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Identifying selection criteria for non-radical hysterectomy in FIGO stage IB cervical cancer

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Abstract

Aim: This retrospective study sought to identify the selection criteria required for a non-radical hysterectomy with minimal parametrectomy in patients with International Federation of Gynecology and Obstetrics (FIGO) stage IB invasive cervical cancer.

Methods: Overall, 461 patients with FIGO stage IB cervical cancer who underwent a radical hysterectomy were reviewed clinicopathologically according to pathological tumor size (≤2 cm, >2 – ≤4 cm, and > 4 cm).

Results: The pathological parametrial involvement rate in the less than equal to 2 cm group (2%) was significantly lower than in greater than 2–less than equal to 4 cm (13%) or greater than 4 cm (29%) groups (both $P < 0.001$). The 5-year overall survival rate was significantly higher in the less than equal to 2 cm group (97%, 95% confidence interval [CI] 94–99%) compared with greater than 2–less than equal to 4 cm (90%, 95% CI 94–86%) and greater than 4 cm (70%, 95% CI 79–60%) groups (both $P < 0.001$). Cox model analysis identified tumor size to be an independent prognostic factor for survival (95% CI 1.33–5.78) and recurrence (95% CI 1.31–5.66) compared to other pathological factors. However, a significant difference between the three groups was not found in rates of Grade 3 or 4 adverse events following radical hysterectomy ($P = 0.19$).

Conclusions: Tumor size is an independent prognostic factor for survival in patients with FIGO stage IB invasive cervical cancer. This retrospective study suggests that FIGO stage IB patients with a less than equal to 2 cm tumor size are optimal candidates for non-radical hysterectomy with minimal parametrectomy, and without resulting bladder dysfunction.

Key words: FIGO stage IB, neurogenic bladder, non-radical hysterectomy, uterine cervical cancer.

Introduction

Radical hysterectomy, corresponding to class III of the Piver–Rutledge classification system,[1] is widely accepted as a standard surgical procedure for patients with International Federation of Gynecology and Obstetrics (FIGO) stage IB–II invasive cervical cancer.[2] During radical hysterectomy, undergoing a parametrectomy is a crucial fundamental procedure.[3] However, surgical damage to the pelvic autonomic nerve can occur after a wide resection of parametrial and paravaginal tissue, causing a severe long-term neurogenic bladder.[4–7] Therefore, the development of a non-radical surgical approach, by resecting a smaller part of the parametrium near the cervix without compromising radicality, among patients with a low risk of parametrial involvement may reduce or avoid postoperative bladder dysfunction altogether.

The difficulty of evaluating microscopic parametrial involvement before surgery means a standard non-

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radical hysterectomy that avoids bladder dysfunction in FIGO stage IB disease has not yet been established. However, if patients who have a low risk of pathological involvement could be identified before surgery, they would be able to undergo a non-radical hysterectomy with minimal parametrectomy. Tumor size in cervical cancer patients is a prognostic factor, with a small tumor size having a good prognosis[8]; it follows that such patients likely have a low risk of parametrial involvement and therefore may be optimal candidates for non-radical surgery. We undertook a retrospective study to identify potential selection criteria for non-radical surgery with minimal parametrectomy to avoid neurogenic bladder in patients with FIGO stage IB disease by analyzing clinicopathological features, including parametrial involvement rates and adverse events, in those patients who underwent a radical hysterectomy according to pathological tumor size.

Methods

Patients and tumors

Medical records were reviewed of 1400 patients with FIGO stage IB – IVA invasive cervical cancer treated at the Department of Gynecology, National Cancer Center Hospital in Tokyo, Japan between 1984 and 2006. Study patients met the following criteria: FIGO stage IB disease; underwent primary surgery consisting of a radical hysterectomy with pelvic systemic lymphadenectomy; and had a squamous cell carcinoma, adenosquamous cell carcinoma, or common histological subtypes of endometrioid adenocarcinoma and mucinous endocervical type adenocarcinoma. Patients with uncommon histological subtypes of other epithelial carcinomas and mesenchymal tumors, or those who received adjuvant therapy before primary surgery, were excluded. All patients were staged according to the FIGO (1994) staging system.[9] Patients treated before 1994 were restaged retrospectively.

