Gynecologic Oncology 139 (2015) 5–9

Contents lists available at ScienceDirect

Gynecologic Oncology

journal homepage: www.elsevier.com/locate/ygyno

Definition of a dynamic laparoscopic model for the prediction of incomplete cytoreduction in advanced epithelial ovarian cancer: Proof of a concept

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HIGHLIGHTS

- The chance of achieving complete PDS in women with AEOC showing a LPS-PIV ≥ 10 was 0.
- The risk of unnecessary laparotomy in patients showing a LPS-PIV < 10 was 33.2%.
- The overall discriminating performance of LPS-PI was very high, with an AUC = 0.885.

ARTICLE INFO

Article history:
Received 11 April 2015
Received in revised form 13 July 2015
Accepted 14 July 2015
Available online 18 July 2015

Keywords:
Primary debulking surgery
Advanced epithelial ovarian cancer
Laparoscopy

ABSTRACT

Objective. To develop an updated laparoscopy-based model to predict incomplete cytoreduction (RT > 0) in advanced epithelial ovarian cancer (AEOC), after the introduction of upper abdominal surgery (UAS).

Patients and methods. The presence of omental cake, peritoneal extensive carcinomatosis, diaphragmatic confluent carcinomatosis, bowel infiltration, stomach and/or spleen and/or lesser omentum infiltration, and superficial liver metastases was evaluated by staging laparoscopy (S-LPS) in a consecutive series of 234 women with newly diagnosed AEOC, receiving laparotomic PDS after S-LPS. Parameters showing a specificity ≥ 75%, PPV ≥ 50%, and NPV ≥ 50% received 1 point score, with an additional one point in the presence of an accuracy of ≥60% in predicting incomplete cytoreduction. The overall discriminating performance of the LPS-PI was finally estimated by ROC curve analysis.

Results. No-gross residual disease at PDS was achieved in 135 cases (57.5%). Among them, UAS was required in 72 cases (53.3%) for a total of 112 procedures, and around 25% of these patients received bowel resection, excluding recto-sigmoid resection. We observed a very high overall agreement between S-LPS and laparotomic findings, which ranged from 74.7% for omental cake to 94.8% for stomach infiltration. At a LPS-PIV ≥ 10 the chance of achieving complete PDS was 0, and the risk of unnecessary laparotomy was 33.2%. Discriminating performance of LPS-PI was very high (AUC = 0.885).

Conclusions. S-LPS is confirmed as an accurate tool in the prediction of complete PDS in women with AEOC. The updated LPS-PI showed improved discriminating performance, with a lower rate of inappropriate laparotomic explorations at the established cut-off value of 10.

1. Introduction

In the last decade, the results of two randomized clinical trials have significantly changed the treatment scenario for advanced epithelial ovarian cancer (AEOC) [1,2]. In fact, even if primary debulking surgery (PDS) remains the cornerstone in the management of advanced disease [3–7], neoadjuvant chemotherapy (NACT) followed by interval debulking surgery (IDS) has emerged as a valuable therapeutic option in cases not suitable for complete PDS [8].

In this context, staging-laparoscopy (S-LPS) has been recognized as an accurate, minimally invasive tool able to properly drive the therapeutic choice between PDS and NACT [9]. In particular, a laparoscopy-based

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http://dx.doi.org/10.1016/j.ygyno.2015.07.095
0090-8258/

