Robot-Assisted Radical Hysterectomy in Cervical Carcinoma

The Belgian Experience

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Objective: The purpose of this study was to report the experience and oncological outcome of robot-assisted radical hysterectomies (RRHs) for cervical cancer performed in Belgium.

Methods: Patients undergoing RRH for cervical cancer (n = 109) were prospectively collected between July 2007 and April 2014 in the 5 Belgian centers performing RRH for cervical cancer.

Results: The median age of the patients was 46 years (range, 31–80 years). Histological types included squamous cell carcinoma in 61 patients, adenocarcinoma in 22 patients, adenosquamous in 8 patients, endometrioid carcinoma in 2 patients, and other types (n = 16). The International Federation of Gynecology and Obstetrics stage distribution was IA (n = 9), stage IB1 (n = 71), stage IB2 (n = 4), stage II (n = 24), and unknown (n = 1). Twenty-four patients received adjuvant therapy, 17 patients underwent radiochemotherapy, and 7 underwent adjuvant radiation. Eighteen patients relapsed, and 5 died of disease. The median follow-up was 27.5 months (range, 3–82 months). The 2- and 5-year overall survivals were 96% and 89%, respectively. The 2- and 5-year disease-free survivals (DFSs) were 88% and 72%, respectively. The 2-year DFS per stage was 100% for IA, 88% for IB1, 100% for IB2, and 83% for II. The 5-year DFS per stage was 100% for stage IA and 75% for IB1. The complications were as expected for radical hysterectomy.

Conclusions: This series confirms the feasibility and safety of RRH not only in cervical cancer stage IA to IB1, but also after neoadjuvant chemotherapy in stage IB2 to IIB.

Key Words: Robot-assisted management, Cervical cancer, Radical hysterectomy

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Recently, robot-assisted management of gynecologic malignancies has been described as a promising new technique that may overcome the surgical limitations seen with conventional laparotomy or laparoscopy. Robotic surgery using the da Vinci surgical system has been applied successfully in urologic, cardiac, and general surgery. In April 2005, the da Vinci (Intuitive Surgical, Sunnyvale, CA) surgical system achieved Food and Drug Administration clearance for

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gynecologic procedures. The first successful report was for tubal reanastomosis.[1] However, also for benign gynecology, the system has proven the use, for example, for hysterectomy, myomectomy, and tubal ligation.[2,3]

The criterion standard for early invasive cervical cancer surgery is still the technique of radical hysterectomy, first carried out by Ernst Wertheim in 1911.[4] Radical hysterectomy has often been associated with severe bladder dysfunction, colorectal motility disorders, and sexual dissatisfaction. Later, different techniques for nerve-sparing radical hysterectomy have been reported. Sert and Abeler[5] performed the first robot-assisted radical hysterectomy (RRH) in 2006, and Magrina et al[6] described the nerve-sparing technique by robot-assisted laparoscopy in 2011.

MATERIALS AND METHODS

Patient Characteristics

Consecutive women (n = 109) undergoing laparoscopic radical hysterectomy using the da Vinci surgical system in Belgium between July 2007 to January 2014 were included. We collected the data of 5 centers (n = 3 − 63). In each center, only 1 surgeon performed the operations. We performed a retrospective analysis after ethical approval from the University of Leuven, Belgium. Indications for surgery were women with newly diagnosed cervical cancer. Twenty-one patients received neoadjuvant chemotherapy (NACT). The median age of the patients was 46 years (range, 27–80 years). The median body mass index was 24.1 kg/m^2 (range, 18.2–40.9 kg/m^2).

All operations were performed using the da Vinci S or Si surgical system with 8-mm EndoWrist instruments (Intuitive Surgical) and a 12-mm endoscope.

Surgical Technique

The operation was started with the preparation of a vagina cuff. A frozen section of the vaginal margins was performed. To avoid dissemination, the vaginal cuff was closed over the cervix. Traction stitches were used to remove the uterus. A port was placed 25 cm above the pubis on the midline for the camera. Two 8-mm da Vinci trocars were placed bilaterally, and symmetrically at 15 degrees, at least 8 cm lateral of the camera, a third trocar was positioned above the crista iliaca at the right or left flank. An additional port was placed 4 cm under the ribs on the left side at the nipple line. The peritoneal cavity was inspected, and the da Vinci system docked.

