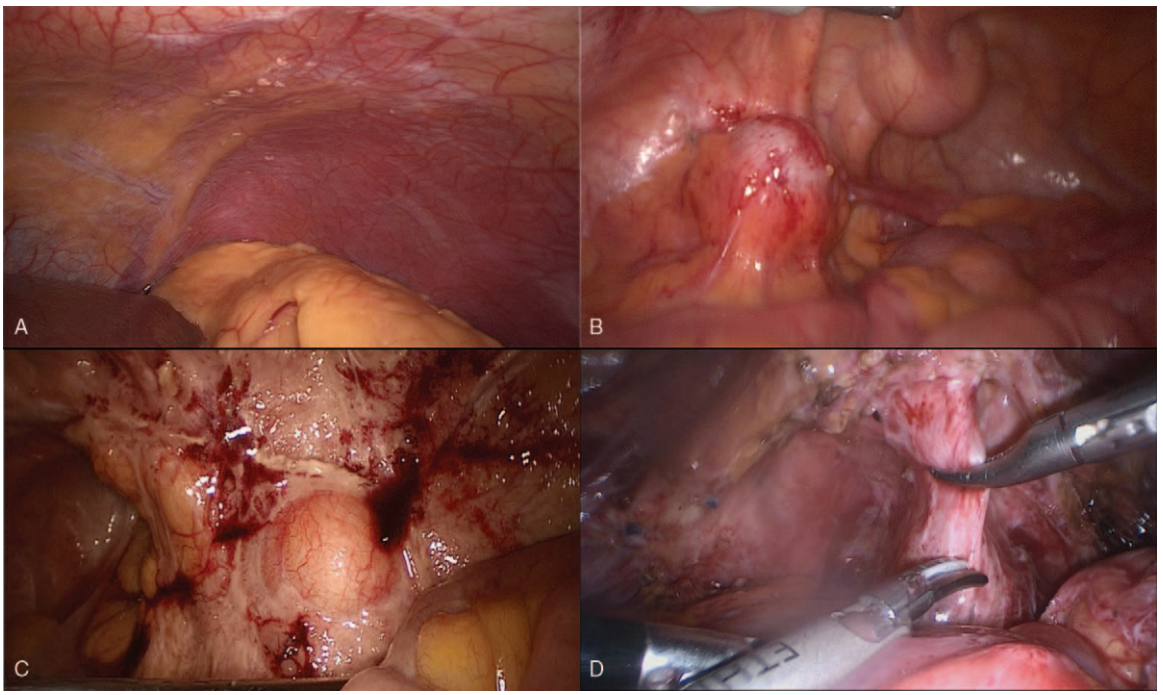

Figure 2. The patients with the laparoscopic-based PIV assessment of <8 underwent secondary cytoreductive surgeries. The procedures include local lesion resection, colectomy, intestinal repairing, and bladder repairing. (A–D) Local and single recurrent lesions from different tissues—(A) tiny diaphragmatic metastasis; (B) retroperitoneal mass on left sidewalls of pelvic cavity, adhering to sigmoid; (C) retroperitoneal mass originating in right sidewalls of pelvic cavity; (D) resection of rectum wall tumor using harmonic scalpel (magnification: ×8). PIV=predictive index value.

4. Discussion

Surgery for recurrent ovarian cancer has been suggested to be associated with increased overall survival. A systematic review on cytoreductive surgery for recurrent ovarian cancer indicated that complete cytoreduction conferred survival benefit.[9] The Eisenkop 2000 study found that women with no visible disease after secondary cytoreductive surgery had 87% less risk of death compared to women with macroscopic disease (HR 0.13; *P* value=.007).[3] But how to select ideal candidates to perform secondary cytoreduction and how to successfully predict the chance for optimal cytoreduted surgery in ROC patients have remained unclear.[10] Last decade, a laparoscopic-based score has been proposed to predict R0 or optimal cytoreduction in management of advanced ovarian cancer.[11] Several studies showed that the evaluating criteria helped to improve the rate of R0 or optimal cytoreduction and was associated with the increasing of patients' overall survival.[7,11–13] Similarly, M.D. Anderson Cancer Center put forward the Anderson Algorithm and suggested that the algorithm was a reliable predictor of R0 resection.[7] Our study tried to apply the laparoscopic-based PIV score plus MDT to treat ROC in order to select the appropriate candidates for optimal cytoreduction and perform personalized surgical treatment for ROC.