Treatment

Our standard surgical procedure for patients with FIGO stage IB disease is radical hysterectomy with a systemic pelvic lymphadenectomy, based on Kobayashi's technique and the Tokyo method,[10] and corresponding to class III or IV of the Piper–Rutledge classification system.[1] When using this technique, the anterior, medial and posterior retinacula were divided and cut along the pelvic side wall while preserving the pelvic autonomic nerve bundle under the cardinal ligament. The vaginal canal, including the paracolpium, was cut for at least 3 cm.[3,11] During the study period, laparoscopic or robotic surgery, or radical trachelectomy were not employed.

A bladder catheter was inserted in patients before the operation and maintained for 7–14 days following surgery. Patients were encouraged to void themselves every 4 h after catheter removal. The residual urine volume was measured every urination by a temporary catheter. Measurements ceased when the residual urine volume decreased to less than 50 mL.

In patients with pelvic lymph node metastasis (pT1bN1, pT2aN1 or pT2bN1) or parametrial involvement (pT2b) proven by pathological examination, adjuvant postoperative irradiation of the whole pelvis was performed. The total irradiation dose for the whole pelvis was 50 Gy in 25 fractions administered by external beam radiation therapy. If the surgically cut vaginal margin was positive, then high-dose rate intracavitary brachytherapy was performed using a remote after-loading system of 192Ir at a one fraction dose of 6 Gy to 5 mm under the vaginal surface, for a total of two fractions. Concurrent chemoradiotherapy was not administered.

Pathology

The maximum horizontal extension of the tumor was examined microscopically. Tumor size was defined by maximum diameter. Regarding the cut margin of the vaginal canal, a tumor-free space greater than 10 mm in length was defined as a tumor-free surgical margin. A tumor-free space less than 10 mm in length was defined as a close surgical margin. The resected parametrium was sectioned into proximal, center and distal portions. Parametrial lymph node metastasis was classified as a positive pelvic lymph node, and any lymph–vascular space invasion (LVSI) observed in the parametrium was classified as parametrial involvement.[3] Histological typing was evaluated according to the World Health Organization International Histological Classification of Tumors.

Statistical analysis

The impact of pathological variables, such as tumor size, parametrial involvement, number of positive nodes, depth within the cervical wall, LVSI, infiltration into the vagina, adnexal metastasis and histological subtype on survival and recurrence were analyzed. Overall survival (OS) and recurrence-free

survival (RFS) curves were obtained by the Kaplan–Meier method and compared by nonparametric survival analysis (log-rank test). Patients were followed up through May 2013 for survival and RFS analyses. Pathological variables were also analyzed based on a Cox proportional hazard model with a stepwise method (forward selection). A *P*-value of 0.05 was adopted as an inclusion criterion, and a *P*-value of 0.10 was adopted as an exclusion criterion for the forward selection. Fisher's exact or χ^2 tests were used to examine the differences in distribution for categorical variables. A two-sample *t*-test or one way-analysis of variance was used for the statistical analysis of continuous variables. $P < 0.05$ was considered statistically significant. Adverse events were assessed using the Common Terminology Criteria for Adverse Events version 4.0. All statistical analyses were performed with SPSS statistics (version 19) software.

Ethics

All authors observed the ethical guidelines for medical and health research involving human subjects of the Ministry of Health, Labor and Welfare, Japan. The study was approved by the institutional review board of the National Cancer Center, Japan and conforms to the provisions of the Declaration of Helsinki as revised in Tokyo 2004.

Results

Patients and tumor characteristics

Overall, 461 patients with FIGO stage IB cervical cancer met the study criteria. Table 1 summarizes the characteristics of patients according to tumor size (≤2 cm, >2 – ≤4 cm and >4 cm). The mean tumor size was 14.6 ± 3.9 mm, 30.2 ± 5.4 mm and 54.3 ± 12.3 mm for patients in less than or equal to 2 cm, greater than 2 – less than or equal to 4 cm and greater than 4 cm groups, respectively. The pathological parametrial involvement rate for patients in the less than or equal to 2 cm group (2%) was significantly lower than that of patients in the greater than 2 – less than or equal to 4 cm group (13%; $P < 0.001$). Five other pathological variables, including number of positive pelvic lymph nodes, proportion of advanced pathological stages, proportion of deep cervical wall invasion, degree of LVSI and vaginal infiltration rate, were also significantly lower for patients in the ≤2 cm group compared with those in the greater than 2 – less than or equal to 4 cm group ($P < 0.05$). Thus, pathological variables, including the parametrial involvement rate, were significantly lower in patients with a small tumor size.