At first, we started with the bilateral pelvic lymphadenectomy in some institutions with a sentinel procedure using patent blue and technetium colloid. Pelvic lymphadenectomy and type B or C radical hysterectomy were performed according to Querleu et al.[7] In cases with a cervical carcinoma stage IB1 (>2 cm) or higher, a nerve-sparing radical hysterectomy type C1 was performed. In patients with an International Federation of Gynecology and Obstetrics (FIGO) stage IA or IB1 (<2 cm), an RRH type B1 was performed. The uterus and/or adnexa were removed through the vagina, then the vaginal cuff was closed with a double layer of V-Lock (Covidien, Minneapolis, MN); after hemostatic control, the robot was disengaged. A suprapubic catheter was placed in the bladder. After 1 to 2 weeks, the bladder catheter was removed. The suprapubic catheter was kept in until residual urine volumes less than 100 mL, which were twice obtained.

Statistical Analysis

Statistical calculations have been performed using SAS software, version 9.3 of the SAS System for Windows (SAS Institute Inc, Cary, NC). The Kaplan-Meier method is used to estimate overall survival (OS) and disease-free survival (DFS) rates. Overall survival is the time between diagnosis and death of any cause. Disease-free survival is the time between diagnosis and recurrence or death of any cause. Cases without events are censored at the last visit. Patients with unknown time-to-event (due to unknown diagnosis date) are excluded from all analyses. One patient who was alive (N.E.D.) and 1 patient who died without recurrence were excluded for the analysis of the median time to recurrence.

RESULTS

Perioperative Parameters

Patient's characteristics and results of the operative outcomes are summarized in Table 1.

Operative time was measured from skin to skin. The median duration of the operation was 281 minutes with a median console time of 240 minutes. The median docking time was 8 minutes. If we just focus on the results of the biggest center (Leuven), we will see a decreasing time as the learning curve grow. For the first third of these patients (n = 21), the operative time was 290 minutes; for the second, the operative time was 277 minutes; and for the last, the operative time was 235 minutes. Docking time evolved from 9 to 7 on 5 minutes.

Estimated blood loss was calculated by measuring the difference between the volumes of aspirated and irrigated fluids. The median blood loss was 150 mL (15-1500 mL). In 2 patients, technical problems (technical failure of the bipolar electrosurgical system) resulted in additional blood loss (500

TABLE 1. Patients characteristics and results of the operative outcomes

	n = 109
Age, median (range), y	46 (31–80)
Body mass index, median (range), kg/m^2	24.1 (18.2–40.9)
No. pelvic nodes, median (range)	23 (6–70)
Operative blood loss, median (range), mL	150 (15–1500)
Hospital stay, median (range), d	4.5 (3–19)
Operative time, median (range), min	281 (160–550)
Follow-up, median (range), mo	27.5 (3–82)
FIGO stage, patients	
IA	9
IB1	71
IB2	4
IIA	11
IIB	13
Unknown	1

and 1000 mL). Eleven patients needed blood transfusions in our population; 2 of them received NACT preoperatively. There were 5 patients requiring blood transfusion in the first 15 cases of Leuven. All other patients requiring blood transfusion belonged to the first 5 patients of each center.

Unilateral ovarian transposition was performed in 8 patients (age between 27 and 42 years). The median hospital stay was 4.5 days. In Belgium, the median hospital stay for radical hysterectomy via laparotomy is 11 days. In this series, all patients received a bladder catheter postoperatively. Urinary retention was defined as more than 100 mL residual urine after spontaneous urination 1 week after surgery.

Complications

Intraoperative complications occurred in 5 patients. A bladder lesion had to be sutured in 2 instances. One of those patients was our first patient complicated postoperatively with urinary retention and a vesicovaginal fistula who was surgically corrected; it prolonged the hospital stay till 19 days. One serosal lesion on the bowel was sutured robotically. In 2 patients, bleeding in the right obturator fossa (estimated blood loss [EBL], 500 mL) and left iliac region (EBL, 1500 mL) occurred. All operations were completed robotically with no conversions to laparotomy.

Postoperative complications were recorded the first 30 postoperative days. They included urinary retention (7 patients), urinary tract infection (8 patients), bleeding (4 patients), peritonitis (2 patients), compartment syndrome (1 patient), and vesicovaginal fistula (2 patients). All urinary retentions resolved resulting in complete recovery at the time of the last follow-up, except 1 patient. She was comfortable with a suprapubic urinary drainage and refused a technique with neurostimulation. Bleeding occurred from the left obturator artery. One patient had peritonitis with a *Streptococcus pyogenes* infection. Both patients with the fistulas were successfully reoperated vaginally. No deaths due to complication were reported.

