An evaluation of 721 women with Stage IA1 cervical cancer: is conservative surgical approach safe?

J. Zhu*, X. Wu*, X. Liu

Department of Obstetrics and Gynecology, Shanghai Obstetrics and Gynecology Hospital, Fudan University, Shanghai (China)

Summary

Objective: To assess the outcomes of women with Stage IA1 cervical cancer received conization, simple hysterectomy (Class I/Type A), modified radical hysterectomy (Class II/Type B), radical hysterectomy (Class III/Type C), and identify the pathologic characteristics after conization which might correlate with the residual disease in cervix uteri. *Materials and Methods:* A cohort of 721 Stage IA1 cervical cancer patients treated in the present hospital from January 2005 to December 2014 were evaluated retrospectively. Clinical parameters from the patients underwent conization and three types of hysterectomies as definitive surgery were compared, and pathologic characteristics from patients receiving diagnostic conization before hysterectomy were also analyzed. *Results:* The conization outperformed three types of hysterectomy in aspects of significant shorter operating time, less blood loss, and shorter urinary catheterization time and hospital stay. However, incidences of perioperative complication and recurrence were comparable among different surgical approaches. Positive margin status and lymphovascular space invasion (LVSI), rather than pathology of conization, the higher level pathology between biopsy and conization, scope of surgery, and pathologic subtype, were significantly associated with the residual disease in hysterectomy specimens. *Conclusion:* There was no distinction between prognosis of conization and three types of hysterectomy for Stage IA1 cervical cancer patients. Margin status of conization and LVSI might predict the residual disease in cervix uteri.

Key words: Stage IA1; Cervical cancer; Conization; Hysterectomy; Margin status; LVSI.

Introduction

The cervical cancer rate remains high in China. The estimated yearly cervical cancer incidence of China was 98,900 and the annual death rate was 30,500 in 2015 [1]. Although the new cases in the United States have been decreasing during the last years [2], cervical cancer is still an important problem for women in developing countries. With the widespread of cervical screening programs, the cases of micro-invasive cervical cancer in China have been increasing over the last decades; this early detection of disease might lead to a down-staging of the disease. It is sure to be an item on the agenda to tailor treatment for micro-invasive cervical cancer to the individual.

According to 1994-2009 International Federation of Gynecology and Obstetrics (FIGO) staging system, Stage IA1 cervical cancer has been defined to be invasive carcinoma detected only by microscopy with measured stromal invasion 3.0 mm or less in depth and 7.0 mm or less in horizontal spread. Stage IA1 cervical cancer has a 99% survival rate and an excellent prognosis [3]. If there is low risk of metastasis, recurrence, and death from the disease of Stage IA1, radical hysterectomy may be not the first choice for those patients. According to a British society for colposcopy and cervical pathology audit, primary treatment options for Stage IA1 patients should take into account

whether they want to preserve their fertility and whether they have lymphovascular space invasion (LVSI) [4]. With a younger tendency of cervical cancer patients at diagnosis, more conservative surgical approaches might find general acceptance in young women and should be considered in the primary treatment of the patients.

The aim of the present study is to determine whether the outcomes of Stage IA1 cervical cancer patients varied between different surgical approaches, in order to evaluate the capability of simple hysterectomy as the first choice of primary treatment for patients without fertility desire. The authors also examined the correlation between pathological characteristics after conization and residual diseases in specimens of simple (Class I, Piver-Rutledge classification system [5] /Type A, Querleu-Morrow classification system [6]), modified radical (Class II/Type B), and radical hysterectomy (Class III/Type C), to identify the suitable patients to undergo conservative surgery.

Materials and Methods

After approval was granted by Institutional Review Board of Shanghai Obstetrics and Gynecology Hospital, Fudan University, documents of 3,582 consecutive cervical cancer patients from the hospital's cancer data base over a ten-year period from January 2005 to December 2014 were reviewed retrospectively. According to medical paper records and electronic records, a list of 721

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*Contributed equally.

Stage IA1 cervical cancer women treated with non-radical or radical surgery were identified. Relevant demographic and surgery pathologic data were extracted from the archived medical records and a standardized data collection form was compiled by two superior gynecologists. The follow-up surveys were also carried out by two superior gynecologists.

Information filled in the form included: age at diagnosis, year of diagnosis, presenting symptoms, gravidity and parity, marriage status, menopausal status, cytology of Pap smear or Thinprep cytologic test (TCT) at diagnosis, pathology of biopsy, pathology of conization, margin status of conization specimen, hysterectomy histology result, LVSI, pelvic lymph node involvement, types of hysterectomy, laparoscope applied or not, operating room time, estimated blood loss, peri-operative complications, retention time of catheterization, length of hospital stay, adjuvant chemotherapy, adjuvant radiotherapy, the length of follow up, time to relapse and recurrent site, and dead or alive at conclusion of the study.

