

Laparoscopic Pelvic Lymphadenectomy in 32 Pregnant Patients With Cervical Cancer

Rationale, Description of the Technique, and Outcome

Giuseppe Filiberto Vercellino, MD,* Christardt Koehler, MD,† Evrim Erdemoglu, MD,‡
Mandy Mangler, MD,† Malgorzata Lanowska, MD,† Al-Hakeem Malak, MD,*§ Achim Schneider, MD,*†
and Vito Chiantera, MD*

Objective: Individualized treatment of pregnant patients with cervical cancer is mandatory; hence, information on nodal status is pivotal to allow a waiting strategy in early-stage disease. We aimed to verify the oncological safety and surgical reproducibility of a standardized laparoscopic pelvic lymphadenectomy in pregnant patients with cervical cancer.

Methods: We standardized laparoscopic pelvic lymphadenectomy during the first and second term of gestation in 32 patients with cervical cancer since 1999. According to gestational week (GW) of less than 16 GWs or more than 16 GWs, 2 different techniques were used.

Results: The International Federation of Gynecology and Obstetrics stages were IA in 10 patients, IB1 in 17 patients, IB2 in 4 patients, and IIA in 1 patient. Mean (SD) GW was 17.5 (5.1) weeks. Mean (SD) operative time was 105.4 (29) minutes. Mean (SD) blood loss was 5.3 (10.2) mL. There were no conversion to laparotomy and no intraoperative complications. A median number of 14 pelvic lymph nodes (range, 8–57) were harvested. Median hospital stay was 6 days. Median follow-up is 42.5 months (range, 17–164). Four patients had lymph node metastases. Five patients interrupted their pregnancy. Fourteen patients were given neoadjuvant platin-based systemic therapy. All patients are alive and disease free. All children born through cesarean delivery at a mean (SD) 34 (1.9) GWs are well and show normal clinical neurological development.

Conclusions: To the best of our knowledge, this is the largest series so far reported on laparoscopic pelvic lymphadenectomy during pregnancy. This procedure is safe and associated with good oncological and obstetrical outcomes.

Key Words: Cervical cancer, Pregnancy, Laparoscopy, Staging, Lymphadenectomy

Received October 13, 2013, and in revised form November 11, 2013.

Accepted for publication November 11, 2013.

(*Int J Gynecol Cancer* 2014;24: 364–371)

*Department of Gynecology, Charité-Campus Benjamin Franklin, Hindenburgdamm, †Department of Gynecology, Charité-Campus Charité Mitte, Charité Platz, Berlin, Germany; ‡Department of Gynecology and Gynecologic Oncology, Faculty of Medicine, Suleyman

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ISSN: 1048-891X

DOI: 10.1097/IGC.0000000000000064

Demirel University, Isparta, Turkey; and §Department of Gynecology, College of Medicine, King Saud University, Riyadh, Saudi Arabia.

Address correspondence and reprint requests to Evrim Erdemoglu, MD, Department of Gynecology and Gynecologic Oncology, Faculty of Medicine, Suleyman Demirel University, Cunur, 32040, Isparta, Turkey. E-mail: evrimmd@yahoo.com.

The authors declare no conflicts of interest.

In the last decades, delayed age at parenthood has increasingly confronted doctors, with a growing number of patients with cervical cancer still seeking parenthood.¹ The radical trachelectomy of Dargent et al² first allowed uterine conservation in patients with cervical cancer. Moreover, fertility sparing and tailor-made treatments have been successfully introduced to help preserve fertility.^{3,4}

With a reported incidence of 0.05% to 0.1%, cervical cancer is rare in pregnancy.⁵ The often conflicting interests of mother and child, the different scenarios of 3 distinct pregnancy terms, and the various histological cancer types and tumor stages, despite international recommendation, often hinder in daily practice individualized approaches for pregnant patients.^{6–8}

In recent years, neoadjuvant chemotherapy (NACT) has been administered during pregnancy with promising results; however, maternal deaths during follow-up have been reported, possibly on account of poor patient selection.^{9–13} Treatment individualization is mandatory and pivotal to prevent avoidable abortions or risky treatment delay for the patients, associated with poorer survival.^{14–18}

Lymphadenectomy before chemotherapy in pregnancy can fill up this diagnostic gap. Lymph nodes are the most important prognostic factors in cervical cancer, and laparoscopic lymph node staging is an established procedure outside pregnancy.^{19–21}

There are a few reports of lymphadenectomy in pregnancy complicated by cervical cancer.^{22–28}

This article describes the oncological safety of our standardized technique of pelvic lymphadenectomy (P-LNE) during the first and second terms of pregnancy.