The study showed that the values of specificity and PPV gradually added with the increasing of PIV score. Both of specificity and PPV achieved 100% when PIV ≥8, with sensitivity, NPV, and accuracy values of 60%, 25%, and 64%, respectively. Seventeen cases with PIV ≥8 who underwent laparoscopic biopsy and subsequent secondary platinum-based

Table 2

Laparoscopic PIV assessment.

PIV score	Specificity, %	Sensitivity,%	PPV, %	NPV, %	Overall accuracy, %
≧0	73.9	62.9	78.6	56.7	67.2
≧2	76.5	62.5	83.3	52	67.3
≧4	81.8	60.7	89.5	45	66.7
≧6	85.7	60.9	93.3	40	66.7
≧8	100	60	100	25	64.7
≧10	100	50	100	25	57.1

NPV=negative predicted value, PIV=predictive index value, PPV=positive predicted value.
Specificity=true negatives/(true negatives + false positives) ×100%
Sensitivity=true positives/(true positives + false negatives) ×100%
PPV=true positives/(true positives + false positives) ×100%
NPV=true positives/(true negatives + false negatives) ×100%
Overall accuracy=(true positives + true negatives)/total number of patients ×100%
True positives were defined as the number of suboptimally cytoreduced patients who were correctly identified. True negatives were defined as the number of optimally debulked patients who were correctly identified.

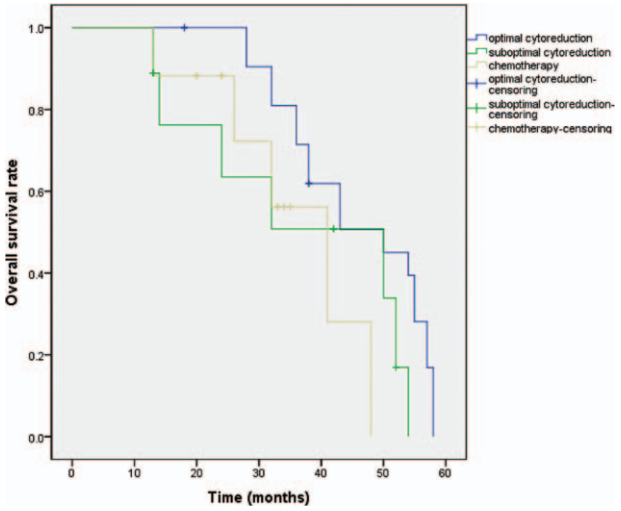

Figure 3. Kaplan–Meier method was used to draw the overall survival curve: green meant suboptimal cytoreduction; yellow meant chemotherapy; blue meant optimal cytoreduction.

chemotherapy avoided unnecessary exploratory laparotomy in the study. Twenty-three (23/41, 56.1%) cases performed optimal secondary cytoredution. It suggested that the cutoff value of PIV = 8 was feasible to predict the chance for optimal resection in ROC. The laparoscopic-based PIV score presented effectiveness in the management of ROC. Brun et al[12] evaluated the utility of the same score system in a cohort of 55 patients with stage III-IV ovarian cancer. Twenty-six patients had primary cytoreductive surgery after diagnostic laparoscopy, and the remaining 29 patients were treated with neoadjuvant chemotherapy following subsequently cytoreduction. A PIV of ≥8 was associated with suboptimal cytoreduction with sensitivity, specificity, PPV, NPV, and accuracy values of 46%, 89%, 89%, 44%, and 60%, respectively. Fanfani et al[13] evaluated the positron emission tomography–laparoscopy-based method for the prediction of complete/optimal cytoreduction in platinum-sensitive recurrent epithelial ovarian cancer patients. Laparoscopy obtained a PPV of 91.3%. Laparoscopy recovered to secondary cytoreduction in 13 of 60 patients (21.7%) deemed as not resectable according to AGO (Arbeitsgemeinschaft Gynaekologische Onkologie) score. In total, 48 of 150 AGO score positive patients (32%) were judged nonresectable by laparoscopy. It indicated that the laparoscopic-based score assessment could be more accurate and effective to select the patients who were suitable for performing complete cytoreduction.