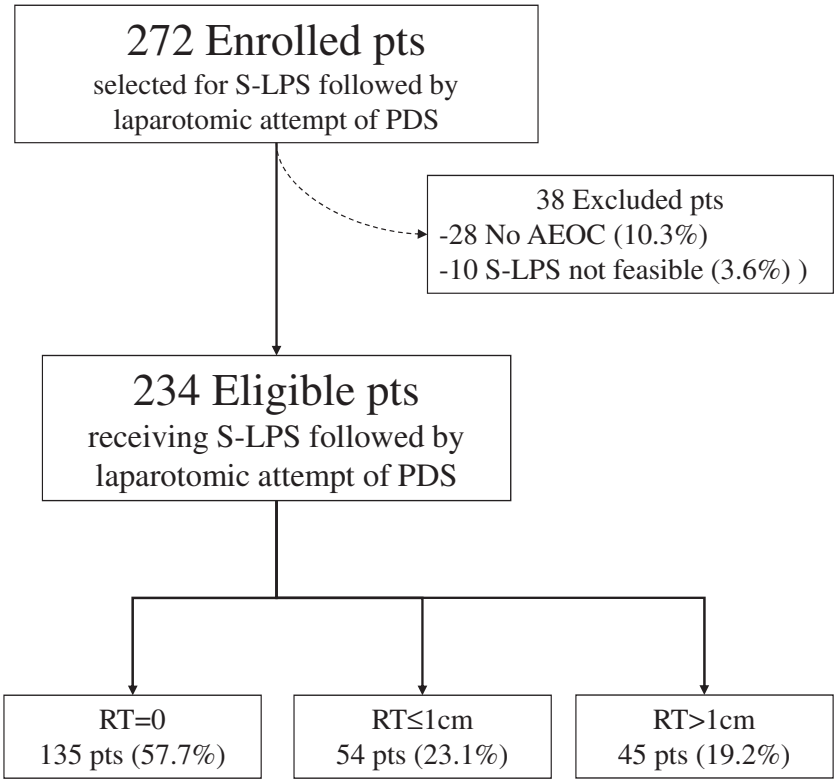

Fig. 1. Flow-chart of our study population.

predictive index model (LPS-PI), initially developed in 2005, has been shown to accurately predict the chance of achieving an optimal PDS (residual tumor ≤ 1 cm). However, complete PDS (no gross residual tumor) has been more recently recognized as the real goal to be pursued in the up-front surgical management of women with AEOC [9–11].

Furthermore, the LPS-PI was initially designed, and prospectively validated, before the achievement of relevant improvements in the surgical management of AEOC. In fact, the recent introduction of upper abdominal surgery (UAS) in the surgical skills of gynecologic oncologists has significantly increased the chance of achieving a complete PDS, with significant survival benefit [12–14].

Therefore, it is conceivable to hypothesize that some updates are needed to allow an accurate application of the LPS-PI in the current therapeutic scenario. For these reasons, we have retrospectively analyzed a large single Institution series of AEOC patients, who received S-LPS followed by a maximal laparotomic surgical effort, after the introduction of UAS, with the aim of developing an updated LPS-PI able to predict the chance of complete PDS.

2. Patients and methods

2.1. Patients' selection

After a training period, from June 2007 UAS was routinely employed in the surgical management of AEOC patients in our Institutions [14]. Therefore, a consecutive series of women submitted to S-LPS, and further laparotomic attempt of PDS from June 2007 and June 2014 will be analyzed in the present study (Fig. 1). All eligible women included in the final analysis received S-LPS followed by standard longitudinal laparotomy, by the same surgical teams at the Catholic University of the Sacred Heart of Rome and Campobasso. Since mesenteral retraction and miliaric carcinomatosis on the serosa of the small bowel are widely recognized as absolute criteria of unresectability, all patients showing at S-LPS the presence of one of these two parameters did not receive a laparotomic attempt of PDS, and therefore were not included in the final analysis.

For all cases, clinico-pathological characteristics, surgical procedures, and residual disease at PDS were prospectively collected, and retrospectively analyzed for the purpose of the present study. Residual tumor (RT) at PDS was defined as follows: complete in the absence of residual macroscopic disease, optimal when a RT ≤ 1 cm was achieved, and suboptimal in the presence of a RT > 1 cm. Post-operative complications have been recorded and classified according with Clavien/Dindo classification [15]. The study has received the Institutional Review Board approval.

2.2. Laparoscopic parameters

The following modifications have been inserted in the new model:

(a) laparoscopic assessments of mesenteral retraction and miliaric carcinomatosis on the serosa of the small bowel are considered as absolute criteria of unresectability, and so these two parameters have been excluded from the updated version of the model; and
(b) as previously described [16], the following laparoscopic parameters were included: (1) massive peritoneal involvement and/or a miliary pattern of distribution for parietal peritoneal carcinomatosis; (2) wide spread infiltrating carcinomatosis, and/or confluent nodules to the most part of the diaphragmatic surface; (3) tumor diffusion along the omentum up to the large stomach curvature; (4) possible large/small bowel resection (excluding, recto-sigmoid involvement, giving its pelvic localization and since posterior exenteration is considered a standard surgical procedure in AEOC); (5) obvious neoplastic involvement of the stomach, and/or lesser omentum, and/or spleen; and (6) liver surface lesions larger than 2 cm [16,17].

In all cases, laparoscopic parameters were assessed by two experienced gynecologic oncologists in order to minimize the scoring bias.