MATERIALS AND METHODS

Between September 1999 and April 2013, we performed P-LNE in 32 pregnant patients with cervical cancer in the first and second trimester of gestation and a very strong desire to continue the gestation, and we prospectively collected patients' data. We previously reported the results of a pilot study.²³ Staging was performed clinically by investigation under anesthesia, according to the International Federation of Gynecology and Obstetrics (FIGO) criteria. Preoperative pelvic magnetic resonance imaging (MRI) was performed without contrast agent in patients with FIGO IB2 and patients with R1 status to evaluate the possibility of tumor resectability with regard to the preservation of cervical competence and also in the former group of patients to estimate the risk of nodal metastases. Patients, together with close family members supporting them, were offered a multidisciplinary consultation with gynecologist-oncologist, medical oncologist, obstetrician, neonatologist, and psychologist and were always given some additional time before giving written consent both to the procedure and to the image and video archive of their operation.

To minimize iatrogenic jeopardy to the pregnancy, pregnant patients in more than 16 gestational weeks (GWs) were administered prophylactic preoperative and postoperative tocolysis, with a 50-mg indometacin 1 hour before and 6 hours after surgery, or atosiban infusion, despite a lack of evidence at

this gestational age, and prophylactic corticosteroid, when GW is more than 24 weeks. The kind of tocolysis was decided by the internal panel of the obstetrical department.

All laparoscopic P-LNEs were performed by 4 surgeons in our institution. We developed 2 different techniques of P-LNE in singleton pregnancies up to 16 GWs or from 16 + 1 GWs to 24 to 25 GWs and from 15 GWs in twin pregnancies, which we named 16 and 24, respectively. The cutoff values of less than 16 GWs or more than 16 GWs were arbitrarily chosen on account of the uterus size, clinically and sonographically measured, and the experience of the surgeon.

The patient was put in a lithotomy position with straight legs and both arms tucked parallel to the body. A shoulder support was routinely used to allow an intraoperative Trendelenburg up to 30 degrees and a nasogastric tube to deflate the stomach. Before the operation started, the vitality of the fetus was checked by a transabdominal sonography, and the height of the fundus was marked on the patient's abdomen. In group 16 (11 patients), 2 surgeons performed the procedure through 4 trocar accesses, generally contralaterally, although ipsilateral P-LNE was also possible. In group 24 (21 patients), 1 leading surgeon, always working ipsilaterally; 2 assistant surgeons, facing him; and 5 abdominal incisions were necessary. A 10-mm trocar with conical tip was inserted subcostally at the Palmer's point directly or after insufflation of CO₂ via the Veress needle, with an intra-abdominal pressure of 12 to 20 mm Hg, compared with a 10-mm 0-degree telescope with a mounted high-definition camera being advanced in the abdominal cavity. After visual confirmation of abdominal entry, the intra-abdominal pressure was set to 12 mm Hg. A constant anesthesiologic intraoperative maternal Pco₂ level was maintained. All trocars were placed with the patient in the 0-degree position. Preventive coagulation of all vessels was performed throughout the surgery. Contralateral tilting of the patient up to 20 degrees, to achieve a better approach to the pelvic side wall, was routinely used regardless of GW.

We now describe separately the following distinctive features of the 2 techniques:

Group 16

For right P-LNE under laparoscopic inspection, a second 10-mm trocar was inserted in the umbilicus, followed by an introduction of 2 ancillary 5-mm trocars, lateral to the epigastric vein, 2 to 3 cm below the umbilical level, in the midclavicular line bilaterally (Fig. 1). The leading surgeon brought a 5-mm bipolar overhold clamp through the 10-mm umbilical trocar and a 5-mm lymph node grasping forceps through the left 5-mm trocar.