For patients with positive pelvic nodes, positive common iliac nodes were observed in 7.6% (1/13) of patients in the less than or equal to 2 cm group, 20.7% (11/53) of those in the greater than 2 – less than or equal to 4 cm group, and 26.8% (11/41) of those in the greater than 4 cm group. Two patients in the greater than 2 – less than or equal to 4 cm group and one patient in the greater than 4 cm group had positive paraaortic nodes.

Among patients with pathological parametrial involvement, 66.6% (38/57) showed involvement in the proximal portion of the parametrium, 21.1% (12/57) in the central portion, and 12.3% (7/57) in the distal portion. All patients with positive parametrial involvement in central or distal portions also had parametrial involvement in the proximal portion; 34.0% (16/47) showed involvement on both sides of the parametrium.

Survival

All 461 patients were followed for between 1 and 305 months (median, 92), including those who eventually died. OS and RFS were assessed using a log-rank test for patients stratified by eight pathological subgroups (tumor size, parametrial involvement, number of positive nodes, depth in cervical wall, LVSI, infiltration into vagina, adnexal metastasis and histological subtype [Table 2]). The 5-year OS rate for patients with a tumor size less than or equal to 2 cm was 97% (95% CI, 94–99%), which was significantly greater than those of patients with a tumor size greater than 2 – less than or equal to 4 cm, or greater than 4 cm ($P = 0.001$ for both). Multivariate analysis of the eight subgroups using a Cox model demonstrated that tumor size, number of positive nodes, and adnexal metastasis were independent adverse risk factors for survival (Table 3). Using the same subgroups as for OS, the RFS rate at 5 years was 95% (95% CI, 92–99%) for patients with a tumor size less than or equal to 2 cm, which was significantly better than that for patients with a tumor size greater than 2 – less than or equal to 4 cm, and greater than 4 cm ($P = 0.001$ for both; Table 2). A Cox model analysis showed that the tumor size and number of positive nodes were significant adverse risk factors for cancer recurrence (Table 3; $P < 0.001$ for both). Thus, a small tumor size is linked to increased survival and is an adverse risk factor for cancer recurrence.

Table 1 Patient and tumor characteristics

	Tumor size			*P*-value
	≤2 cm	>2–≤4 cm	>4 cm	
	n = 148	*n* = 226	*n* = 87	
	No. (%)	No. (%)	No. (%)	
Mean (range) age, (years)	44 (23–66)	45 (24–71)	47 (25–68)	<0.001
Pathological stage				<0.001
pT1b	134 (91)	169 (75)	46 (53)	—
pT2a	11 (7)	28 (12)	16 (18)	—
pT2b	3 (2)	29 (13)	25 (29)	—
Pathological parametrial involvement				<0.001
Negative	145 (98)	197 (87)	62 (71%)	—
Positive	3 (2)	29 (13)	25 (29)	—
Number of positive pelvic lymph nodes				<0.001
0	135 (91)	173 (76)	46 (53)	—
1–4	11 (7)	44 (20)	28 (32)	—
>5	2 (2)	9 (4)	13 (15)	—
Depth in cervical wall				<0.001
<1/3	74 (50)	43 (19)	1 (1)	—
1/3–2/3	52 (35)	67 (30)	9 (10)	—
>2/3	22 (15)	116 (51)	77 (89)	—
Lymph–vascular space invasion				<0.001
None	73 (49)	68 (30)	11(13)	—
Few	50 (34)	76 (34)	30 (34)	—
Several	18 (12)	59 (26)	25 (29)	—
Many	7 (5)	23 (10)	21 (24)	—
Infiltration to vagina				<0.001
Negative	135 (91)	189 (84)	58 (67)	—
Positive	13 (9)	37 (16)	29 (33)	—
Adnexal metastasis				<0.001
Negative	113 (76)	179 (79)	75 (86)	—
Positive	0 (0)	0 (0)	5 (6)	—
Not resected	35 (24)	47 (21)	7 (8)	—
Histological subtype				0.010
Squamous cell carcinoma	84 (57)	166 (73)	52 (60)	—
Adenosquamous cell carcinoma	17 (11)	20 (9)	11 (13)	—
Adenocarcinoma	47 (32)	40 (18)	24 (27)	—
Surgical margin				0.001
Free	148 (100)	226 (100)	83 (95)	—
Close or involved	0 (0)	0 (0)	4 (5)	—
Postoperative therapy				<0.001
None	136 (92)	158 (70)	30 (35)	—
Radiotherapy	11 (7)	66 (29)	55 (63)	—
Chemotherapy	0 (0)	2 (1)	1 (1)	—
Radiotherapy followed by chemotherapy	1 (1)	0 (0)	1 (1)	—