2.3. Data analysis

Sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), and overall accuracy were calculated for each laparoscopic parameter [18]. Sensitivity was defined as the number of patients with RT > 0 at PDS who were correctly identified (true positives) divided by the total number of patients with RT > 0 (true positives + false negatives). Specificity was defined as the number of patients with RT = 0 at PDS who were correctly identified (true negatives) divided by the total number of women receiving PDS with RT = 0 (true negatives + false positives). PPV was calculated as the number of true positives divided by the total number of positive results (true positives + false positives), and NPV was defined as the number of true negatives divided by the total number of negative results (true negatives + false negatives). Accuracy was calculated as the number of true positives plus true negatives (total number correct) divided by the total number of patients studied. As previously reported, we assigned a LPS-PI score of 1 to each laparoscopic parameter showing all the following performances: specificity ≥ 75%, PPV ≥ 50%, and NPV ≥ 50%. We assigned also an additional one point to all parameter reaching an accuracy of >60% [18,19]. By using this scoring system, a LPS-PI model was designed; PPV and NPV were calculated for each predictive index value (PIV), from 0 through 12. The lower PIV reaching a PPV = 100% was considered as the cut-off value to be used in clinical practice, in order to minimize the risk of patients inappropriately unexplored [18].

3. Results

Between June 2007 and June 2014, 272 women with suspicious AEOC were admitted at the Gynecologic Oncology Unit of the Catholic University of the Sacred Heart of Rome and Campobasso to receive an attempt of S-LPS and PDS. Among them, final histology did not confirm EOC in 28 cases (10.3%), whereas S-LPS was not feasible in 10 patients (3.6%), due to the presence of extensive and tenacious adhesions. Therefore, 234 patients were considered eligible for final analysis (Fig. 1).

The clinical-pathologic characteristics of the overall series have been summarized in Table 1. The vast majority of women showed serous (86.7%), FIGO Stage IIIc (82.5%) epithelial ovarian cancer. At laparotomy, PDS with no-gross residual disease was achieved in 135 cases (57.7%), 54 women (23.1%) showed a RT ≤ 1 cm, with the remaining 45 patients (19.2%) experiencing suboptimal PDS (Table 1). The surgical procedures performed in the 135 women receiving complete PDS included pelvic and abdominal peritonectomy in 101 (74.8%) and 89 (65.9%) cases, respectively. Forty-two patients (31.1%) were submitted to rectosigmoidectomy, and 32 women (23.7%) received large bowel resection. In 72 patients (53.3%) at least one UAS was required to achieve complete PDS, and 110 UAS procedures were performed in the overall series, including diaphragmatic peritonectomy/resection, splenectomy, pancreatic resection, and liver resection. Major post-operative (Grades 3–5) complications were observed in 12 out of 14 cases with a PIV ≥ 10 (85.7%), and in 65 out of 220 cases with a PIV < 10 (29.5%), with an overall incidence of major post-operative complications of 40.7%.

All the laparoscopic parameters were easily assessable in almost all cases (Table 2). Furthermore, we observed a high overall agreement between S-LPS and laparotomic findings, which ranged from 88.6% for bowel infiltration to 97.0% for peritoneal carcinomatosis (Table 2).

As shown in Table 3, all the six laparoscopic parameters reached a specificity ≥ 75%, a PPV ≥ 50%, and a NPV ≥ 50%, with an overall accuracy of ≥60%. As a consequence, we assigned a PI score of 2 to all the parameters. Omental cake and peritoneal carcinomatosis showed the lowest specificity (75.4% and 76.1%, respectively), and PPV (69.7% and 67.0%, respectively), in predicting a PDS with RT > 0. On the other hand, infiltration of the stomach, bowel (excluding recto-sigmoid involvement), and liver showed a very high specificity, ranging from 98.5% for stomach infiltration to 94.8% for liver metastases (Table 3). Applying this scoring system to our population, we observed the peak of distribution with PIV = 4, which was assigned to 54 cases (23.1%). In 50 patients (21.4%), we documented a high tumor load with a PIV ≥ 8; while, 83 women (35.4%) showed a low intraperitoneal dissemination with a PIV ≤ 2 (Fig. 2).

Table 1
Clinico-pathological characteristics of the study population.