The peritoneum was opened by bipolar coagulation on the right side, laterally to the ligamentum infundibulopelvicum and under the ligamentum rotundum. The pararectal, paravesical, and obturator fossae were opened. The external and internal iliac arteries were displayed. The lateral limit of the dissection was the psoas muscle. The obturator fossa was cleared to the level of the obturator nerve, which was visualized and preserved. All vessels were skeletonized from the midportion of the common iliac artery to the deep circumflex iliac vein, and all nodal tissues were removed en bloc with intact capsule, carefully secured in an

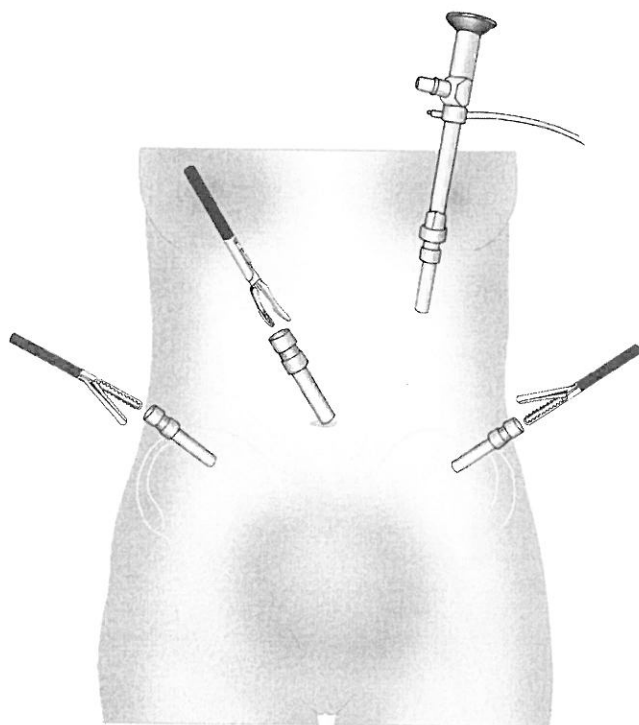


FIGURE 1. Instruments and positioning in pregnant patients less than 16 GWs.

endobag, and finally pulled out through the 10-mm umbilical trocar.

For the left-sided P-LNE, the 2 surgeons exchanged sides and held the instruments in a symmetrical way. Moreover, if both surgeons could lead, they did not switch sides but simply exchanged the instruments. Eventually, an ipsilateral left-sided P-LNE was also possible.

Group 24

In technique 24 for the right P-LNE, the telescope was shifted to the 10-mm subcostal trocar. Under a laparoscopic inspection, a second 10-mm midline trocar was inserted 2 cm above the umbilicus. To further increase secured trocar introduction, despite camera control, when inserting a third 10-mm midline trocar 2 cm below the umbilicus, we shortly elevated the intra-abdominal pressure to 20 mm Hg. Finally, 2 ancillary 5-mm trocars were introduced laterally, like previously described for group 16. A 10-mm spoon forceps was inserted into the infraumbilical 10-mm trocar, and an assistant surgeon brought it to the right isthmus of the uterine corpus and pushed the uterus to the left side. The leading surgeon brought in a 5-mm lymph node grasping forceps through the supraumbilical 10-mm trocar and a bipolar 5-mm overhold clamp through the right 5-mm trocar. Finally, the second assistant surgeon introduced a lymph node grasping forceps through the ipsilateral 5-mm lateral trocar (Figs. 2 and 3).

Right P-LNE was then performed alike group 16. For left-sided P-LNE, the telescope was switched to the 10-mm supraumbilical trocar. Uterus lateralization was performed