Failure sites and spread pattern

Seventy-four patients suffered tumor recurrence at a median interval of 14 months (range, 1–132 months). An analysis of the distribution of initial failure sites showed that in 148 patients with a tumor size less than or equal to 2 cm, 8 (5%) suffered a tumor recurrence, with initial failure sites inside and outside the pelvis in four (50%) patients, respectively. Of 226 patients with a tumor size greater than 2–less than or equal to 4 cm, 34 (15%) patients suffered a tumor recurrence. Of these, initial failure sites were found inside the pelvis for 15 (44%) patients, outside the pelvis for 18 (53%) patients, and inside and outside for one (3%) patient. Of the 32 (37%) patients with a tumor size >4 cm who suffered a tumor recurrence, initial failure sites were found inside the pelvis for 11 (34%) patients, outside the pelvis for 19 (60%) patients, and both inside and outside for two (6%)

Table 2 OS and RFS in 461 patients with stage IB disease

	No. (%)	5-year OS (%)	Log-rank *P*-value	5-year RFS (%)	Log-rank *P*-value
Tumor size (cm)	—	—	<0.001	—	<0.001
≤2	148 (32)	97	—	95	—
>2–≤4	226 (49)	90	—	88	—
>4	87 (19)	70	—	66	—
Parametrial involvement	—	—	<0.001	—	<0.001
Negative	404 (88)	91	—	90	—
Positive	57 (12)	68	—	61	—
Number of positive nodes		—	<0.001	—	<0.001
0	354 (77)	93	—	92	—
1–4	83 (18)	79	—	74	—
5<	24 (5)	45	—	37	—
Depth in cervical wall	—	—	<0.001	—	<0.001
<1/3	118 (26)	96	—	95	—
1/3–2/3	128 (28)	92	—	91	—
2/3 <	215 (46)	81	—	78	—
LVSI	—	—	<0.001	—	< 0.001
None	152 (33)	96	—	94	—
Few	156 (34)	89	—	87	—
Several	102 (22)	84	—	84	—
Many	51 (11)	74	—	66	—
Infiltration into vagina	—	—	<0.001	—	<0.001
Negative	382 (83)	90	—	88	—
Positive	79 (17)	79	—	77	—
Adnexal metastasis	—	—	<0.001	—	0.001
Negative	367 (80)	88	—	86	—
Positive	5 (1)	20	—	25	—
Not resected	89 (19)	94	—	89	—
Histological subtype	—	—	0.905	—	0.114
Squamous cell	302 (66)	89	—	87	—
Adenosquamous cell	48 (10)	89	—	81	—
Adenocarcinoma	111 (24)	87	—	86	—

OS, overall survival; RFS, recurrence-free survival; LVSI, lymph-vascular space invasion.