Characteristics	Nr. (%)
All cases	234
Age, median (range), years	57 (25–84)
FIGO stage	
IIIc	193 (82.5)
IV	41 (17.5)
Ascites	
Yes	126 (53.8)
No	108 (46.2)
CA125 median serum levels	
≤500 UI/ml	80 (34.2)
>500 UI/ml	154 (65.8)
Tumor histotype	
Serous	203 (86.7)
Endometrioid/clear cell	31 (13.2)
PS ECOG	
0–1	212 (90.6)
2	22 (9.4)
Residual tumor at 1st surgery	
RT = 0	135 (57.7)
RT ≤ 1 cm	54 (23.1)
RT > 1 cm	45 (19.2)

PPV, NPV, the percentage of women unnecessarily explored (1-NPV), and inappropriately unexplored (1-PPV) have been presented in Table 4. As previously reported, our LPS-PI model was designed to minimize the rate of "inappropriate unexploration", thus ensuring the prognostic benefit of a complete PDS to all suitable patients. As a consequence, the best cut-off value was observed with a PIV ≥ 10, which corresponded to a PPV = 100%. This means that the probability of achieving a complete PDS in AEOC patients with a PIV ≥ 10 is null, even performing UAS. In this specific group of women with a PIV ≥ 10 optimal cytoreduction was achieved in 6 out of 14 cases (42.8%).

At the same time, the attempt of PDS in patients with a PIV < 10 is associated with a 33.2% risk of not reaching the complete debulking (Table 4). In this group of patients with PIV < 10 the presence of diffuse pleural or retroperitoneal involvement not predictable at S-LPS were detected at the time of PDS in 43% of cases. In particular, focusing on retroperitoneal adenopathy, bulky lymph nodes were identified in 36 cases (16.3%), with 4 women showing a celiac trunk involvement (1.8%).

Finally, a receiver operating characteristic curve analysis was performed, showing an area under the curve of 0.885, thus confirming the high discriminating performance of the new model (Supplementary Fig. 1).

4. Discussion

Scoring systems are successfully employed in several fields of medicine in order to assist physicians in drawing appropriate complex therapeutic decisions [20]. The choice between NACT and PDS certainly represents an hot topic in the management of AEOC, deeply influencing the natural history of newly diagnosed disease [21,22]. Staging LPS score has emerged over the last years as a reliable tool to correctly identify women suitable for optimal PDS [10,16,18]. However, it has to be considered that all predictive systems need to be continuously updated to

Table 2
Evaluability and correspondence of laparoscopic parameters with laparotomic findings.

Laparoscopic parameters	Not evaluable at S-LPS Nr. (%)	Present at S-LPS Nr. (%)	Overall agreement with laparotomic findings Nr. (%)
Omental cake	0 (0.0)	172 (73.5)	219 (93.6)
Peritoneal carcinomatosis	1 (0.4)	143 (61.1)	227 (97.0)
Diaphragmatic carcinomatosis	1 (0.4)	116 (49.5)	218 (93.2)
Bowel infiltration	3 (1.3)	50 (21.4)	206 (88.6)
Stomach infiltration	3 (1.3)	8 (3.4)	222 (94.8)
Liver metastases	0 (0.0)	22 (9.4)	216 (92.3)

keep in pace with therapeutic innovations, and technical advancements introduced in clinical practice [20]. For these reasons, the relevance of the present study, which provides an updated version of the previously developed LPS-PI is not to be underestimated.

First, we can confirm that LPS-PI is a feasible procedure. In fact, in the present series, only 10 women (2.4%) were judged unsuitable for S-LPS, compared with a percentage ranging from 4.7% to 8.8%, reported in previous studies [16–18]. This relevant increase in the feasibility rate of S-LPS could be related to the use of subcostal access in women with previous longitudinal laparotomic surgeries, as well as to the long experience achieved by the surgical and anesthesiological team. Despite the significant changes achieved in the surgical management of AEOC, six previously selected laparoscopic parameters retained high predictive performances, and persisted in the updated model. In fact, they were assessable in around 99% of cases, which is significantly higher compared to previous findings [16,18]. In particular, the most relevant increase was observed for stomach infiltration, bowel infiltration, and diaphragmatic carcinomatosis which were previously reported to be assessable in 85.8%, 84.9%, and 91.1% of cases, respectively [16].

We also confirmed a very high agreement between laparoscopic and laparotomic findings, which is above 90% for all the parameters, with the exception of bowel infiltration (overall agreement = 88.6%). These data can be explained considering the difficulty to accurately explore the entire large and small bowel segments, due to the extensive diffusion of the disease, and the presence of adhesions.

