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Multi-center experience of robot-assisted laparoscopic para-aortic lymphadenectomy for staging of locally advanced cervical carcinoma

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Key words
Cervical neoplasms, disease-free survival, laparoscopy, lymph node excision, para-aortic, robotics

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Conflict of interest
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Abstract

Objectives. FIGO classification is commonly used for staging of locally advanced cervical cancer. Laparoscopic para-aortic lymphadenectomy is currently used as a diagnostic tool, since we know that presence of para-aortic lymph node metastases identifies patients with poor prognosis. The application of robotics during this procedure needs to be investigated. *Design.* Retrospective multi-center study. *Setting.* Three centers participated in building one database. *Population.* Thirty-seven patients with locally advanced cervical cancer underwent a robot-assisted laparoscopic para-aortic lymphadenectomy. *Methods.* Patients were prospectively enrolled in one register. Retrospective analysis of the whole database was performed. *Main outcome measures.* Surgical outcomes of the robot-assisted procedure and follow-up data. *Results.* Median number of lymph nodes collected was 27.5 (1–54) per patient. Five of 37 patients had para-aortic node metastases. The false negative rate for PET-CT diagnosing para-aortic node metastases was 11.4% (4/35). Two major intra-operative complications occurred (5.4%). Postoperative morbidity was low (13.5%). Median follow-up was 27 months [95% confidence interval (95% CI) was 24–30]. Median disease-free survival was 16 months (95% CI 2.4–29.6). Patients with negative nodes had a median disease-free survival of 24 months (not assessable), although patients with positive nodes had a median disease-free survival of 9 months (95% CI 6.9–11.9). *Conclusions.* In this series we report that robot-assisted laparoscopic para-aortic lymphadencetomy provided the surgeon with useful information, diagnosing 11.4% of occult para-aortic lymph node metastases in women with locally advanced cervical cancer. Intra-operative and postoperative morbidity were low. The presence of para-aortic lymph node metastases correlated with shorter disease-free survival.

Abbreviations: CT, computed tomography; FIGO, International Federation of Gynecology and Obstetrics; LACC, locally advanced cervical cancer; LN, lymph node; MRI, magnetic resonance imaging; PET, positron emission tomography; PET-CT, positron emission tomography coupled with computed tomography.

Introduction

Staging of locally advanced cervical cancer (LACC) must be completed before treatment. The International Federation of Gynecology and Obstetrics (FIGO) classification is based on clinical examination. Use of computed tomography (CT), magnetic resonance imaging (MRI),

Key Message

Robot-assisted laparoscopic para-aortic lymphadenectomy helps gynecologic oncologists to diagnose 11.4% of occult para-aortic lymph node metastases in women with locally advanced cervical cancer. These data are comparable with data published in the same population after conventional laparoscopic staging.

positron emission tomography (PET) or surgical techniques including para-aortic lymphadenectomy is now encouraged by the FIGO to complete the clinical staging (1–5). The rationale for the FIGO approach is to provide a template so that both resource-rich and resource-poor countries can compare data by stage in order to standardize management of the disease.

Clinical examination is used to assess tumor size, parametrial and pelvic side-wall invasion but does not provide any information about the status of pelvic and/or para-aortic lymph nodes (LNs). This leads to underestimation of the pathological extension of the tumor in some patients (6,7). Involvement of LN is associated with worse prognosis. Management of patients should be adapted to their LN status (8,9). One option consists of evaluating the LN invasion using imaging techniques. However, as published by Mortier et al. (10), false negative rates as high as 11% have been reported when comparing PET with lymphadenectomy in LACC. This data has been confirmed in two more recent studies in a comparable population (11,12). Uzan et al. (11) and Ramirez et al. (12) reported a false negative rate of respectively 8.4 and 12% for PET-CT diagnosing para-aortic LN metastases compared with laparoscopic LN dissection. This false negative rate for PET-CT diagnosing para-aortic LN metastases rises to 22% when pelvic nodes are suspected to be involved on PET-CT (12). Analyzing these data, surgical staging of patients with suspected positive pelvic LN on PET-CT seems to be helpful to adapt further management. Recent data suggest that para-aortic lymphadenectomy in patients with negative PET-CT for pelvic LN remains debatable. The rate of false negative para-aortic LN is, in those patients, equivalent to the complication rate of staging surgery, especially if followed by extended chemoradiation (13).