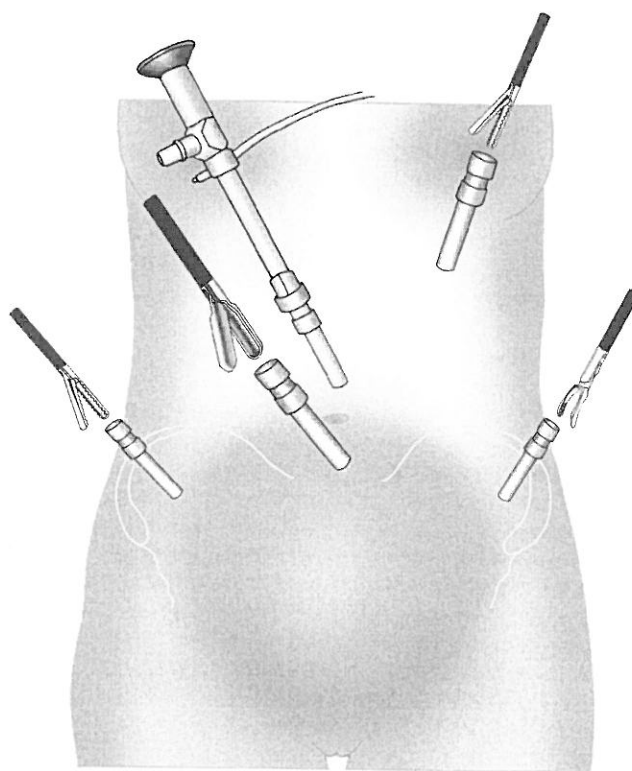


FIGURE 2. Instruments and positioning in pregnant patients more than 16 GWs.

symmetrically to the right side. The leading surgeon brought a 5-mm lymph node grasping forceps in the subcostal 10-mm trocar and a bipolar 5-mm overhold clamp in the left 5-mm trocar.

Lymph node retrieval and closure of the abdominal incisions were alike for both techniques. Before the patients left the operating theater, the bladder catheter was removed, and a transabdominal sonographic check of fetal vitality was performed. Thrombosis prophylaxis with dalteparin 5000 IU was routinely administered postoperatively to all the patients during the hospital stay.

In case of extremely expanded uterus, that is, 25 GWs or twin pregnancy 21 GWs, after completing the left-sided P-LNE, exceptionally, an additional 10-mm trocar was introduced in

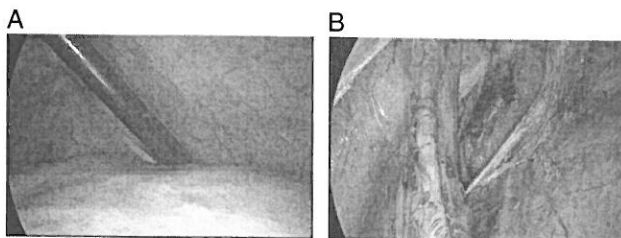


FIGURE 3. Visualization of pregnant uterus situs and retroperitoneum. A, Intraoperative view of the uterus of pregnant patients and left round ligament. B, Left retroperitoneal exploration during lymphadenectomy.

TABLE 1. Demographic, Oncological, and Obstetrical Features of Pregnant Patients with Cervical Cancer

No. patients	32
Mean (SD) age, y	33.2 (3.8)
Parity, n (%)	
Nullipara	14 (42.4)
One para	8 (27.3)
Multipara	10 (30.3)
FIGO stages, n (%)	
IA1	3 (9.3)
IA2	7 (22)
IB1	17 (53.1)
IB2	4 (12.5)
IIA	1 (3.1)
Histological type, n (%)	
Squamous cell cancer	17 (53.1)
Adenocarcinoma	15 (46.9)
Grading, n (%)	
G1	3 (9.4)
G2	18 (56.2)
G3	11 (34.4)
LVSI, n (%)	
Positive	14/32 (43.7)
Negative	14/32 (43.7)
Unknown	4/32 (12.6)
R1 (loop or conus), n (%)	11/32 (34.4)
GW at LNE time, mean (SD), wk	17.5 (5.1)
LNE, n (%)	
First trimester	4 (12.5)
Second trimester	28 (87.5)
LNE, n (%)	
GW ≤ 10	4 (12.5)
GW ≥ 22	7 (21.8)
LNE, n (%)	
GW ≤ 16	11 (34.3)
GW > 16	21 (65.6)
Twin pregnancy	15 GW (n = 1) 21.2 GW (n = 1)
Additional procedure	3 conizations 11 LEEP
Patients with delayed therapy	27/32
Patient with positive pelvic lymph nodes, n (%)	4/32 (12.5)
Induced abortion (patients)	5/32
Induced abortion (GW)	7, 8, 15, and 17 1 Wertheim operation–sectio parva (21 GW)

TABLE 1. (Continued)

Additional therapy	14 chemotherapy 4 primary chemoradiation
Delay in therapy, median (range), wk	16 (7–32)
GW at delivery, mean (SD), wk	34 (1.9)
Route of delivery	Cesarean delivery (100%) (n = 27)
Baby's weight at birth, mean (SD), g	2341 (551)
Surgical treatment (27 patients)	20/27 Wertheim operation–sectio parva + LNE 1/27 Wertheim operation + LNE 6/27 RVT + LNE
No. children delivered	29/27 pregnancies
Discharge, median (range), d	6 (3–17)

LEEP, loop electrosurgical excision procedure.

the upper right abdomen to perform the right-sided P-LNE because the instruments could not be brought over the uterus of the pregnant patient contralaterally.

