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Diagnostic flow-chart to identify bowel involvement in patients with stage IIIC-IV ovarian cancer: Can laparoscopy improve the accuracy of CT scan?

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HIGHLIGHTS

- CT-scan alone provides a middling diagnostic power to detect bowel involvement (sensitivity 57.5%, specificity 72.2%).
- The combination of CT with EXL provides a higher diagnostic power (sensitivity 94.3% and accuracy of 71%).
- The integrated diagnostic flow-chart using CT-scan and EXL, improves the diagnostic power to detect bowel involvement.

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ABSTRACT

Objective: This study investigates the diagnostic power of CT scan combined with exploratory laparoscopy (EXL) at identifying large bowel involvement in patients with stage IIIC-IV primary Epithelial Ovarian Cancer (EOC) by comparing with the macroscopic surgical findings at laparotomy.

Methods: All patients with FIGO Stage IIIC-IV EOC who had Visceral Peritoneal Debulking (VPD) were included in the study. Results of CT scan, EXL and laparotomy (LPT) with regards to the bowel involvement were prospectively recorded in an ad hoc study form. Setting LPT findings as the gold standard, positive and negative predictive value (PPV/NPV), sensitivity, specificity and accuracy of CT and EXL were calculated. In addition, the diagnostic power of the combination CT scan + EXL was investigated.

Results: Ninety-four out of 177 patients (53.2%) had a bowel resection during VPD. CT-scan alone had sensitivity, specificity, PPV, NPV and accuracy of 56.7%, 72.4%, 70.8%, 58.5% and 63.8% respectively. EXL alone 84.4%, 93.8%, 93.8%, 84.3%, 88.8%. CT combined with EXL detected bowel involvement with a sensitivity, specificity, PPV, NPV and accuracy of 87.5%, 70.4%, 77.8%, 82.6% and 79.6% and respectively. The combined tests showed a statistically significant improvement vs. CT scan alone ($p < 0001$) in sensitivity, NPV and accuracy, with non-significant difference in specificity and PPV.

Conclusions: CT-scan alone shows a limited diagnostic power at detecting large bowel involvement in patients with stage IIIC-IV EOC. The combination of CT scan with EXL increases the diagnostic power and enables to appropriately plan the bowel resection and consent the patients.

1. Introduction

Over 75% of the patients with Epithelial Ovarian Cancer (EOC) are diagnosed with a FIGO stage IIIC-IV. The standard treatment is surgery followed by chemotherapy or neoadjuvant chemotherapy followed by surgery. Irrespective of the surgical timing, the complete resection (CR) of all visible disease is associated with the best prognostic outcome [1–4]. Several studies reported that in 10–70% of the patients a bowel resection is needed to achieve a CR [5,6]. Usually the diagnosis of cancer invading adjacent organs from a primary site is suggested by radiology and it's based on the histology of a pre-operative biopsy. In patients with ovarian cancer, it is difficult to confirm bowel involvement before surgery [7]. In fact, ovarian cancer spreads to the bowel from the external layer and only invades the mucosa at a late stage, often denying the possibility of an endoscopic biopsy [8]. Also, a CT guided biopsy is not

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without risks because of the matted anatomic planes. Therefore, the diagnosis of bowel involvement relies on the imaging, particularly CT scan, as this is most commonly used in patients with ovarian cancer. Surprisingly, only few studies have compared the radiological reports of bowel involvement with the actual intra-operative findings [9,10]. Although a bowel resection is common during debulking surgery, guidelines on who should undertake the surgery in patients presenting bowel involvement are elusive, particularly in some countries [11,12]. To plan the operation in terms of complexity, patient consent and preparation towards possible intestinal diversion, it is very important to establish as accurately as possible the diagnosis of bowel involvement before the surgery. Also, while some Gynaecologic Oncologist are independently doing bowel surgery, others will need to summon the appropriate specialist to undertake the bowel surgery. In the present study we aimed to investigate the diagnostic power of CT scan combined with exploratory laparoscopy (EXL) at identifying sigmoid-rectum involvement in patients with stage IIIC-IV EOC by comparing with the macroscopic findings at surgery.