The updated LPS-PI reached a null rate of inappropriate unexplorations (PPV = 100%) at a cut-off value of 10. Raising the threshold compared with the previous model can be explained considering that the relevant improvement in terms of post-operative care, as well as the introduction of UAS, changed our surgical attitude allowing to achieve a complete PDS, even in women with a PIV = 8. As a consequence, applying this updated model, the percentage of women showing at S-LPS no chance of achieving complete PDS (PIV ≥ 10) is low accounting for around 6% (14 cases out 234). This apparently low percentage of patients selected for NACT can be explained also considering that, outside from our study analysis focused on the development of an updated PI model, S-LPS was able to identify the presence of mesenteral retraction and extensive small bowel involvement in around 10% of the overall population of AEOC patients, directly selecting these women for NACT without laparotomic exploration.

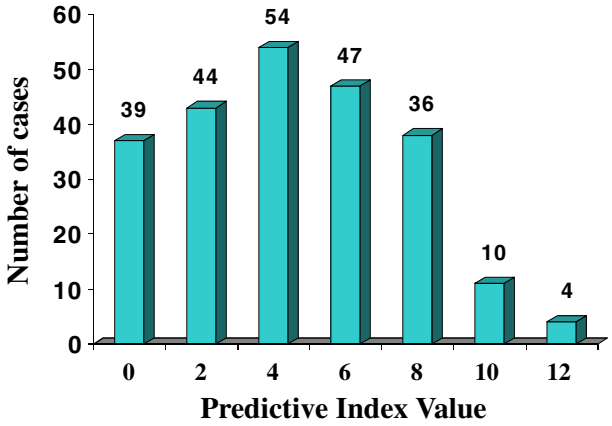

Fig. 2. Distribution of predictive index values in the current population.

On the other hand, it should be noted that using a cut-off value of 10, the risk of inappropriate laparotomic explorations remains not negligible accounting for around 33.2%, but anyway this rate is 10% lower compared with the previous model [16]. Even this finding can be attributed to the introduction of UAS, which ensured a complete PDS to a higher percentage of women with PIV < 10. As a consequence, the updated LPS-PI showed an increased discriminating performance (AUC = 0.885) (Supplementary Fig. 1) compared with previously reported data (AUC = 0.750) [23].

Despite the high discriminating performance of our model in predicting the chance of complete PDS, no data are currently available regarding the survival outcome of patients treated with complete/optimal PDS or NACT followed by IDS according with different LPS-PIV. The results of the ongoing SCORPION randomized clinical trial (NCT01461850) will clarify this crucial point helping to draw definitive recommendations. In the meantime, this updated LPS-PI represents a reliable tool to assist gynecologic oncologists in properly balancing the decision making process about PDS or NACT in the upfront management of AEOC.

In conclusions our findings emphasize that the proper application of the LPS-PI always requires to carry on maximal surgical effort, including if necessary UAS and a multidisciplinary team with surgical oncologists, in all women selected for PDS. In all Institutions in which UAS is routinely adopted, and complete PDS is considered the real goal to be pursued, this updated LPS-PI model with a cut-off value of 10 should be applied with better discriminating performances. Further reduction of inappropriate explorations, while maintaining a PPV = 100%, will represent the goal to be pursued for the future development of predictive index models [24]. The proper integration of the LPS-PI with the recently developed molecular [25], and clinico-radiological predictive models [26] including several factors such as age, CT scan findings (thoracic disease, retroperitoneal involvement), CA125 levels and performance status will help to further personalize the decision making process.

Supplementary data to this article can be found online at http://dx.doi.org/10.1016/j.ygyno.2015.07.095.

Table 3
Scoring of laparoscopic parameters included in the predictive index model.

Laparoscopic parameters	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)	Point value
Omental cake	76.0	75.4	69.7	80.8	78.2	2
Peritoneal carcinomatosis	65.7	76.1	67.0	75.0	71.6	2
Diaphragmatic carcinomatosis	81.8	80.6	75.7	85.7	81.1	2
Bowel infiltration	47.9	97.2	71.8	94.0	76.9	2
Stomach infiltration	6.1	98.5	75.0	62.7	62.3	2
Liver metastases	15.0	94.8	68.2	59.9	60.7	2

Table 4
Performances of laparoscopic predictive index model at different cut-off values.

PIV	NPV (%)	Unnecessarily explored (1-NPV) (%)	PPV (%)	Inappropriately unexplored (1-PPV) (%)
≥0	100	0.0	39.6	60.4
≥2	91.5	8.5	54.3	45.7
≥4	87.9	12.1	74.5	25.5
≥6	79.0	21.0	84.6	15.4
≥8	71.7	28.3	91.7	8.3
≥10	66.8	33.2	100	0
12	64.6	35.4	100	0

Conflict of interest statement

The authors declare that there are no conflicts of interest.

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