Laparoscopic para-aortic node sampling has been shown to be feasible in gynecological malignancies (14–21). Its only technical limitation occurs in obese patients. However, using the classical laparoscopic approach, the surgeon is limited in the degrees of his movements. Robot-assisted laparoscopic para-aortic lymphadenectomy avoids some of these limitations. The feasibility of a robotically assisted para-aortic lymphadenectomy has been described by several authors (22–25), who reported that the procedure was safe and provided the surgeon with great precision and comfort dissecting para-aortic nodes. Morbidity in these series was low and the authors judged that larger trials were needed to validate the use of this technique (24). The present report provides data that were prospectively collected in three Belgian centers to assess oncological safety and complication rates of this procedure. Follow-up data was also analyzed in our series in order to compare the findings with previous reports.

Material and methods

Three Belgian centers participated in this study (here called centers 1, 2 and 3). We prospectively followed 37 patients from October 2007 to December 2011. In all three centers, physicians offered pretreatment robot-assisted laparoscopic para-aortic lymphadenectomy to patients with advanced cervical carcinoma (FIGO IB2 – IVA) or patients with early stage disease (FIGO IA1 – IB1) who had histologically proven positive pelvic LN. The surgical results of some of these patients were reported earlier (22,23). The patient characteristics are presented in Table 1.

In brief, our protocol is the following: cervical carcinoma should be confirmed using cervical biopsy and/or conization. FIGO classification is defined for each patient by clinical pelvic examination. Pelvic MRI, thoracic CT scan and PET are performed in all patients. Examination under anesthesia and cystoscopy is systematically performed by a senior gynecologic oncologist. Recto-sigmoïdoscopy is performed when invasion of the bowel mucosa is suspected. After clinical examination under anesthesia and cystoscopy, a robot-assisted laparoscopic para-aortic lymphadenectomy is performed in all patients. Prior to surgery, patients undergo bowel preparation consisting of a three- to five-day fiber-free diet and a complete intestinal enema the day before the procedure.

Robotic retroperitoneal lower para-aortic lymphadenectomy has been described previously by Vergote et al. (22). Robot-assisted laparoscopic transperitoneal para-

Table 1. Patient characteristics in each center and Belgian data.

Institution	Location	Patients *n*	LACC (FIGO IB2-IVA) or FIGO IB1 N^+ SCC[a]	Median age	Median body mass index (kg/m^2)
Center 1	Brussels	22	22	55 (32–78)	27 (17–37)
Center 2	Liège	8	8[a]	54.5 (36–73)	24.5 (17–32)
Center 3	Leuven	7	7	50.5 (27–74)	24 (19–29)
Belgian data	Belgium	37	37	52.5 (27–78)	27 (17–37)

[a]One patient with operated FIGO IB1 squamous cervical carcinoma (SCC) and positive pelvic node underwent a para-aortic lymph node staging and was included in the database.
LACC, locally advanced cervical carcinoma.

aortic lymphadenectomy has been descibed previously by Fastrez et al. (23). The present study has been approved by the steering committee of the Belgian Gynecologic Oncology Group (BGOG). Follow-up data were collected prospectively until 31 December 2011.

Statistical analysis

Descriptive statistics were used to summarize the clinicopathologic characteristics of the study sample. The Kaplan–Meier method was used to estimate overall survival and disease-free survival; the reverse Kaplan–Meier method was used to estimate median length of follow-up.