Statistical Analysis

Distributions of the continuous variables were assessed by D'Agostino-Pearson test, and the histograms were plotted. Student *t* test and Mann-Whitney *U* test were performed to compare the groups and were expressed as mean and median, respectively. Categorical variables were compared by using χ^2 test. Correlation analysis was performed using rank correlation test. All statistical analyses were undertaken using Medcalc (Broekstraat, Belgium).

RESULTS

Demographic characteristics and oncological features of the patients are given in Table 1. All patients had preoperatively a very strong desire to continue the pregnancy, including four 10 GWs or less, and postoperatively, only 1 patient with pN0 status decided to interrupt her pregnancy. One patient had a history of laparotomy due to volvulus. The mean (SD) time of P-LNE was 105.4 (29) minutes. Mean operation time was not statistically different in groups 16 and 24 ($P = 0.59$). Blood loss was less than 20 mL in all patients, except in 1 patient (50 mL); in 59.4% of the patients, no drain was placed (Table 2).

Intraoperative maternal CO₂ level was always normal; no intraoperative complication occurred, and no conversion to laparotomy was necessary. No maternal and neonatal complications related to anesthesia or directly to the surgical procedure arose. Unrestricted early mobilization, starting 4 to 6 hours after surgery, was encouraged. Discharge from hospital was generally delayed until day 6, mostly on patients'

TABLE 2. Mean Operation Time and Lymph Node Count

Operation time, mean (SD), min	105.4 (29)
Group 16 operation time, mean (SD), min	109.3 (38)
Group 24 operation time, mean(SD), min	103.4 (23.8)
Blood loss, mean (SD), mL	5.3 (10.2)
Drains (placed), n (%)	13/32 (40.6)
No. pelvic lymph nodes, median (range)	14 (6–57)
No. pelvic lymph nodes (group 16), mean (SD)	21.1 (10.6)*
No. pelvic lymph nodes (group 24), mean (SD)	17.2 (12.1)*
No. pelvic lymph nodes (≤ 10 GW), mean (SD)	31 (11.7)*
No. pelvic lymph nodes (≥ 22 GW), mean (SD)	17.1 (17.7)*

* $P > 0.05$.

request because the majority of them were residing outside Berlin.

The extent of P-LNE depended both on FIGO stage and sometimes on the express wish of the patients: 2 patients refused systematic P-LNE because of fear of developing edema; hence, a lymph node sampling was performed. The mean (SD) GW at P-LNE was 17.5 (5.1) weeks, 7 patients being on 22 GWs or more (Table 3). The median number of pelvic lymph nodes harvested was 14 (range, 8–57), and their count was not related to the gestational age. Fourteen patients with macroscopic residual tumor received additional loop or conization on an individual basis to improve local tumor

TABLE 3. FIGO Stages of Pregnant Patients in 10 GWs or Less and in 22 GWs or Greater

FIGO Stages	GW
IA2	6
IIA	7
IB1	7
IA2	10
IB2	22
IA1	22
IB1	23
IA2	23
IB1	25
IA2	25
IB1	25

TABLE 4. Complications of Laparoscopic Lymphadenectomy in Pregnant Patients With Cervical Cancer

	No. Patients	GW at Surgery	No. Retrieved Lymph Nodes
Intraoperative complications	0		
Postoperative early complications (UTI, DVT, and lymphocele)	5		
UTI	1	20	24
DVT	1	21	28
Lymphocele	3	21, 14, 21	13, 12, 57
Long-term complications (edema)	5	14, 14, 15, 7, 20	12, 6, 29, 21, 8

