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Observational BGOG Study of the Results of Robot-assisted Laparoscopy in 166 Patients with FIGO 2009 Stage IA1-IB1 Cervical Cancer

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ABSTRACT **Study Objective:** Two recent studies (the Laparoscopic Approach to Cervical Cancer [LACC] trial and a cohort study based on the National Cancer Database) raise the question of whether minimally invasive surgery (conventional and robot-assisted laparoscopy) is inferior to open abdominal surgery in early-stage cervical cancer. In the laparotomy group of the LACC trial, the low rates of recurrence and death are notable. The present study wants to elucidate the current situation of patients with early-stage cervical cancer treated with robot-assisted laparoscopy in hospitals of the Belgium and Luxembourg Gynaecological Oncology Group (BGOG).

Design: This is a prospective follow-up study.

Setting: The combined data obtained from different BGOG hospitals were analyzed regarding patients similar to those included in the LACC trial in terms of cervical cancer recurrence and survival.

Patients: We included patients with stage IA1, IA2, or IB1 cervical cancer with a histologic subtype of squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma.

Interventions: All patients were treated with robot-assisted laparoscopy.

Measurements and Main Results: The outcomes were disease-free and overall survival at 3 and 5 years after surgery. A total of 270 patients were included, and 166 were found suitable for analysis. The median age was 45 years. Most patients had International Federation of Gynecology and Obstetrics stage IB1 cervical cancer (84.9%) and squamous cell carcinoma as the histologic subtype (71.7%). The median follow-up time was 44 months, with a range of between 1 and 131 months. Twenty-one recurrences and 12 deaths were noted. Of the deaths, 8 were related to cervical cancer. Disease-free survival was 86% at 3 years (95% confidence interval [CI], 78.52−90.80) and 85% at 5 years (95% CI, 77.03−89.95). Overall survival was 96% at 3 years (95% CI, 90.11−98.22) and 91% at 5 years (95% CI, 82.54 95.17).

Conclusion: The results of this BGOG study show disease-free and overall survival rates after robot-assisted laparoscopy in early-stage cervical cancer that are at least similar to previous reported recurrence and survival data. We expect that the results of the Robot-assisted Approach to Cervical Cancer trial will elucidate the place of robot-assisted laparoscopy in early-stage cervical cancer. Journal of Minimally Invasive Gynecology (2021) 28, 1920−1926. © 2021 AAGL. All rights reserved.

Keywords: Cervical neoplasms; Da Vinci robot; Recurrence; Survival

Current guidelines [1,2] for the treatment of early-stage cervical cancer (i.e., International Federation of Gynecology and Obstetrics [FIGO] 2009 stages IA2, IB1, IB2, and IIA1) state that surgery is the preferred approach.

The authors declare that they have no conflict of interest.

A subset of the results of this study was presented as a poster at the European Society of Gynaecological Oncology Congress in Athens, Greece, on November 2 - 5, 2019.

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available because they contain information that could compromise the privacy of the research participants.

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Radical hysterectomy with pelvic lymphadenectomy remains the cornerstone of the treatment. This can be performed as an open or minimal invasive procedure. Retrospective studies [3−5] show less intraoperative blood loss, shorter hospital stay, and fewer postoperative complications when it is conducted using a minimally invasive approach. Multiple retrospective studies [3,4,6,7] showed no inferiority in disease-free survival and overall survival for the minimal invasive procedures (conventional laparoscopy and robot-assisted laparoscopy) in comparison with open surgery. These results were in line with the results [8−12] of endoscopic surgery for other malignancies. Near the end of 2018, 2 articles (the Laparoscopic Approach to Cervical Cancer [LACC] trial [13] and a 2-part registry study [14] based on the National Cancer Database (NCB) and the Surveillance, Epidemiology, and End Results [SEER] database) were published that raised the question of whether the laparoscopic approach to early-stage cervical cancer is inferior to open surgery. The present study sought to elucidate the current situation of patients with early-stage cervical cancer treated with robot-assisted laparoscopy in hospitals that are part of the Belgium and Luxembourg Gynaecological Oncology Group (BGOG). We examined data concerning patients similar to those included in the LACC trial in terms of cervical cancer recurrence and survival.