Table 3 Multivariate analysis of prognostic factors for OS and RFS in 461 patients with stage IB disease (with a stepwise method, forward selection)†

	OS			RFS		
	HR	95% CI	*P*-value	HR	95% CI	*P*-value
Tumor size (cm)						
≤2	1	—	—	1	—	—
>2–≤4	2.78	1.33–5.78	0.006	2.72	1.31–5.66	0.007
>4	4.69	2.14–10.26	<0.001	4.84	2.22–10.55	<0.001
Number of positive nodes						
0	1	—	—	1	—	—
1–4	1.915	1.14–3.19	0.013	1.97	1.18–3.28	0.009
>5	4.05	2.14–7.68	<0.001	4.4	2.31–8.35	<0.001
Adnexal metastasis						
Negative	1	—	—	—	—	—
Positive	3.29	1.22–8.85	0.018	2.58	0.96–6.93	0.060
Not resected	0.52	0.25–1.11	0.092	0.52	0.25–1.10	0.091

OS, overall survival; RFS, recurrence-free survival; HR, hazard ratio; CI, confidence interval. †The analysis was adjusted for tumor size, parametrial involvement, cervical wall depth, number of positive nodes, lymph–vascular space invasion, infiltration into vagina, adnexal metastasis and histological subtype.

patients. A significant difference in the location of initial failure sites according to tumor size between groups was not found ($P = 0.838$).

The pelvic control rate was 97% for patients in the less than or equal to 2 cm group, 93% for those in the greater than 2–less than or equal to 4 cm group, and 85% for patients in the greater than 4 cm group; the pelvic control rate for patients in the less than or equal to 2 cm group was significantly higher compared to that of patients in the greater than 4 cm group ($P = 0.002$). Of 33 patients with pelvic recurrence, 14 (42%) showed central recurrence, and 19 (58%) had a lateral recurrence. Thus, a small tumor size is associated with a higher pelvic control rate.

Complications

The mean period of continuous bladder drainage by retention urine catheter inserted before surgery was 14 ± 13 days (median 14 days, range, 4–233 days). After removal of the catheter, 69% (318/461) of patients could initiate micturition immediately, a total of 94% (433/461) could initiate micturition within 7 days, and 96% (444/461) initiated micturition by 14 days after removal of the catheter. Thirteen patients (3%) who could not self-micturate left the hospital after self-catheterization from 10 to 65 days after surgery. Excluding the 13 patients who could not self-micturate, the mean period between removal of the retention catheter and initiating self-micturition was 1.0 ± 2.8 days (median 0 day, range 0–37 days) in 448 patients. Forty-two patients with residual urine and one patient with a vesicovaginal fistula left the hospital after self-catheterization. Of the remaining 405 patients, the mean period between the removal of the retention catheter and the disappearance of residual urine was 8.4 ± 7.5 days (median 6 days, range 0–51 days). Of all 461 patients, the population of patients with residual urine, according to a Kaplan–Mayer estimate, was 88% 3 days after the removal of the retention catheter, 54% at 7 days, 26% at 14 days, 16% at 21 days, 8% at 28 days, and 4% at 56 days. Finally, none of the 461 patients needed permanent self-catheterization.

Other morbidities are summarized in Table 4. A significant difference in the rate of grade 3 or 4 adverse events according to tumor size between the three patient groups was not evident: 6.8%, 8.8% and 13.8% for patients in less than 2 cm, greater than 2 – less than or equal to 4 cm, and greater than 4 cm groups, respectively ($P = 0.191$). Significant differences in the mean volume of blood loss for patients in all groups (1134 mL, ≤2 cm; 1314 mL, >2 – ≤4 cm; 1343 mL, >4 cm groups) or in the mean operating time ($P = 0.693$; 355 min, ≤2 cm; 359 min, >2 – ≤4 cm; 358 min, >4 cm groups) were not noted ($P = 0.088$). In summary, the rate of grade 3 or 4 adverse events was not associated with tumor size.

Discussion

The present study suggests that patients with a pathological tumor of less than or equal to 2 cm are suitable candidates for non-radical hysterectomy with minimal parametrectomy. Tumor size was found to be an independent prognostic factor for survival and recurrence, with the prognosis for patients with a small tumor size (≤2 cm) significantly better than for those with a larger tumor size. Furthermore, those with a small tumor size (≤2 cm) were found to have a low risk for pathological parametrial involvement (2%). However, a statistical difference was not found in the incidence of complications or tumor spread between the three groups of patients with different tumor sizes and FIGO stage IB disease who underwent radical hysterectomy, especially those with bladder dysfunction.