control. The median delayed time between P-LNE and final treatment was 16 weeks (range, 7–32 weeks). Postoperatively, 1 patient developed an uncomplicated urinary tract infection (UTI), 2 had a symptomatic lymphocele, and 1 of them underwent a second laparoscopy 1.5 weeks after the LNE because of failed drainage attempt with computed tomography; another patient developed deep vein thrombosis (DVT) 17 days after the surgery. One more patient developed an asymptomatic lymphocele, discovered during the routine obstetrical visit, and 5 patients experienced a long-term complication, that is, edema either of the leg and/or of the pubic area. These latter patients had all FIGO stage IB: 1 had positive lymph nodes (1/21) and was in the eighth GW and the other 4 had pN0 status (Table 4). A total of 14 patients with pN0 status underwent a low-dose NACT with cisplatin during pregnancy, 20 mg/m² dL—3q21X3 (9 patients), X4 (4 patients), X2 (1 patient) because of a combination of additional risk factors, that is, positive resection margins, lymph vascular space invasion (LVSI) and/or G3, histotype, and tumor dimension. The patient who got 2 cycles was originally scheduled for 3 cycles (Table 5). Exceptionally, 1 patient at 21 GW with a squamous epithelial cancer pT1a2(m) pN0(0/30) G2R0L1V0 and an extensive LVSI as a single risk factor received NACT because of maximal security expectations.

In 2 patients, the MRI findings of pelvic suspect lymph nodes were not confirmed histologically. Of the 32 patients, 4 had lymph node metastases (3 have FIGO stage IB1 and 1 FIGO stage IIA). They all interrupted the pregnancy and underwent primary chemoradiation. Two were at less than 10 GWs, and 2 were at 15 and 17 GWs. Finally, 1 patient with negative nodes in the 21st GW but with multiple risk factors changed her mind after P-LNE and also asked for pregnancy termination. She underwent a cesarean delivery (sectio parva)–Wertheim operation.

TABLE 5. Features of Patients with Cervical Cancer Given NACT During Pregnancy

	GW	FIGO Stage	Histological Findings	Grade	LVSI	No. Cycles	R1
1	22	IB2	Adenocarcinoma	2	Unknown	3	Yes
2	21	IB1	Adenocarcinoma	2	Negative	3	Yes
3	21	IA2	SCC	2	Positive	3	No
4	20	IB1	SCC	2	Positive	3	Yes
5	20	IB1	Adenocarcinoma	3	Positive	3	No
6	18	IA2	Adenocarcinoma	3	Negative	3	No
7	14	IB1	SCC	2	Positive	3	No
8	17	IB2	SCC	3	Negative	3	Yes
9	14	IB1	SCC	3	Positive	3	Yes
10	13	IB2	SCC	1	Unknown	4	No
11	16	IA2	Adenocarcinoma	3	Positive	4	Yes
12	15	IB2	Adenocarcinoma	2	Positive	4	Yes
13	18	IB1	Adenocarcinoma	3	Positive	4	Yes
14	23	IB1	SCC	2	Negative	2*	Yes

*Originally planned 3 cycles.

Histological data are available for 23 of the 27 patients and specifically for all patients who underwent NACT and missing for 4 patients who had the cesarean delivery–Wertheim operation outside our institutions. Of the 14 patients with pN0 status undergoing NACT, 4 patients had tumor persistence and 1 patient had a minimal tumor left; no patient had tumor progression. In addition, 1 patient who underwent simple loop excision and P-LNE also had 10-mm tumor persistence in the hysterectomy specimen despite previous R0 resection.

No patient was lost to follow-up. Patients with follow-up 12 months or less ($n = 9$) are excluded from the oncological outcomes, that is, overall survival and disease-free survival; on the other hand, they are included in the evaluation of postoperative complications and short-term obstetrical results. Twenty-seven patients with pN0 status delivered 29 healthy babies through cesarean delivery, between the 31st and 39th GW. The mean (SD) GW at delivery was 34 (1.9) weeks. The subsequent yearly clinical neurological development of babies at follow-up has been normal. Twenty patients underwent Wertheim operation at the time of the cesarean delivery, and 1 patient 6 weeks afterward for expressed desire; 6 had radical vaginal trachelectomy (RVT) 6 weeks after delivery.

The median follow-up for 23 of the 32 patients is 42.5 months (range, 17–164 months). All the 23 patients, 4 of whom underwent chemoradiation after the medically induced abortion because of pN1 status, are alive and disease free (Table 6).