Informed consent was obtained after thorough counseling about risks of recurrence and complications with each patient and her authorized dependents. All surgeries were performed by experienced gynecologists at Shanghai gynecology and obstetrics hospital. All hysterectomy frozen section evaluations were carried out by the specialized gynecologic pathologists. If the surgical margin of hysterectomy was positive for dysplasia or micro-invasive cancer on frozen sections, the patient underwent immediate additional resection of apical vagina or conversed to type B or type C hysterectomy. Patients diagnosed with micro-invasive cervical cancer by biopsy or conization or incidental finding on hysterectomy specimen were enlisted for analysis. Archived pathology slides from biopsy, conization, and three types of hysterectomy were reviewed by two certified gynecologic pathologists to confirm the pathologic diagnosis and margin status. After the establishment of diagnosis, staging of disease was made according to FIGO staging system (1994-2009). Patients were scheduled to have a follow-up visit one month after surgery, and every three to six months for five years, then have a follow-up visit every year. Physical examination and vaginal cytologic test and sonography (or MRI) were included in a follow-up visit.

Using the Wilcoxon signed-rank test and Kruskal-Wallis test, distributions of independent groups were compared; The Fisher's exact test calculated an exact probability value for the relationship between two dichotomous variables; Spearman's rank correlation coefficient was also applied to evaluate correlations between two groups; A logistic regression model was carried out to estimate whether the incidence of residual disease after conization was associated with pathologic parameters, such as pathologic subtype, pathology of conization, the higher level pathology between biopsy and conization, margin status of conization, LVSI, and types of hysterectomy. A p value of less than 0.05 was considered statistically significant. All analyses were performed using SPSS 20.0 software.

Results

Seven hundred and twenty-one (721 /3582, 20.1%) Stage IA1 cervical cancer patients were identified from 3,582 women with invasive cervical cancer evaluated at Shanghai Obstetrics and Gynecology Hospital between January 2005 and December 2014. Of 721 patients, the median age at diagnosis was 42-years-old (mean age 42.4 ± 7.58, 24-68 years) (Table 1). Of 721 women with Stage IA1 cervical cancer, 700 (97.1%) patients had squamous cell carcinoma (SCCA), 15 (2.1%) patients had adenocarcinoma (AC), and

Table 1. — *Demographics and clinical characteristics of patients.*

Clinical characteristics	Number of patients
Age (mean ± SD, in years)	42.41 ± 7.58
20-29	22 (3.1%)
30-39	227 (31.4%)
40-49	357 (49.5%)
50-59	98 (13.6%)
60-69	17 (2.4%)
Presenting symptom	721 (100.0%)
No chief complaint	396 (54.9%)
Contact vaginal bleeding	212 (29.4%)
Irregular vaginal bleeding	55 (7.6%)
Postmenopausal bleeding	10 (1.4%)
Abnormal vaginal discharge	48 (6.7%)
Histology	721 (100.0%)
Squamous	700 (97.1%)
Adenocarcinoma	15 (2.1%)
Adenosquamous	6 (0.8%)
HPV infection	163 (100.0%)
Yes	148 (90.8%)
No	15 (9.2%)
Surgical procedure	721 (100.0%)
Laparoscopy	471 (65.3%)
Laparotomy	221 (30.7%)
Transvaginal procedure	29 (4.0%)
Pelvic lymph node involvement	141 (100.0%)
Yes	0
No	141 (100.0%)
Adjuvant chemotherapy	686 (100.0%)
Yes	8 (1.2%)
No	678 (98.8%)
Adjuvant chemoradiotherapy	686 (100.0%)
Yes	684 (99.7%)
No	2 (0.3%)

six (0.8%) patients had adeno-squamous carcinoma (AS) (Table 1). The lymph vascular space invasion (LVSI) occurred in 20 (2.8%) patients. There was no pelvic lymph node involvement in 141 patients who underwent pelvic lymphadenectomy. Imaging examination also showed no diseased pelvic lymph node with 721 patients. Of 163 patients had HPV test at diagnosis, 148 (90.8%) patients showed HPV high-risk type infection.