2. Materials and methods

2.1. Study design and data collection

Between February 2009 and April 2015, 200 consecutive patients with FIGO stage IIIC–IV EOC were candidate to Visceral Peritoneal Debulking (VPD) at one of 3 institutions: Istituto Clinico Humanitas (ICH, Milan, Italy), Fondazione San Raffaele Giglio (Cefalù, Palermo, Italy) and the Oxford University Hospital (OUH, Oxford, UK) under the care of one of the authors (RT). All patients were seen in the Department of Gynaecologic Oncology and discussed in the local multi-disciplinary team (MDT) meeting. The triage process elected patients to VPD if: 1. the performance status (PS) was scored as ASA < 2 at pre-operative assessment 2. CT review showed no lung or multiple parenchymal liver metastases and 3. Exploratory laparoscopy demonstrated no small bowel serosal disease or porta hepatis encasement according to the inclusion/exclusion surgical criteria (Table 1). In 2009 we registered a Service Evaluation Protocol (registration number 3267) approved by the Oxford University Hospital (OUH) Trust on the use of an exploratory laparoscopy (EXL) before VPD. All patients underwent at least one pre-operative CT-scan 6 weeks prior to the surgery. Each patient was asked to sign an informed consent on the use of EXL. A departmental Ovarian Cancer Surgical Database was used to record, monitor and audit surgical data. An ad-hoc designed form was filled to record the findings of CT scan, EXL and the laparotomy (LPT) with respect to all abdominal organs. The form presented 3 possible results: Y, yes (involved); N, not involved; D, doubtful. EXL and LPT were performed by different surgeons in the mentioned institutions. The operation would proceed to a VPD only if the exclusion criteria were ruled out. All data regarding pre-operative CT scan, EXL, macroscopic findings at LPT and final histology were collected in a dedicated electronic database. In this study we verify the accuracy of the diagnostic pathway with regards to the sigmoid-rectum involvement. Ninety-four out of 177 patients (53.2%) had an En-bloc resection of the pelvis including a sigmoid-rectum resection and they formed group A. Eighty-three patients (46.8%) had an En-bloc resection of pelvis with peritoneum but without a bowel resection forming group B. For the purpose of this report we reviewed all the study forms filled for the CT, EXL and LPT focusing on the bowel. Considering the macroscopic finding at LPT as the gold standard, we calculated the diagnostic power, defined by sensitivity, specificity, accuracy, positive predictive value (PPV) and negative predictive value (NPV) of CT scan and EXL. The results of each test were matched with the LPT and were compared among them individually. We also investigated whether the combination of these 2 tests can increase the diagnostic power. In addition, we reviewed the histology results for each patient. The latter was used to verify the accuracy of LPT at detecting bowl involvement. The study was written according the STARD 2015 guidelines for reporting diagnostic accuracy studies [13]. Study flow chart is displayed in Fig. 1.

Table 1
Inclusion/exclusion criteria for Visceral Peritoneal Debulking (VPD).

Inclusion criteria
• Histology proven or suspected stage IIIC–IV ovarian, tubal or peritoneal cancer with proven or suspected of large bowel involvement
• Performance status (PS), scored as ASA < 2 at pre-operative assessment
• Post-chemotherapy patients: stable disease or response at 3 or 6 cycles
Exclusion criteria
• Pre-operative: CT-scan: lung metastases, 3 or more liver segments involvement, disease progression following chemotherapy
• Intra-operative: diffuse small bowel miliary serosal deposits.
• Porta hepatis encasement
• Any evidence of other malignant neoplastic disease regardless the state of treatment

2.2. CT-scan

CT was performed on GE LightSpeed 64-slice MDCT (GE, Waukesha, Wisconsin, USA) scanner. Bowel preparation was not used. All patients received intravenous (150 cc Omnipaque-300) contrast medium before the examination. Scanning was commenced at 20–25 s at chest region and 70–80 s at abdomen and pelvis regions after injection. Images from both scanners were reconstructed at 1: 20 per 1·5 mm. In each institution, all CT scans were reviewed by consultant radiologists specialized in Gynaecologic Oncology, who were blinded to all patient information, including the final histopathologic diagnosis.