Materials and Methods

Study Population

In this prospective follow-up study, the combined data obtained from different BGOG hospitals were analyzed regarding patients with early-stage cervical cancer treated by robot-assisted laparoscopy. The 5 hospitals that cooperated were AZ Klina (Brasschaat), UZ Leuven (Leuven), CHR de la Citadelle (Luik), OLV Ziekenhuis (Aalst), and AZ Sint Jan (Brugge). We used the same inclusion and exclusion criteria as in the LACC trial. Patients were included if they had stage IA1, IA2, or IB1 cervical cancer (using the FIGO classification [15] of 2009) and a histologic subtype of squamous cell carcinoma, adenocarcinoma, or adenosquamous carcinoma.

The exclusion criteria were poor performance status (i.e., Eastern Cooperative Oncology Group score >1), positive lymph nodes on imaging, neoadjuvant therapy, and trachelectomy or simple hysterectomy instead of radical hysterectomy.

The study was approved by the ethics committee of AZ Klina (approval number: 115/200/020).

Outcomes

Recurrence status was checked during standard follow-up visits with clinical examination and imaging (ultrasonography or positron emission tomography−computed tomography [CT]). In case of recurrence, additional imaging was executed (positron emission tomography−CT, CT, or magnetic resonance imaging) so that the location and extent of the relapse could be visualized and proven on biopsy. The recurrences were divided into solitary and multiple recurrences, and the solitary recurrences were subdivided into vaginal, pelvic, and other locations.

The primary outcomes were postoperative disease-free survival at 3 and 5 years. The secondary outcomes were overall survival at 3 and 5 years.

Data Analysis

All data were collected in March 2019 using Microsoft Excel (Microsoft Corporation, Redmond, WA). Analyses were performed with SAS v.9.4 (SAS Institute Inc., Cary, NC). Kaplan-Meier estimates were used for all time-to-event outcomes. A log-rank test was used for comparing groups on time-to-event outcomes. Disease-free survival was defined as the months between the date of surgery and the date of the last follow-up visit during which there was no sign of recurrence or the date on which the recurrence was diagnosed. Overall survival was calculated by counting the months between the date of surgery and the date of death or the date of the last visit.

A p value of .05 was used as a cutoff for statistical significance.

Results

Study Protocol

In total, 270 patients were operated on with the Da Vinci robot (Intuitive Surgical, Sunnyvale, CA) between July 2007 and February 2019. One hundred four patients were excluded from the analysis. The reasons for exclusion were premalignant stage (cervical intraepithelial neoplasia III) (n = 1), FIGO >stage IB1 (n = 62), Eastern Cooperative Oncology Group score >1 (n = 2), histologic type (total, n = 11: neuroendocrine, n = 4; neuroepithelioma, n = 1; small cell, n = 1; Brenner, n = 1; sarcoma, n = 1; lymphoepithelial, n = 1; glassy cell, n = 1; and fibroblastic malignant peripheral nerve sheath tumor, n = 1), positive lymph nodes on imaging (n = 3), neoadjuvant therapy (n = 10), and the performance of only a trachelectomy or simple hysterectomy instead of radical hysterectomy (n = 4). Furthermore, patients who had had a recent operation (follow-up time <1 month) (n = 4) and those who were lost to follow-up after the operation (n = 7) were excluded.

A total of 166 patients remained. Eleven patients in this group only received a pelvic sentinel procedure; no complete lymphadenectomy was performed.

Three patients received only a lymphadenectomy, without radical hysterectomy, because the sentinel node biopsy was positive on frozen section.

In our cohort, no intrauterine manipulators were used during surgery.

Table 1

Patient and operation characteristics

Characteristics	Values
Age, median (range), yrs	45 (29−80)
Premenopausal state, %	62.7
Body mass index, median (range), kg/m^2	23.6 (15.6−41.2)
Ethnicity	
White race, %	94.6
FIGO stage, %	
IA1	8.43
IA2	6.63
IB1	84.94
Operation time (skin to skin), median (range), min	252 (63−445)
Hospital stay, median (range), d	3 (1−40)

FIGO = International Federation of Gynecology and Obstetrics.