Recent studies have focused on the use of non-radical hysterectomy or the minimization of hysterectomy for early stage cervical cancer.[12–14] Several studies described retrospective case series of microinvasive (stage IA) and early invasive disease (stage IB), with the risk of parametrial invasion less than 4% in patients with a less than or equal to 2 cm tumor size.[15,16] Furthermore, for patients with lesions with a limited depth of stromal invasion, and without LVSI or node metastasis, the risk was less than 1%.[14–19] In accord with these findings, the present study suggests that FIGO stage IB patients with a less than or equal to 2 cm tumor size may be appropriate candidates for non-radical hysterectomy. Currently, the standard surgical option for patients with microinvasive disease is a simple extrafascial hysterectomy for stage IA1 disease, and modified radical hysterectomy for stage IA2 disease; these rationales are universally accepted.[2] However, a standard surgical option does not exist for patients with a frank small-sized invasive carcinoma who usually undergo radical hysterectomy. A study of 83 FIGO stage IB patients, with a squamous cell lesion of greater than 3 mm stromal invasion depth, a less than or equal to 2 cm size tumor, no LVIS and who underwent radical hysterectomy, showed a lack of parametrial nodal

Table 4 Morbidities

	Tumor size											
	≤2 cm				>2–≤4 cm				>4 cm			
	n = 148				*n* = 226				*n* = 87			
Adverse event	Grade 3	Grade 4	Grade 5	Grade 3 or 4 (%)	Grade 3	Grade 4	Grade 5	Grade 3 or 4 (%)	Grade 3	Grade 4	Grade 5	Grade 3 or 4 (%)
Morbidity during surgery												
Procedural complications												
Ureteral injury	0	0	0	0	2	0	0	0.9	0	0	0	0
Early morbidity												
Urinary disorders												
Fistula	2	0	0	1.3	0	0	0	0	2	0	0	2.3
Vascular disorders												
Lymphocele	1	0	0	0.6	1	0	0	0.4	0	0	0	0
Thromboembolic event	0	0	0	0	0	0	0	0	0	0	1†	1.1
Gastrointestinal disorders												
Ileus	1	0	0	0.6	0	0	0	0	0	0	0	0
Perforation	0	0	0	0	0	1	0	0.4	0	0	0	0
Wound complications												
Abdominal hernia	0	0	0	0	1	0	0	0.4	0	0	0	0
Wound separation	0	0	0	0	1	0	0	0.4	0	0	0	0
Infections												
Urinary tract infection	1	0	0	0.6	1	0	0	0.4	1	0	0	1.1
Late morbidity												
Urinary disorders												
Fistula	0	0	0	0	0	0	0	0	1	0	0	1.1
Urinary tract obstruction	0	0	0	0	2	0	0	0.9	1	0	0	1.1
Bladder perforation	0	0	0	0	0	0	0	0	2	0	0	2.3
Vascular disorders												
Lymphocele	2	0	0	1.4	1	0	0	0.4	0	0	0	0
Lymphedema	0	0		0	1	0	0	0.4	1	0	0	1.1
Gastrointestinal disorders												
Ileus	0	0	0	0	2	0	0	0.9	0	0	0	0
Wound complications												
Abdominal hernia	2	0	0	1.4	0	0	0	0	0	0	0	0
Infections												
Urinary tract infection	1	0	0	0.7	4	0	0	1.8	2	0	0	2.3
Lymphocele infection	0	0	0	0	3	0	0	1.3	1	0	0	1.1
Lymph channel	0	0	0	0	0	0	0	0	1	0	0	1.1
Total	10	0	0	6.6	19	1	0	8.6	12	0	1	14.5

†One patient died of a pulmonary thromboembolism.

metastasis, and a 5-year disease-free survival rate of 97.6%.[17] Another study of patients with stage IB squamous cell or adenocarcinoma who underwent radical hysterectomy (Piver class III) followed by concurrent chemoradiotherapy showed the 5-year OS rate was significantly longer in patients with a less than or equal to 2 cm tumor size (94.0%) compared with patients with a tumor size of greater than 2–less than or equal to 4 cm (85.1%) or greater than 4 cm (69.9%).[20] In the present study, pathological parametrial involvement spread from the proximal to distal portion of the parametrium. All patients with positive parametrial involvement in central or distal portions showed parametrial involvement in the proximal portion. This pathological finding indicates that a minimal resection of the parametrium along the cervix may be safe without compromising radicality. On the basis of these and previously described findings, patients with a less than or equal to 2 cm tumor size may be considered candidates for a non-radical hysterectomy of minimal parametrectomy without bladder dysfunction.