2.3. Surgical procedures

All patient underwent an EXL with a 10 mm port for the camera and one or two additional 5 mm trocars (Karl Storz, Tuttlingen, Germany) to manipulate organs or adhesiolysis. Once the possibility of a complete resection (CR) was confirmed, the patients underwent to a xifo-pubic laparotomy. The VPD technique was previously described [14]. The goal of the VPD was a CR of all visible tumours.

2.4. Histology

Dedicated pathologists specialized in gynaecologic oncology reported all VPD specimens. Samples were fixed in 4% formaldehyde for 12 h and then embedded in paraffin. The bowel specimen was opened longitudinally and 2-mm longitudinal bands of bowel wall, reaching the two resection margins and passing through all macroscopically visible lesions, were cut. These bands were sampled in tissue blocks and 5-μm sections were obtained for microscopic evaluation. Bowel involvement was defined when evidence of tumor was seen at least in the serosa. Among group B patients, the margins of the en-bloc resection closest to the bowel (Douglas pouch peritoneum) were assessed as a surrogate marker of bowel involvement.

2.5. Reference standard

LPT was elected as the reference standard because the decision on the performance of the bowel resection was made at time of surgery. The histology reports were not considered suitable because patients in group B did not undergo bowel resection. To

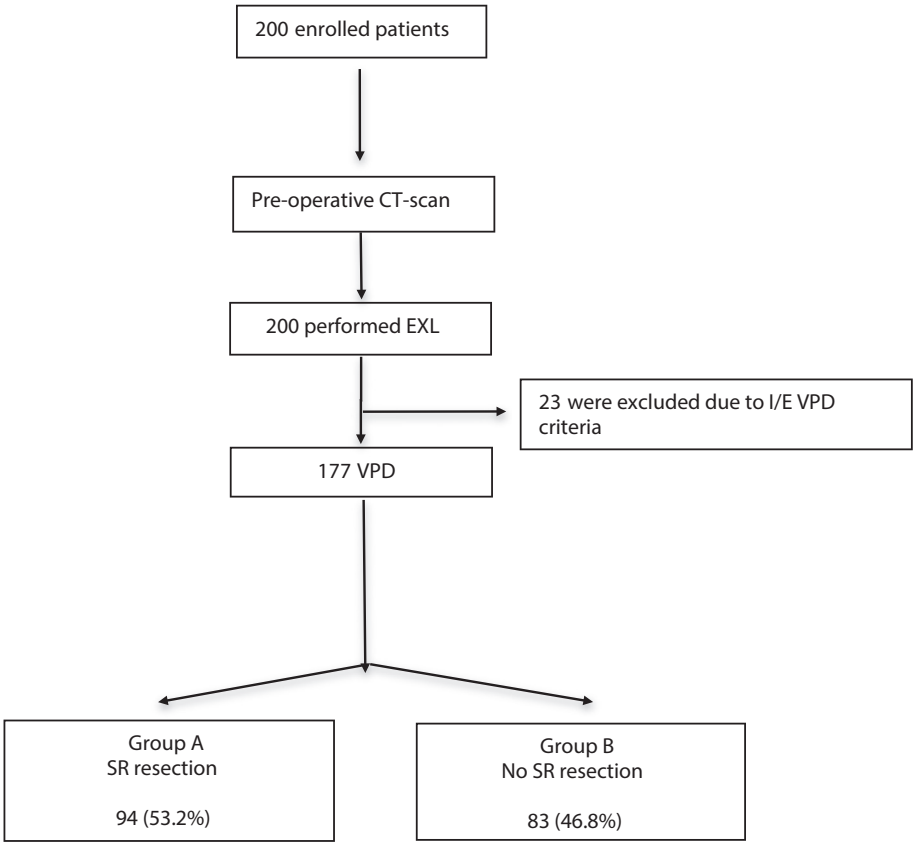

Fig. 1. Patient's selection process and results reported for each test (CT-scan, EXL, LPT). Legend: VPD, Visceral Peritoneal Debulking; CT, computed tomography; EXL, exploratory laparoscopy; SR, sigmoid rectum; LPT, xifo-pubic Laparotomy.

validate LPT as the standard reference, we compared the LPT findings with histology.

2.6. Statistics

Based on the Weinstein report [15], when combining CT scan with EXL findings, we considered these in parallel (i.e., at the same time and interpreted together) and we use the "OR rule". Accordingly, if CT scan and EXL were both negative, the combined result was negative. If either or both were positive, and/or one was doubtful, the combined result was positive. If either doubtful, the other test was used. Data were analysed using the chi-square test or Fisher's exact test for categorical variables and the Student's *t*-test for continuous variables. A p value +/> 0.05 was considered statistically significant. Specificity, sensitivity, positive and negative predictive value and accuracy were reported were calculated using a standard online statistical calculator program (© 1993–2016 MedCalc Software Version 16.4.3).