Not only the role of prediction of optimal debulking, but the laparoscopic-based score combined with MDT promised the secondary cytoreduction by laparoscopic approach. In the study, there were 8 cases who completed laparoscopic optimal resection instead of laparotomy debulking following laparoscopic evaluation. Of the 8 patients, 6 ones were evaluated with the score of PIV = 0 including 2 involving localized diaphragmatic lesion, 2 showing single retroperitoneal disease and 2 presenting isolated mesenteric mass with the size of $< 4\,cm \times 4\,cm$ (Fig. 2A–C). Considering the single, isolated and small lesions, we tried to perform laparoscopic resection after the consensus assessment by MDT consultants and achieved optimal cytoreduction. The other 2 ones acquired the score of PIV = 2 in terms of involved colon infiltration and bowel resection assumed to be required (Fig. 2D). MDT consultants deemed that the colon disease was limited in 1 section of intestinal tube and was the unique found lesion. Therefore, laparoscopic resection was agreed and 2 patients received laparoscopic optimal cytoreduction successfully. It suggested that the laparoscopic secondary cytoreduction is feasible for appropriate selected patients. Trinh et al[14] reported that 36 consecutive ROC patients who underwent laparoscopic debulking and the surgery was successful in 34 (34/36, 94%) without requiring laparotomy. However, 74% of patients had a complete response after laparoscopic debulking and chemotherapy, with a median progression-free survival of 1.1 years. In a retrospective analysis, Nezhat et al assessed the safety and efficacy of laparoscopic debulking in management of recurrent ovarian, fallopian, and primary peritoneal cancers. Twenty-three appropriate patients were recruited and underwent laparoscopic surgery. Except for 1 who performed the converted laparotomy, 18 patients (81.8%) achieved optimal secondary cytoreduction (residual lesion < 1 cm). The study showed that a median disease-free survival was 71.9 months with a median follow-up of 14 months.[15,16] So it was concluded that laparoscopic secondary cytoreduction was technically feasible in a well-selected population. Laparoscopic-based score plus MDT evaluation helped to identify the appropriate patients to produce optimal secondary cytoreduction and provide personalized surgical management for ROC.

With the mean follow-up time of 35.2 ± 14.3 months, overall survival in the 23 patients who received optimal cytoreduction was 45.9 ± 2.5 months, which was significantly higher than in suboptimal cytoreduction and chemotherapy (36.7 ± 4.3 months, $P = .047$; 35.8 ± 3.4 months, $P = .027$). It is the comparative results when compared with other literatures. The ALYPSO trial confirmed that secondary cytoreductive surgery was associated with improved overall survival in ROC, compared with chemotherapy alone (median 49.9 vs 29.7 months).[17] The large multicenter prospective trial DESKTOP I (Descriptive Evaluation of Preoperative Selection Criteria for Operability) [18] has clearly demonstrated that only complete debulking has prognostic influence for recurrent ovarian cancer. At present, secondary cytoreductive surgery is the most common strategy recommended by Gynaecologic Oncology Units worldwide in platinum-sensitive ovarian cancer recurrence, as well as in terms of improvement of quality of life.[3,19] The laparoscopic-based score made the evaluating prediction for R0/optimal cytoreduction in ROC and presented the important clinical value.

In the study, 4 suspected patients were excluded due to the results of pelvic abscess or inflammatory mass confirmed by laparoscopy exploration. Laparoscopy assessment helped to confirm the diagnosis of ROC and avoid unnecessary exploratory laparotomy and chemotherapy. What's more, laparoscopy assessment plus MDT guidance improved the quality of the surgical management of recurrent ovarian cancer and guided the personalized therapeutic approach. Recently, new therapeutic strategies focus on molecular target treatment (i.e., bevacizumab) and alternative immune agents (i.e., CAR-T, Chimeric Antigen Receptor T-Cell Immunotherapy). Laparoscopy assessment provided the chance to collect tissue specimens of recurrent tumor especially for the patients with PIV≥8 who would proceed upfront chemotherapy instead of surgical resection. The acquirement of tissue was associated with the novel molecular therapeutic agents which may contribute to reciprocal improvement in survival.

Our data showed that laparoscopic assessment plus MDT contributed to the prediction of optimal secondary cytoreduction and the guidance for the personalized surgical approach

(laparoscopy or laparotomy cytoreduction). Laparoscopic-based score evaluation combined with MDT was feasible and should be recommended in management of ROC. Of course, the study was limited due to the small-sample and single institution research. In further clinical trial, the large-sample, multiple-center study is needed, focusing on the necessity and feasibility of laparoscopy assessment.

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