Results

In center 1, 22 patients underwent a robot-assisted transperitoneal para-aortic lymphadenectomy up to the renal vein. In center 2, eight patients underwent a robot-assisted laparoscopic transperitoneal para-aortic lymphadenectomy up to the inferior mesenteric artery, whereas in center 3, seven patients underwent a robot-assisted retroperitoneal lower para-aortic lymphadenectomy up to the inferior mesenteric artery. The median age was 52.5 years (range 27–78) and the median body mass index 27 kg/m^2 (range 17–37). Details by center are reported in Table 1. All 37 patients had been diagnosed with locally advanced squamous cell carcinoma or adenocarcinoma of the cervix (FIGO IB2 – IVA) with the exception of one of the eight patients from center 2, who had a stage FIGO IB1 squamous cell carcinoma with metastatic pelvic node suspected on pre-operative PET-CT. She underwent a pelvic node surgical staging, confirming the presence of metastatic pelvic node at frozen section. Para-aortic staging was then conducted in the same operating time and the patient was included in our database. In one patient of the 22 from center 1, who had previously undergone a radical hysterectomy (laparoscopic Wertheim–Meigs procedure) for a stage FIGO IB2 squamous cell carcinoma, one of the pelvic nodes was invaded (pTIB2N1Mx), indicating a para-aortic lymphadenectomy to complete the staging. This patient was also included in our database.

Results of pre-operative PET-CT for para-aortic LN examination and their correlation to LN histological analysis are presented in Table 2. Five patients of 37 had isolated para-aortic LN metastatsis, although four of them had negative pre-operative PET-CT for para-aortic LNs. Three of these four had suspiscious positive pelvic LN on pre-operative PET-CT. In this series, the false negative rate for diagnosis of para-aortic LN metastatses in LACC with PET-CT was 11.4%.

Operative characteristics are summarized in Table 3. We encountered two major intra-operative incidents: one partial section of the right ureter occurred during a retroperitoneal LN dissection (ureter was sutured robotically) and one aortic injury during a transperitoneal para-aortic dissection, which necessitated conversion to laparotomy to suture the defect in the vessel. One patient needed transfusion of two units of blood to correct loss of hemoglobin due to an abdominal wall hematoma by the right robotic port, that we imputed was due to an injury of the right epigastric artery.

Table 2. Results of pre-operative positron emission tomography-computed tomography (PET-CT) in relation to lymph node histological status.

	Lymph node positive	Lymph node negative	Total
PET+	1	1	2
PET–	4	31	35
Total	5	32	37

False negative rate for PET detecting positive lymph node was 4/35 (11.4%).

Table 3. Intra-operative data detailed by center.

	Center 1	Center 2	Center 3	Belgium
Trans/retro peritoneal dissection	Trans	Trans	Retro	
Level (no. of patients)	Infra-renal (22)	Infra-mesenteric (8)	Infra-mesenteric (7)	37
Da Vinci system	Da Vinci (3 arms)	Da Vinci S (4 arms)	Da Vinci S (4 arms)	
Median operating time (skin to skin)	165 min (90–240)	220 min (120–340)	100 min (60–140)	200 (60–340)
Concomitant procedure	No	Yes (5/8)[a]	No	5/37
Number of lymph nodes dissected	19.5 (1–38)	29.5 (5–54)	9.5 (7–12)	27.5 (1–54)
Patients with positive lymph nodes	3/22	1/8	1/7	5/37 (13.5%)
Hemoglobin fall postoperative day 1 (g/dL)	0.85 (0–1.7)	1.35 (0–2.7)	0.95 (0–1.9)	1.35 (0–2.7)
Intra operative incident	arterial injury à laparotomy	No	1 ureteral injury robotic management	2 major incidents/37 (5.4%)

[a]Concomitant procedures included pelvic lymphadenectomy and/or ovarian transposition. All procedures were managed robotically.

Table 4. Postoperative data detailed by center.