3. Results

In the study period, 200 consecutive patients with FIGO stage IIIC–IV EOC were candidates to have a VPD based on the CT scan. Of these, 177 proceeded to a VPD, while 23 (11.5%) did not due to exclusion criteria (Fig. 1). Patient's characteristics are reported in Table 2. Ninety-four (53.2%) had an En-bloc resection of pelvis with sigmoid-rectum resection (group A). Eighty-three patients out of 177 (46.8%) had En-bloc resection of the pelvis with peritonectomy without sigmoid-rectum resection (group B). The average age was 62 years (range 40–78), most women of both groups had stage IIIC disease and serous histology. In group A, 82 patients out of 94 (87.2%) had a sigmoid-rectum resection, 6 (6.4%) had sigmoid-rectum and colon resection, 6 (6.4%) had a sigmoid-rectum, colon and small bowel resection. The mean time between CT- scan and EXL/LPT (which were on the same day) was 32 days (range 18–90). No complications were recorded from the EXL. The results of the CT-scan, EXL, LPT and histology are reported in Table 3a. At LPT 96 patients had findings of large bowel involvement and 81 didn't; no doubtful results were recorded. Two patients had evidence of bowel involvement at LPT but didn't undergo bowel resection due to the impossibility to accomplish a CR (which was overlooked at EXL). Histology confirmed bowel invasion in 87 patients out of 94

Table 2
Patients' characteristics and surgical outcomes of Group A vs. Group B.

–	Group A	Group B
Patients, n (%)	94 (53.2%)	83 (46.8%)
Age, median (range)	63	61
Upfront, n (%)	42, (44.6%)	47, (56.6%)
Interval, n (%)	52, (55.4%)	36, (43.4%)
Tumor stage, n (%)		
IIIC	63 (67%)	58 (79.8%)
IV	31 (33%)	17 (20.2%)
Histology type, n (%)	On 94 patients	On 83 patients
Serous	62 (66%)	71 (85.5%)
Others	33 (34%)	12 (14.4%)
Type of bowel resection, n (%)	On 94 patients	–
Sigmoid-rectum resection, n (%)	82 (87.2%)	–
Sigmoid-rectum and colon resection, n (%)	6 (6.4%)	–
Sigmoid-rectum, colon and small bowel resection, n (%)	6 (6.4%)	–
Bowel involvement at histology, n (%)		
Yes	87 (92.5%)	–
No	7 (7.5%)	–

Table 3a
Results of CT-scan, EXL, LPT and Histology on bowel involvement.