Pathological Results and Adjuvant Treatment

The FIGO stage distribution was IA (9 patients), stage IB1 (71 patients), stage IB2 (4 patients), stage IIA (11 patients), and stage IIB (13 patients).

Pathologic results are summarized in Table 2. Histologic types were squamous cell carcinoma (56%) adenocarcinoma (20%), adenosquamous (7%), endometrioid (2%), and other such as villoglandular, warty, glass cell, and small cell neuroendocrine types (14%). Twenty-one patients received NACT. The FIGO stage distribution was IB1 (1 patient), stage IB2 (3 patients), stage IIA (5 patients), stage IIA1 (2 patients), and stage IIB (11 patients).

There were 3 patients with positive resection margins (2 after NACT). The first patient had a positive margin at the anterior side of the cervix after NACT (3 cycles of paclitaxel-ifosfamide-cisplatinum every 3 weeks) for a stage IIB. The second patient had a positive margin at the cervix at 3 and 9 o'clock after 9 weekly courses of paclitaxel-carboplatin also for a stage IIB. The third patient with stage IIA1 (and without NACT) had a positive margin at the posterior side of the cervix. Parametrial invasion was found in 9 patients. Twenty-four patients underwent postoperative treatment: 17 patients received radiochemotherapy (weekly cisplatinum) and 7 adjuvant radiation (brachytherapy or pelvic radiotherapy).

Oncological Outcomes

The median follow-up was 27.5 months (range, 3–82 months). For the first 2 years, we saw the patients every 3 months, afterwards every 6 months until 5 years after the diagnosis. From then, the patients were followed yearly. Recurrence was observed in 18 patients (16.5%), of which 1 patient was with stage IA, 11 with stage IB1, 1 with stage IB2, and 5 with stage II (2 with stage IIA and 3 with stage IIB). Recurrence was observed in the pelvis (n = 8, 2 died of disease), in the abdomen (n = 2, both died of disease), in the liver and lung (n = 1), in the bone (n = 1), and presacral (n = 1). Five patients with a solitary recurrence at the vaginal cuff are disease-free after (chemo)radiation, after a median follow-up time of 3.3 years (range, 0.6–6.2 years). The median time to recurrence was 1.8 years within a range of 0.3 to 6.1 years. The 2-year DFS percentage was 88% (95% confidence interval [CI], 79–94), and the 5-year DFS percentage was 72% (95% CI, 57–83). The 2-year DFS per stage was 100% for IA, 88% for IB1, 100% for IB2, and 83% for II. The 5-year DFS per stage was 100% for IA and 75% for IB1 (Figs. 1 and 2). The 2-year OS percentage was 96% (95% CI, 88–90), and the 5-year OS percentage was 89% (95% CI, 75–95). In total, 6 patients died, 5 of progressive disease and 1 of another non–cancer-related cause (Fig. 3).

DISCUSSION

The first experience of robot-assisted hysterectomy was described by Marchal et al[8] in 2005 for uterine cancer (n = 12) and benign indications (n = 18). In 2006, Sert and Abeler[5]

TABLE 2. Pathology

	n = 109
Histological type	
Epidermoid	61
Adenocarcinoma	22
Adenosquamous	8
Endometrioid	2
Other	16
LVSI	
Yes	30
No	64
Unknown	15
Parametrial invasion	
Yes	9
No	93
Unknown	7
Positive resection margins	3

LVSI, lymphovascular space involvement.