Patient and Tumor Characteristics

The median age of the patients was 45 years, with a range of between 29 and 80 years. The median body mass index was 23.6 kg/m^2. Most patients were premenopausal (62.7%), and almost all patients were of the white race (94.6%). The patients' and operations' characteristics are summarized in Table 1.

Most patients had FIGO stage IB1 cervical cancer (84.9%). Squamous cell carcinoma was the most frequent histologic subtype (71.7%), followed by adenocarcinoma (24.7%) and adenosquamous carcinoma (3.6%). Of the patients, 7.3% had lymph node invasion; 18.7% received adjuvant therapy, which consisted mostly of chemoradiation (67.7%); 29% received only radiation; and 3.3% received only chemotherapy. Details of the patients' tumor pathologic findings are summarized in Table 2.

Table 2

Tumor pathologic findings

Tumor pathology	Values
Histologic type, %	
Squamous cell carcinoma	71.7
Adenocarcinoma	24.7
Adenosquamous carcinoma	3.6
Postoperative tumor size, %	
A (<2 cm)	64.5
B (≥2 cm to <4 cm)	19.9
C (≥4 cm)	2.4
Unknown	13.3
Lymphovascular space invasion	
Negative, n/N (%)	91/138 (65.94)
Positive, n/N (%)	47/138 (34.06)
Parametrial invasion	
Negative, n/N (%)	149/156 (95.51)
Positive, n/N (%)	7/156 (4.49)
Positive lymph nodes, %	7.3
Adjuvant therapy, %	18.7
Chemoradiation	67.7
Radiation	29
Chemotherapy	3.3

Survival Analysis

The median follow-up time was 44 months, with a range of between 1 and 131 months. A total of 21 recurrences occurred in our study population. Most patients had a solitary metastasis when the recurrence was noted in the vaginal vault (8 patients) or in another location in the pelvis (7 patients). Details of the patients with a recurrence are listed in Tables 3 to 5.

Twelve deaths were noted, of which 8 were related to cervical cancer. Disease-free survival was 86% at 3 years (95% confidence interval [CI], 78.52−90.80) and 85% at 5 years (95% CI, 77.03−89.95) (Fig. 1). Overall survival was 96% at 3 years (95% CI, 90.11−98.22) and 91% at 5 years (95% CI, 82.54−95.17) (Fig. 2).

Discussion

Our results are consistent with survival data of the American Cancer Society (5-year survival rate of 92% in localized cervical cancer [using the SEER stages]) and the Canadian Cancer Society (5-year survival rates with early-stage cervical cancer of 93% [stage IA] and 80% [stage IB]).

The LACC trial [13] is a randomized study, which compared laparotomy with minimally invasive surgery (MIS) in early-stage cervical cancer. The trial was prematurely closed because of the discrepancy in survival outcome in favor of the open approach (99.0% survival [open approach] after 3 years vs 93.8% [laparoscopic approach]).

Concerns about the LACC trial had already been published [16,17]. Only 37% of the data had been completed. In 30% of the patients, no final tumor size or invasion depth was mentioned. Adjuvant therapy was not specified. Recurrences in the MIS group were focused on only 14 of the 33 participating sites. And the very high survival rate in the open group remains remarkable [18].

The reasons for the discrepancy in survival outcome in favor of the open approach had been previously suggested [17]. The length of the vaginal cuff might be harder to assess with laparoscopy, and the anterior traction needed to perform a proper resection of the uterosacral ligaments might be harder to establish because of the limited working space. Other hypotheses suggested the dissemination of tumor cells by carbon dioxide (although this was not noted for other tumor types) and the spilling of cells with intracorporeal colpotomy or when a uterine manipulator was used [19]. Furthermore, it has been suggested that the learning curve for MIS is a contributor, especially in sites with low incidence.