Results	CT-scan	EXL	LPT	Histology
Yes, involved, (Y)	72	81	96	87
Not involved, (N)	94	89	81	90
Doubtful, (D)	11	7	0	0

(92.5%). Among group B ($n = 83$), none of the pelvic specimens had peritoneal margins involved by disease, indirectly confirming the lack of bowel involvement. The comparison between LPT and the histology reports is displayed in Table 3b. LPT had a sensitivity, specificity, PPV, NPV and accuracy of 100%, 92%, 92%, 100% and 94.9% respectively. Seven patients with false positive, were all interval VPD. Sensitivity, specificity, Positive Predictive value (PPV), Negative Predictive Value (NPV) and accuracy of CT-scan, EXL and CT-scan + EXL were calculated by comparing to LPT and are reported in Tables 4a; 4b.

3.1. CT-scan diagnostic power

CT scan reported 72 patients (40.6%) as having evidence of bowel involvement, 94 (53.1%) no evidence, 11 (6.2%) having doubtful results. The 11 doubtful reports were excluded from the evaluation of the CT scan alone but were included in the combined statistical analysis with EXL as explained above. CT scan detected bowel involvement with a sensitivity, specificity, PPV, NPV and accuracy (95% CIs) of 56.7%, 72.4%, 70.8%, 58.5% and 63.8% respectively.

3.2. EXL diagnostic power

EXL reported 81 patients (45.7%) as having evidence of bowel involvement, 89 (50.2%) no evidence. In 7 patients (2.9%) the bowel involvement was not assessable and were classified as doubts. EXL detected bowel involvement with a sensitivity, specificity, PPV, NPV and accuracy of 84.4%, 93.8%, 93.8%, 84.3%, and 88.8% respectively.

3.3. CT scan + EXL diagnostic power

Combining CT scan with EXL, the 11 doubtful CT-scan reports were helped by the EXL results; the 7 doubtful EXL reports were ed. by the helped by the CT-scan results. In no patients the two tests were doubtful simultaneously. The results of the joined tests reported 108 (61%) patients as having evidence of bowel involvement, 69 (40%) as no evidence. Considering LPT as the standard reference, CT scan + EXL detected bowel involvement with a sensitivity, specificity, PPV, NPV and accuracy of 87.5%, 70.4%, 77.8%, 82.6% and 79.6% respectively. The diagnostic power of CT-scan + EXL was compared with the diagnostic power of CT scan alone. The combined tests showed statistically significant improvement ($p < 0001$)

Table 3b
LPT macroscopic findings of bowel involvement compared to histology reports.

	LPT	Histology
Positive	94	87
Negative	81	81
False positive	7	
False negative	0	
	LPT vs. histology (%), [95% CI]	
Sensitivity	100% [0.97–1]	
Specificity	92% [0.86–0.95]	
PPV	92% [0.87–0.95]	
NPV	100% [0.97–1]	
Accuracy	94.9%	

Legend: VPD, Visceral Peritoneal Debulking; CT, computed tomography; EXL, exploratory laparoscopy; LPT, xifo-pubic Laparotomy.

Table 4a
CT-scan, EXL and CT + EXL evaluations compared to LPT.

	CT-scan	EXL	CT + EXL
Positive	51	76	84
Negative	55	75	57
False positive	21	5	24
False negative	39	14	12

in sensitivity, NPV and accuracy, whereas no significant differences were seen for specificity and PPV (Table 5). Finally comparing EXL with CT scan + EXL, EXL alone showed significantly higher specificity, PPV and accuracy ($p < 0.05$) but no significantly better sensitivity and NPV (Table 6). In all patients with CT-scan doubtful results, EXL correctly identified the bowel involvement as compared with LPT and histology. On the other hand, I patients with doubtful EXL results, in one patient only CT-scan correctly identified bowel involvement as per LPT and histology.