	Center 1	Center 2	Center 3	Belgium
Post-op stay (days)	6 (2–10)	3 (2–4)	2.5 (2,3)	6 (2–10)
Post-op morbidity (number of patients)	4/22 (1 chylous ascitis, 2 symptomatic lymphocoele, 1 epiploïc hernia through umbilical port)	1/8 (1 symptomatic lymphocoele)	0/7	5/37 (13.5%)
Re intervention	1/22	0/8	0/7	1/37
Blood transfusion	1/22	0/8	0/7	1/37

The median number of para-aortic LNs resected was 27.5 (range 1–54). Post-operative data are summarized in Table 4. The median hospital stay after surgery was 6 days (range 2–10). Recovery after the procedure was rapid. Postoperative morbidity included one chylous ascitis, three symptomatic lymphoceles and one epiploic hernia through the umbilical port on postoperative day 7. There was only one re-intervention, to re-integrate the epiploic hernia inside the abdomen and correct the fascial defect due to the port.

Thirty patients (one with stage pTIB2N1Mx, one with FIGO IB1 and positive pelvic nodes, and 28 patients with FIGO stage IB2 to IVA cervical cancer, all staged with negative para-aortic nodes) were eligible for pelvic radiotherapy, 45 Gy in 25 fractions combined with weekly concomitant cisplatinum 40 mg/m^2 followed by brachytherapy. Five patients with positive para-aortic LNs confirmed by microscopical examination were eligible for pelvic extended to para-aortic region radiation, 75 Gy in 25 fractions combined with weekly concomitant cisplatinum 40 mg/m^2 + brachytherapy. One patient with stage IVA squamous carcinoma, who had previously been treated with pelvic radiotherapy combined with weekly cisplatinum and brachytherapy in India, and who had negative para-aortic nodes, was eligible for posterior pelvic exenteration. One patient with a FIGO IIA2 squamous cell carcinoma and negative para-aortic nodes was eligible for neoadjuvant chemotherapy followed by radical surgery.

Median follow-up of the patients was 27 months [95% confidence interval (95% CI) 24–30]. Two patients were lost to follow-up after respectively 10 and 7 months. At the time of analysis, 20 patients had relapsed and 15 had died. Fourteen of 15 patients died of disease. One patient died of a stroke during treatment. Median disease-free survival was 16 months (95% CI 2.4–29.6). Patients with negative LN had a median disease-free survival of 24 months (not assessable), whereas patients with positive LN had a median disease-free survival of 9 months. Site of recurrence was pelvic only in 35.3% (6/17) and extra-pelvic, including peritoneum, liver and/or chest, in 64.7% (11/17). Statistical analysis on overall survival was not performed. Longer follow-up is needed.

Discussion

The feasibility and safety of robot-assisted laparoscopic para-aortic lymphadenectomy has been described previously (22,23). Two larger cohorts have been published to assess the technical outcome of this procedure (24,25). The registration of robotic surgical procedures in gynecologic oncology in a national register is an initiative of the Belgian Gynecologic Oncology Group with the purpose of establishing a large prospective database to follow complication rates, pathological findings and oncological outcome of patients. Using this series, we report the results of 37 patients who underwent a robot-assisted laparoscopic para-aortic lymphadenectomy with the specific indication of staging LACC.

In our study there were two major differences regarding the operative technique used in the three centers. The first difference relates to the lymphadenectomy access: one center performed dissection of para-aortic LNs through a retroperitoneal access, whereas the other two centers used a transperitoneal approach. The second difference relates to the level of dissection: in two of the three centers, infra-mesenteric para-aortic lymphadectomy was performed, whereas surgeons in the third center dissected para-aortic nodes up to the renal vein (see Table 3).

Postoperative stay was short in our experience: 2.5 days (2,3) in center 3 and 3 days (2–4) in center 2. It was significantly higher in center 1: 6 days (2–10). In some cases, prolonged hospitalization occurred due to the pre-existing anemia and inflammatory syndrome, symptomatic lymphocoele, or social context. Intra- and postoperative morbidity rates were, respectively, 5.4% (2/37) and 13.5% (5/37), which is comparable, considering our learning curve, to data available for the same procedure performed by laparoscopy (4).