Another study [14] added to the uproar: a 2-part registry study in which the authors reviewed 2 large databases: the

Table 3

Details recurrences

Recurrences	Age at diagnosis, yrs	Histologic type	FIGO stage	Postop Tx	Type of adjuvant Tx
1	40	Epidermoid	IB1	None	
2	80	Epidermoid	IB1	None (refused by patient)	
3	39	Epidermoid	IB1	None	
4	80	Adenocarcinoma	IB1	None	
5	42	Adenocarcinoma	IB1	None	
6	41	Adenocarcinoma	IB1	None	
7	46	Epidermoid	IB1	None	
8	63	Epidermoid	IB1	Yes	EBRT + concomitant chemotherapy
9	38	Epidermoid	IB1	Yes	EBRT
10	59	Epidermoid	IB1	None	
11	34	Squamous	IB1	None	
12	42	Squamous	IB1	None	
13	42	Adenocarcinoma	IB1	None	
14	41	Squamous	IA2	None	
15	31	Squamous	IB1	Yes	Concomitant chemoradiotherapy
16	64	Adenocarcinoma	IB1	None	
17	34	Villoglandular	IB1	None	
18	35	Squamous	IB1	None	
19	45	Squamous	IB1	None	
20	33	Squamous	IB1	None	
21	48	Squamous	IB1	None	

EBRT = external beam radiotherapy; FIGO = International Federation of Gynecology and Obstetrics; Tx = treatment.

NCB and the 18-registry SEER database. In their primary analysis, the authors conducted an inverse probability of treatment propensity-score weighting with the NCB data of radical hysterectomies for stage IA2 or IB1 cervical cancer between 2010 and 2013. This revealed a higher mortality risk within 4 years after diagnosis in the MIS group. However, if we look at the tumor characteristics, the patients in the laparotomy group had a more favorable profile.

Table 4

Details recurrences - part 2

Recurrences	Months after surgery	Solitary or multiple	Location	Death	Number of months between surgery and death
1	24	Solitary	Pelvic	No	
2	20	Solitary	Vaginal	No	
3	30	Solitary	Pelvic	No	
4	14	Multiple	Vaginal, rectum, bladder	Yes	20
5	11	Solitary	Vaginal	No	
6	25	Multiple	Vaginal, bladder, sigmoid	No	
7	7	Solitary	Vaginal	Yes	42
8	27	Solitary	Pelvic	Yes	30
9	9	Solitary	Pelvic	No	
10	14	Solitary	Pelvic	No	
11	16	Solitary	Pelvic	Yes	42
12	23	Solitary	Vaginal	No	
13	7	Solitary	Presacral	Yes	24
14	71	Solitary	Vaginal	No	
15	13	Solitary	Pelvic	Yes	20
16	38	Solitary	Acetabulum	Yes	94
17	5	Solitary	Vaginal	No	
18	2	Multiple	Vaginal, rectosigmoid, ureter, iliacal	Yes	19
19	15	Solitary	Vaginal	No	
20	8	Solitary	Vaginal	No	
21	4	Multiple	Vaginal, abdominal wall, left psoas muscle	No	

Table 5

Details recurrences - part 3

Recurrences	Node+	Parametrial+	LVSI	Tumor size (A <2 cm; B ≥2 cm to <4 cm; C ≥4 cm
1	No	Neg	No	A
2	No	Neg	Yes	B
3	No	Neg	Yes	B
4	No	Neg	No	B
5	No	Neg	No	A
6	No	Neg	Yes	A
7	No	Neg	Yes	B
8	No	Pos	Yes	B
9	No	Pos	Yes	B
10	No	Neg	No	Unknown
11	No	Neg	No	A
12	No	Pos	Yes	A
13	No	Neg	Yes	A
14	No	Unknown	Unknown	A
15	No	Neg	No	A
16	No	Neg	Unknown	A
17	No	Neg	No	A
18	No	Neg	Yes	B
19	No	Neg	No	A
20	No	Pos	No	A
21	No	Neg	No	A

LVSI = lymphovascular space invasion; Neg = negative; Pos = positive.

The authors' second analysis was an interrupted time series analysis, which showed a decline in the 4-year relative survival rate of 0.8% per year after the adoption of MIS. Before this adoption, the 4-year relative survival rate showed a (nonsignificant) trend of longer survival (0.3% per year).

The strengths of these studies are the large sample sizes and the randomized controlled setting of the LACC trial. The retrospective studies that showed no inferiority were much smaller and were sequential in comparison with the unmatched groups, with—most importantly—unequal follow-up time. Furthermore, their primary end points were perioperative complications instead of oncologic outcomes.