4. Discussion

The results of this study provide valuable information in the management of patients with stage IIIC-IV EOC. Bowel involvement in these patients is common and gynaecologic oncologist are traditionally used to deal with it. The finding is so common that a new technique was developed and published by Gynaecologic Oncologist years ago and gained popularity in other surgical disciplines, the en-bloc resection of the pelvis [11,16–18]. Our study demonstrates that the LPT has a high accuracy in detecting sigmoid-rectum involvement as compared to histology. In our reports, none of the patients who did not have a bowel resection had positive peritoneal margins or needed additional surgical procedure for bowel involvement. Only 7 patients (7.5%) who had a bowel resection were found with no bowel involvement at histology. They all had interval VPD after 3 cycles of chemotherapy and were found with a frozen pelvis. We believe that in these patients with matted organs it is often impossible and not safe to separate pelvic organs. In addition, the response to chemotherapy can make difficult to differentiate between active cancer and fibrosis. In these instances, the pelvic disease should be treated with an en-bloc resection as previously published [14]. Of note, 2 patients with evidence of bowel involvement at LPT did not receive bowel resection due to unexpected findings of disease which was overseen at EXL: both patients had small bowel serosa miliary disease. Despite multivisceral surgery with bowel resection is common in Gynaecologic Oncology, in some countries it is still disputed who must deal with bowel involvement. As a reflection of this uncertainty, in some countries, the core training of sub-specialist trainee in Gynaecologic Oncology is insufficient to give them independence [19–21]. Consequently, either they abandon the surgery, do an incomplete resection or involve a colo-rectal surgeon. For these Gynaecologic Oncologist who are not comfortable with bowel surgery, in order to avoid an aborted surgery, an incomplete resection but also to properly plan with other surgical teams, it is essential to have as

Table 4b
Sensitivity, specificity, Predictive Positive value (PPV), Negative Predictive Value (NPV) and accuracy (95% confidence interval, CI) of CT-scan, EXL and CT-scan + EXL by the reference standard (LPT).

	CT-scan (%), 95% CI	EXL (%), 95% CI	CT + EXL (%), 95% CI
Sensitivity	56.7 [0.48–0.64]	84.4 [0.77–0.89]	87.5% [0.81–0.92]
Specificity	72.4 [0.64–0.79]	93.8 [0.88–0.96]	70.4% [0.62–0.77]
PPV	70.8 [0.62–0.77]	93.8 [0.88–0.96]	77.8% [0.70–0.83]
NPV	58.5 [0.50–0.66]	84.3 [0.77–0.89]	82.6% [0.75–0.87]
Accuracy	63.8%	88.8%	79.6%

Legend: CT-scan, Computed tomography; EXL, exploratory laparoscopy; LPT, laparotomy; PPV, positive predictive value; NPV, negative predictive value; CI, confidence interval.

Table 5
CT scan alone vs. CT-scan + EXL.

	CT (%) [95% CI]	CT + EXL (%) [95% CI]	p value
Sensitivity	56.7 [0.48–0.64]	87.5% [0.81–0.92]	0.0001
Specificity	72.4 [0.64–0.79]	70.4% [0.62–0.77]	0.682670
PPV	70.8 [0.62–0.77]	77.8% [0.70–0.83]	0.1382
NPV	58.5 [0.50–0.66]	82.6% [0.75–0.87]	0.0001
Accuracy	63.8%	79.6%	0.0012

Legend: CT-scan, Computed tomography; EXL, exploratory laparoscopy; PPV, positive predictive value; NPV, negative predictive value; CI, confidence interval.