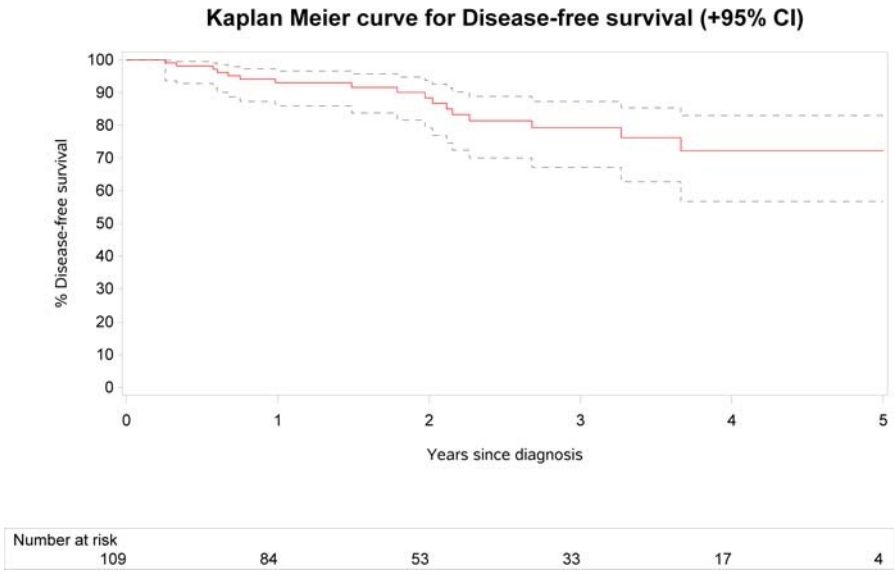

FIGURE 1. Kaplan-Meier curve for DFS (+95% CI).

were the first to perform a Piver type III laparoscopic radical hysterectomy using the da Vinci robotic system for a patient with stage IB1 cervical carcinoma. Magrina et al[6] described the technical aspects of the RRH in 2009[9] as well as the nerve-sparing technique in 2011.

An overview of the current literature of operative results of RRH is summarized in Table 3. Our own experience, which is the second largest series reported, is in line with the literature. Our conversion rate was 0%, and we observed a low blood loss. In addition, the complication rate was acceptable for a series that represents 5 learning curves.

Robotic surgery is a rather new technique, so survival statistics are scarce with small patient cohorts and limited follow-up time. In comparison to most studies, we have a reasonable median follow-up time of 27.5 months (range, 3–82 months). Cantrell et al[22] investigated progression-free survival and OS in women with cervical cancer undergoing type III RRH. In her study, only 7% were stage IB2 to IIB, and the median follow-up was only 12.2 months. At the time of analysis, 62 were disease-free and 1 patient recurred. In our series, the recurrence rate is higher (16%). However, 26% of the patients presented with FIGO stage IB2 to IIB. In the current series, the 2-year DFS in stage IB1, IB2, and IIB was 88%, 100%, and 83%, respectively. This is in concordance with the FIGO annual report on cervical cancer[35] in which a 2-year DFS was observed for FIGO stage IB1, IB2, and II of 93%, 83%, and 83%, respectively. In a smaller group of patients (n = 35), Sert and Abeler[36] saw a recurrence rate of 14.2%, with a median follow-up time of 36 months. One of the 5 patients with recurrent disease died of progressive disease. An observational

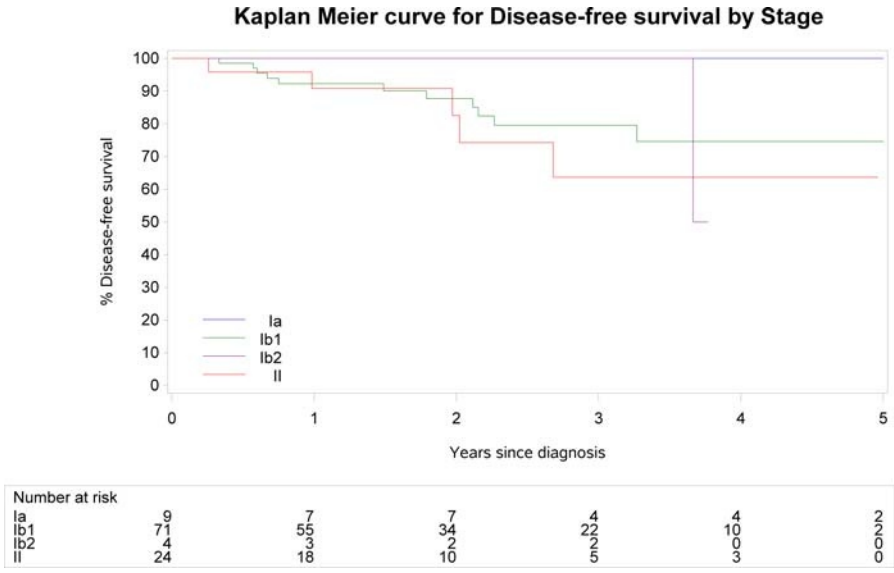

FIGURE 2. Kaplan-Meier curve for DFS (+95% CI) by stage.