The development of a severely neurogenic bladder—an inability to empty the bladder and loss of the sense of urgency to void—is unavoidable after radical hysterectomy. In the present study, the median period between removing the retention catheter and the disappearance of residual urine was 6 days. Patients underwent bladder rehabilitation to reduce straining while micturating and the loss of a sense of urgency to void. This finding is in agreement with a previous study that reported a median of 7 days for complete bladder emptying,[21] although bladder dysfunction existed from several months to years after surgery. Indeed, 12 months after a radical hysterectomy, a urinary reflex was still absent in 70% of patients, while 18% had reduced bladder compliance on a cystomanometric curve and 9% showed stress incontinence.[22] Notably, a bladder residue (>100 mL) remained in 6% of patients 12 months after surgery, further highlighting severe and prolonged bladder dysfunction following radical hysterectomy.

Other common severe complications that follow radical hysterectomy[4] are bowel dysfunction including constipation (18%),[23] sexual dysfunction (26%),[24] urinary tract fistula information (0–12.8%),[14,25] ureteral stenosis (9%),[26] lymphocysts (6%) and lymphedema (8–25%) caused by lymphadenectomy.[23,26] Therefore, it is important to define new selection criteria for non-radical surgery with minimal parametrectomy to prevent the development of unnecessary, severe complications, including bladder dysfunction, associated with radical hysterectomy.

Based on the findings of the present study, non-radical hysterectomy was defined as the following: the cutting of the anterior layer of the vesicouterine ligament, and removal of part of the parametrial tissue. Consequently, almost all of the bladder branch from the inferior hypogastric nerve is preserved. The posterior layer of the vesicouterine ligament is not resected. This procedure is considered to be somewhere between a simple and type II radical hysterectomy.

The present study was based on pathological tumor size, and clearly identified potential selection criteria for non-radical surgery. However, the evaluation of preoperative characteristics, including the measurement of tumor size by diagnostic imaging, was not undertaken. To more decisively demonstrate the efficacy of non-radical hysterectomy for patients with invasive cervical cancer, a prospective study is required. In this regard, four ongoing prospective studies are currently evaluating the use of less invasive and damaging non-radical surgery for patients with small-sized lesions[27,28]: The Japanese Clinical Oncology Group study 1101 is a multi-institutional non-randomized confirmatory Phase III trial that is evaluating the efficacy of modified radical hysterectomy for patients with a less than or equal to 2 cm tumor diameter in FIGO stage IB1 disease confirmed by magnetic resonance imaging (MRI) before surgery in comparison with radical hysterectomy.[28] The eligibility criteria for this study are patients with FIGO IB1 disease, and a clinical maximum tumor diameter (confirmed by MRI) of less than or equal to 2 cm with any depth of invasion or any degree of LVSI. In the present study, MRI was employed for the measurement of tumor size before surgery. In the gynecologic oncology group study 278, changes in bladder, bowel and sexual function in patients with IA1, IA2 or IB1 (tumor size ≤2 cm and depth of invasion ≤10 mm on cone) are being investigated, before and after non-radical surgery.[29] The Conservative Surgery for Women with Low-risk, Early stage Cervical Cancer (ConCerv) trial is currently evaluating the safety and feasibility of performing conservative surgery in patients with stage IA2 or IB1 disease (tumor size ≤2 cm, depth of invasion <10 mm, and no LVSI on conization).[30] Finally, the Gynecologic Cancer Intergroup randomized trial (SHAPE Trial) is comparing radical and simple hysterectomies for patients with IA2 or IB1 disease (tumor size <2 cm, depth of

invasion <10 mm on conization, and < 50% stromal invasion).[31]

In conclusion, this retrospective study suggests that FIGO stage IB patients with a less than or equal to 2 cm tumor size are optimal candidates for non-radical hysterectomy with minimal parametrectomy.

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Disclosure

None declared.

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