Other studies appeared with similar results. A retrospective study by Uppal et al [20] analyzed the data of 8 American sites, including 731 women undergoing radical hysterectomy by open or MIS approach. The recurrence

Fig. 1

Kaplan-Meier curve for disease-free survival (+95% CI). CI = confidence interval.

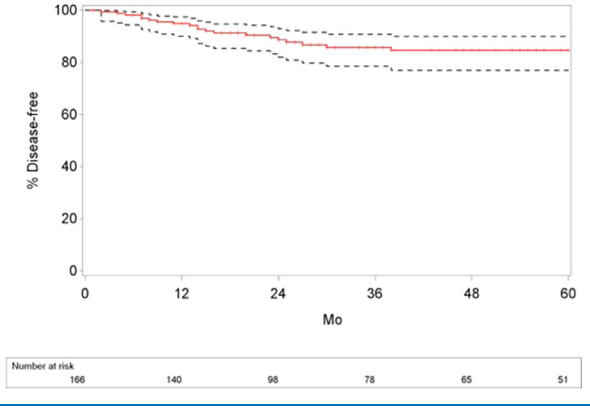
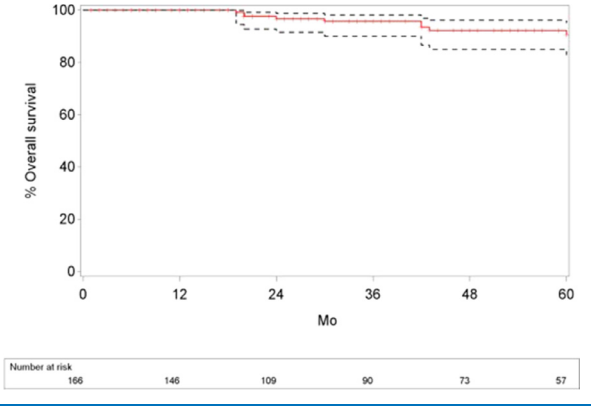


Fig. 2

Kaplan-Meier curve for overall survival (+95% CI). CI = confidence interval.



rate was 6.9% in the open group and 9.3% in the MIS group.

Similarly, Cusimano et al [21] published a Canadian retrospective study on the results of radical hysterectomies, which confirmed the increased death and recurrence rates with MIS in stage IB1 cervical cancer.

A Chinese study by Chen et al [22], which examined radical hysterectomies in patients with IB1 tumors ≤2 cm, showed that laparoscopy was an independent poor prognostic factor for disease-free survival.

In contrast, Alfonzo et al [23] published a Swedish cohort study comparing the data of women with stage IA1-IB cervical cancer undergoing radical hysterectomy through laparotomy or robot-assisted laparoscopy. No differences were seen in overall and disease-free survival.

Kohler et al [24] published the results of a retrospective multicenter analysis of vaginally assisted laparoscopic hysterectomies in early-stage cervical cancer. The authors used a tumor-covering vaginal cuff and avoided the use of uterine manipulators. Although it was not a randomized trial, the results are almost identical to the results of the open arm of the LACC trial, but the study excluded patients with positive lymph nodes on frozen section.

Most mentioned studies made no difference between conventional laparoscopy and robot-assisted laparoscopy in the MIS group. In the LACC trial [13] and the study by Cusimano et al [21], there was a clear dominance of conventional laparoscopy (84.4 % in the former and 89.6% in the latter). Many gynecologic oncologists experienced in robotic surgery assume its superiority over conventional laparoscopy, supported by the study by Alfonzo et al [23]. Currently, the Robot-assisted Approach to Cervical Cancer trial (NCT03719547) is running to compare this technique with laparotomy in a randomized study. If we compare our results with the LACC trial, our postoperative survival at 3 years is better than that of their minimally invasive group but inferior to that of the laparotomy group.

Meanwhile, the European Society of Gynaecological Oncology and National Comprehensive Cancer Network guidelines have been updated: the open approach remains the golden standard.

Conclusion

The current results of the BGOG study show disease-free and overall survival rates after robot-assisted laparoscopy in early-stage cervical cancer that are at least similar to previous reported recurrence and survival data in the literature.

We expect that the results of the Robot-assisted Approach to Cervical Cancer trial will elucidate the place of robot-assisted laparoscopy in early-stage cervical cancer.

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