much information as possible before committing to a xifo pubic laparotomy. Traditionally the staging of patients with stage IIIC-IV ovarian cancer is done by CT scan because of a large field to study, time and costs [22]. Several studies in the past have demonstrated a significant discrepancy between the CT and the surgical findings [23–25]. The consequence is that in some of these patients with stage IIIC-IV ovarian cancer, a xifo-pubic laparotomy is ended with no resection because of surgical findings requiring procedures away from the capacity of the surgeon. These so called "aborted debulking" caused unnecessary morbidity particularly considering the fact that these patients are systemically compromised [12,26]. Beyond an obvious delay on the initiation of chemotherapy, among the reported complications of an "aborted debulking" were ileus, pleural effusion, infection, fluid third spacing, compartmentalization and even mortality [14]. In the last 5–10 years a few groups have introduced the routine use of an exploratory laparoscopy before committing to a xifo-pubic laparotomy [27–30]. The result of this report showed that the diagnostic flow-chart CT-scan + EXL is more reliable in diagnosing the presence of bowel involvement than CT scan alone. EXL excellently complemented CT-scan correctly detecting the presence of bowel involvement in the 11 patients where CT-scan ended with a doubtful result. The advantages of EXL are multiple, including a correct diagnosis based on the histology of tissue biopsy, precise evaluation of disease spread, better selection of the patients for ultra-radical surgery and the accurate planning of resources for the surgery. Arguably, the information about the bowel involvement could be helped by use of an MRI, which is meant to be accurate on soft tissue [31]. However, beyond the bowel involvement the MRI is unlikely to provide information on small miliary disease which EXL could provide. While no study has so far compared the routine use of MRI to CT in the staging of IIIC-IV ovarian cancer patients, the replacement of CT scan with MRI doesn't seem to be cost effective. Same applies to the use of EXL alone which was indeed the most reliable test in this study on bowel but could not replace the CT scan as the initial test as it will disproportionately increase the costs. Based on our results, the combination of CT and EXL displayed a better diagnostic power on the large bowel involvement than CT scan alone. Also, it can reliably anticipate the absence of bowel involvement. The non-randomised nature of this study could be a limit to the validity of this study. However, the consecutiveness of patients and the homogeneity of the groups should rule out any selection bias. The exclusion of patients who were not amenable to a CR was imposed by the method we used, as the surgical findings at laparotomy were elected as the reference standard. However, the number was small and would not affect the significance of our data. We also verified if the results were different braking down the groups by the initial treatment (up-front vs. interval surgery) but we failed to find any significant difference. Another limit concerns the fact that more radiologists evaluated the pre-operative CT-scans in the different hospitals. However, all of them were consultant radiologist dedicated to Gynaecologic Oncology. We believe that these data on the detection of bowel involvement are important. To proceed to a laparotomy without the EXL should a bowel involvement be suspected and pose a challenge to the operating surgeon could be hazardous. Likewise, appropriate consent to bowel resection, potential diversion and morbidity demands the most accurate pre-operative diagnostic power and information to the patients [32]. Some of them may well refuse the idea of a bowel resection with the potential risk of a bowel diversion. In these patients the EXL could be done in a different session from the LPT.

Table 6
EXL vs. CT-scan + EXL.

	EXL (%), [95%, CI]	CT+EXL (%), [95% CI]	p value
Sensitivity	84.4 [0.77-0.89]	87.5% [0.81-0.92]	0.406
Specificity	93.8 [0.88-0.96]	70.4% [0.62-0.77]	0.0001
PPV	93.8 [0.88-0.96]	77.8% [0.70-0.83]	0.0001
NPV	84.3 [0.77-0.89]	82.6% [0.75-0.87]	0.6707
Accuracy	88.8%	79.6%	0.0193

Contribution to authorship

RT designed the study, performed the surgery, data analysis and wrote the manuscript.

RG, MM, RCG, HSM, ZT contributed to the surgery, data collection, data analysis.

GV, YK, AB contributed to data collection and analysis.

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Declaration of competing interest

None.

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