The number of assessed LNs was significantly different between the three centers [19.5 (1–38) in center 1, 29.5 (5–54) in center 2, and 9.5 (7–12) in center 3] due to the use of a different surgical technique in each center. Although we did not observe any difference in the proportion of LN metastases diagnosed between the three

centers (3/22 in center 1, 1/8 in center 2, 1/7 in center 3), our sample is too small to draw conclusions about the significance of this. However, we diagnosed five patients (13.5%) with para-aortic node metastases, although a pre-operative PET-CT was negative for extra-pelvic metastases in four of five patients. This equates to a false negative rate of 11.4% for the diagnosis of para-aortic LN metastases in LACC with PET-CT. This finding is comparable to data reported by other authors in the same population (10–12), performing para-aortic LN staging for LACC in larger cohorts of patients using conventional laparoscopy, which is regarded as the standard procedure for this indication. We therefore think that the oncological safety provided by robot-assisted laparoscopic para-aortic lymphadenectomy is good, avoiding the underestimation of para-aortic microscopic node metastases due to PET-CT limits.

In this series, we observed that disease-free survival was dramatically shorter in patients with para-aortic LN microscopic metastatic involvement than in patients with para-aortic negative LN, despite extension of the radiation field when positive para-aortic LNs were found. These findings are in agreement with those of Vergote et al. (26), who found a high recurrence and mortality rate in patients with para-aortic LN microscopic metastasis in stage IB2 – IIIB LACC. On the other hand, in a retrospective study of 184 patients with LACC, Leblanc et al. (27) found that the number and size of node metasases were important prognostic factors. In their series, para-aortic node dissection seemed to have a therapeutic benefit, as no survival difference was observed between patients with node-negative disease who received a pelvic treatment alone and patients with microscopic nodal disease (≤ 5 mm) managed with definitive extended-field (chemo)radiation therapy. These data remind us of the importance of para-aortic LN staging in LACC in relation to the prognosis of the patient and treatment adaptation.

Recent data concerning the rate of para-aortic LN metastases in relation to pelvic LN status on PET-CT should help physicians to properly select patients eligible for para-aortic lymphadenectomy (13).

Robotic assistance with the Da Vinci system provide the surgeon with more precise dissection conditions thanks to the three-dimensional visualization and instrumentation with articulating tips, which gives the surgeon's hands greater mobility and decreases tremor movements (28,29). This increased precision in procedure compared with a classical laparoscopy is particularly important in the para-aortic region and may enhance safety and decrease intra-operative morbidity. There are several possible theoretical disadvantages to the use of robot surgery: its prolonged operating time, higher cost, and the necessity to use a larger number of trocars.

Regarding operating time, Magrina et al. (29) compared patients undergoing robotic radical hysterectomy with equivalent population of patients operated by laparoscopy and laparotomy. Operating times for robotics and laparotomy were similar, and significantly shorter than with laparoscopy. Blood loss, rate of blood loss, and length of hospital stay were similar for laparoscopy and robotics and were significantly reduced compared with laparotomy. There were no significant differences in intra- or postoperative complications among the three groups (29). Reducing operating time by performing robot-assisted laparoscopic para-aortic lymphadenectomy could lead to a reduction in intra- and immediate postoperative morbidity. This issue needs to be investigated through randomized controlled trials. The use of multiple ports to perform robot-assisted laparoscopic para-aortic lymphadenectomy should also be a matter of future research. The feasibility of this procedure through a single port access in conventional laparoscopy has recently been shown (30). The last generation of Da Vinci systems (Da Vinci Si) has also been developed as a single port technology, and should be investigated with regard to para-aortic lymphadenectomy.

In conclusion, the feasibility and technical safety of robot-assisted laparoscopic para-aortic lymphadenectomy has been assessed in previous studies (22–25). The oncological safety of this procedure in the staging of LACC is indicated by our results, thanks to the diagnostic rate of microscopic para-aortic LNs metastases of 11.4%. This is an important issue that has been assessed before by several authors (10–12). Our disease-free survival data confirm that patients with positive para-aortic LNs have a significantly poorer prognosis than patients without LN metastatses, despite extension of radiotherapy to the para-aortic region. Longer follow-ups are needed to analyze overall survival data. The advantages offered by robot assistance to the conventional laparoscopic procedure should be studied in prospective randomized controlled trials if the cost of the robotic technique is to be justified.

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