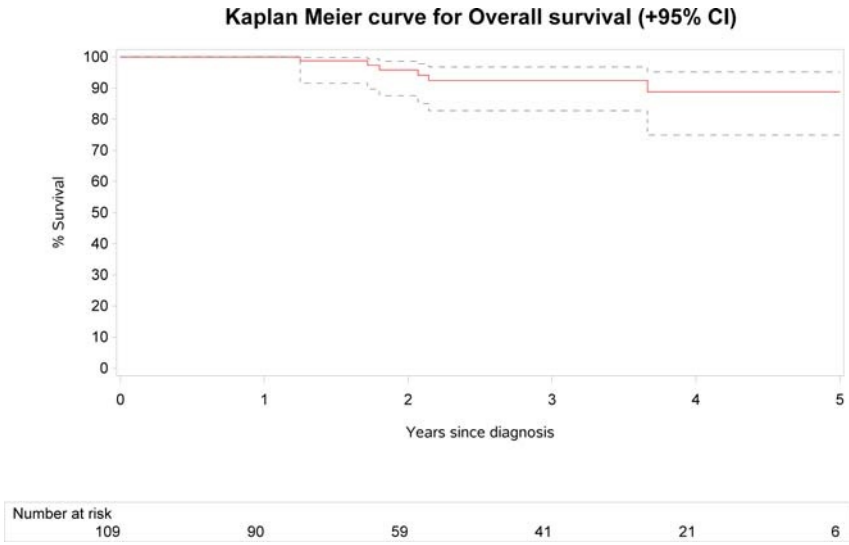

FIGURE 3. Kaplan-Meier curve for OS (+95% CI).

TABLE 3. Published series on operative outcome of RRH

Author	Year	n	Median Operative Time	Median EBL	Median InN*
Marchal et al[8]	2005	7	NR	NR	NR
Reynolds et al[10]	2005	7	257	50	15
Sert and Abeler[5]	2006	15	241	71	NR
Kim et al[11]	2008	10	207	355	28
Ko et al[12]	2008	16	290	82	16
Magrina et al[13]	2008	18	226	175	26
Fanning et al[14]	2008	20	390	300	18
Nezhat et al[15]	2008	13	323	157	NR
Lambaudi et al[16]	2008	28	180	100	25
Lowe et al[17]	2009	74	215	50	25
Estape et al[18]	2009	14	132	130	32
Maggioni et al[19]	2009	40	272	78	20
Persson et al[20]	2009	80	262	150	26
Kruijdenberg et al[21]	2010	11	329	245	20
Cantrell et al[22]	2010	63	213	50	29
Nam et al[23]	2010	32	219	220	20
Geisler et al[24]	2010	30	154	165	25
Tinelli et al[25]	2011	23	323	157	25
Soliman et al[26]	2011	34	328	100	17
Madhuri et al[27]	2012	21			16
Gil-Ibáñez et al[28]	2013	14	260	100	
Vitobello et al[29]	2013	43	260	100	
Narducci et al[30]	2013	30	305	100	18
Reynisson and Persson[31]	2013	180	277	100	23
Yim et al[32]	2013	65	190	260	20
Chong et al[33]	2013	50	230	54.9	25
Hoogendam et al[34]	2014	104	319	185	
Current study	2015	109	281	150	23

* Number of lymph nodes; NR, not recorded.

study by Hoogendam et al[34] (n = 104) shows that the recurrence and survival rates are similar to open surgery. Thirteen cases were diagnosed with a locoregional (8%), distant (4%), or combined (1%) recurrence at a median of 14.4 months. All mortality (7%) were cervical cancer related. The overall 5-year progression-free and disease-specific survival rates were 81.4% and 88.7%, respectively.[34] Various smaller studies (n = 18, 13, 23, 30) showed low recurrence rates with a median follow-up time of 33.3, 12, 24.5, and 11.5 months.[13,15,25,30]

In our series, we also included patients with locally advanced cervical cancer (stage IB2, IIA2, and IIB) who were treated preoperatively with 9 weeks of NACT. The surgicopathological outcomes were comparable for the early stage and the locally advanced cases. This was already reported by Vitobello et al.[29] No differences were found in terms of nodal yield, parametrial, and vaginal cuff length.[29] Vizza et al[37] also showed the feasibility of this technique with good accuracy and safety. Ten of the 60 patients showed a recurrence, with a follow-up time of 31 months. The 3-year DFS and 3-year OS were, respectively, 84.8% and 89.4%, which is in concordance with our study.[37]

In conclusion, RRH performed in Belgium is reported. This series confirms the feasibility and safety of this approach not only in cervical cancer stage IA to IB1, but also after NACT in stage IB2 to IIB.

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