DISCUSSION

Standardized laparoscopic P-LNE of patients with cervical cancer during the first and second term of pregnancy is a safe and reproducible operation with good oncological and obstetrical outcomes. No intraoperative complications occurred. Postoperatively, 2 patients developed a symptomatic lymphocele, and 1 of them, who had no drain after the surgery because of unsuccessful computed tomography–guided

drainage, had to undergo surgery 11 days after the P-LNE; a third patient, later diagnosed with a factor V Leiden mutation, experienced a DVT and was treated with a low-dose heparin throughout the pregnancy. Three weeks after the surgery, all the patients returned back to normal life. Five patients (15.6%) had long-term complications, that is, edemas of lower limbs or vulva, persisting in the follow-up and weekly requiring lymph drainage, consistent with data reported in the literature.^{29,30}

Lymph nodes are the most important prognostic factor of patients with cervical cancer. Neither LVSI nor MRI is a reliable predictor of nodal metastases.^{18,31–33} Eleven patients with LVSI had no nodal metastases; conversely, 2 patients with pN1 status had no LVSI. In addition, 2 patients with suspect nodes on MRI also had no lymph node metastases.

International guidelines recommend P-LNE in pregnant patients with cervical cancer of less than 2 cm.^{6–8} On the other hand, there is no general consensus with bigger tumors.^{6,7,14,25} An individualized decision, at times differing from usual treatment in not pregnant women, is indispensable to tailor the most appropriate therapy for the mother and child and to avoid unacceptable errors. However, we believe that laparoscopic staging in patients with an early-stage cervical cancer plays an important role both to reduce treatment-related morbidity³⁴ and

TABLE 6. Oncological Follow-up of Patients With More Than 12 Months

No. patients	23
Follow-up, median (range), mo	42.5 (17–164)
Patients' disease-free survival rate, n (%)	23/23 (100)
Patients' overall survival rate, n (%)	23/23 (100)
DOD after final therapy (patients)	0/23
DOD, dead of disease.	

to optimize the selection of patients wishing to preserve their fertility, and the evaluation of lymph nodes should take place before NACT.⁵

Every effort should be made to triage patients in lower and higher risk for recurrence to avoid giving low-dose cisplatin monotherapy to pregnant patients with undetected lymph node involvement, which could turn fatal in the years to follow.^{10–12}

Histopathological evaluation of lymph nodes is still the criterion standard to accurately diagnose nodal status,^{19,35} and P-LNE allows optimal selection of pregnant patients with cervical cancer.^{6,7,23} Patients with lymph node metastases should receive primary chemoradiation.^{36,37} Patients without lymph node metastasis needing NACT for other risk factors can safely continue their gestation; however, NACT is not a guarantee for tumor reduction. Of the 14 patients, 4 experienced cancer persistence.

It can be argued that the reported positive surgical results in our study were due to the fact that surgeons involved in this study are quite experienced with laparoscopy P-LNE²¹ and that the incidence of cervical cancer in pregnant patients in our center is 1.8%, that is, 27 of the 1510 treated patients in the last 8 years, well above the one usually reported,⁵ resulting in the high specialization for cervical cancer of our center. Another limitation of our study is that the variability in the uterus dimension among the pregnant patients with identical GW and the anatomical anomalies among individuals do not allow complete standardization of the technique.

At the same time, our study has some decisive strength. The absence of intraoperative complications, despite 87% of the patients being in the second trimester of pregnancy, and the number of retrieved lymph nodes, comparable with that of the historic group of not pregnant patients, regardless of GW, prove the safety and the efficacy of this standardized technique in experienced hands (see videos). The 2 videos clearly show that a standardized approach and the painstaking preventive coagulation are the key for a safe, bloodless, and uncomplicated surgery. Besides, we have a total of 32 patients. To the best of our knowledge, this series is the largest so far reported. Lastly, the median follow-up time available for 23 patients is 42.5 months; thus, the good oncological and obstetrical outcomes, although not definitive, can be considered more than just initial results.²³ All patients are alive and free of disease, although 4 of them, with positive pelvic nodes, interrupted their pregnancy. The number of children, all born through cesarean delivery,³⁸ is small, yet so far, all children are doing fine and have a normal clinical neurological development.

Finally, it is of paramount importance to individualize the therapy for pregnant patients with cervical cancer. In these regards, P-LNE is crucial to optimize patient selection and minimize risks of treatment delay. Intraoperative complications are absent, and postoperative morbidity is limited.

ACKNOWLEDGMENTS

The authors dedicate this article to Anneliese Jähn 1932–2012 who dedicated her professional career to the prevention of cervical cancer at Charité University Medicine, Berlin, Germany.

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For the complete list of references, please contact
evrimmd@yahoo.com.