Conization was performed in 18 cases as definitive surgical approach, type A hysterectomy was performed in 528 cases, type B hysterectomy in 107 cases, and type C hysterectomy in 68 cases. There were significant differences between conization and three types of hysterectomy in blood loss, operating room time, hospital stay, and catheterization (Table 2). Conization had the least blood loss, operative time, hospital stay, and no retention catheterization ($p < 0.01$) (Table 2). Peri-operative complications occurred in 11 patients, six (three poor wound healing in abdomen, one postoperative infection, and two bladder injuries) of whom received type A hysterectomy, three (one postoper-

Table 2. — *Surgical approaches and peri-operative characteristics.*

Type of surgery therapy	C (n=18)	AH (n=528)	BH (n=107)	CH (n=68)	*p*-value
Operative time (minutes)	34.71±30.70	86.67± 32.17	186.95±65.88	226.75±65.15	<0.01
Estimated blood loss (ml)	30.92±10.25	104.65±100.72	351.75± 323.75	494.56±358.46	<0.01
Length of hospital stay (days)	2.22±0.97	5.87±2.16	10.47±3.81	11.74±3.82	<0.01
Urinary catheterization time	18	528	107	68	<0.01
No	18	2	0	0	
Not more than seven days		521	25		
More than seven days and not more than 30 days		5	59	30	
More than 30 days			23	38	
Recurred					1.00
No	18 (100.0%)	502 (99.8%)	98 (100.0%)	64 (100.0%)	
Yes	0	1 (0.2%)	0	0	
Complication index					0.151
No	18 (100.0%)	522 (98.9%)	104 (97.2%)	66 (97.1%)	
Yes	0	6 (1.1%)	3 (2.8%)	2 (2.9%)	
Poor wound healing in abdomen		3 (0.6%)			
Postoperative infection		1 (0.2%)		1 (1.5%)	
Postoperative hematoma			1 (0.9%)		
Bladder injury		2 (0.4%)	1 (0.9%)	1 (1.5%)	
Ureteral injury			1 (0.9%)		

C: conization; AH: type A hysterectomy, simple hysterectomy; BH: type B hysterectomy, modified radical hysterectomy; CH: type C hysterectomy, radical hysterectomy.

ative hematoma, one bladder injury, and one ureteral injury) of whom received type B and two (one postoperative hematoma and one bladder injury) received type C hysterectomy (*p* = 0.151). One patient recrudesced more than three years after type A hysterectomy (*p* = 1.00). Disease recurrence was defined as a histologic diagnosis of invasive carcinoma. There were no deaths during the follow-up period in this cohort study.

Among 692 women that underwent cone excision with identifiable margin status, 683 patients were diagnosed with invasive cancer and nine patients were diagnosed with dysplasia by combining conization pathology with biopsy (Table 3). The diagnosis of nine women with dysplasia was upgraded to stage IA1 after hysterectomy according to pathologist and the operative extent of three women was enlarged according to the fast-frozen section. The management of patients with different pathologic characteristics after conization is showed in Table 3. Of Stage IA1 cervical cancer patients with LVSI, nine (52.9%) patients had type C hysterectomy, four (23.5%) had type B hysterectomy, and three (17.6%) had type A hysterectomy as their definitive treatment (three patients with LVSI found incidentally during hysterectomy for uterine fibroid were not included). One patient with LVSI and positive margin for dysplasia received colposcopy and re-biopsy after conization (loop electrosurgical excision procedure, LEEP) and the other three patients (without LVSI) with positive margin for dysplasia refused to have further surgical approach when the result of colposcopy re-evaluation showed no residual disease. Of 683 Stage IA1 cervical cancer patients diagnosed at conization, eight (53.3%) women with positive margin for invasive carcinoma had type B or type C hysterectomy, 129 (36.4%) women with positive margin for dysplasia had type B or type C hysterectomy, and 25 (8.0%) women with negative margin had radical surgical approaches (*p* < 0.01). Two patients (0.3%), who had positive margins for dysplasia after simple hysterectomy and colposcopy re-evaluation showed residual dysplasia on vaginal stump, then received chemoradiotherapy. Six (1.2%) patients with LVSI received adjuvant chemotherapy after surgery.

The present authors made an attempt to clarify the potential risk factors predicting the residual disease on the cervix after conization. The higher grade of pathology between conization and biopsy represented the pathologic diagnosis before hysterectomy. Using Logistic regression analysis, the authors found positive margin status (*p* < 0.01) and LVSI (*p* = 0.034), rather than pathology of conization, pathology before hysterectomy, scope of surgery, and pathologic subtype, were associated with the residual disease in following hysterectomy specimens. Table 4 shows the residual disease found in three types of hysterectomy specimens for groups of different combination of pathologic diagnosis, margin status, and LVSI after cone excision. Six hundred and eighty-six (95.1%) patients had follow up visits with an average duration of 3.67 ± 2.19 years.

Discussion

This study retrospectively reported different surgical approaches of 721 women with Stage IA1 cervical cancer during a period of decade. The low recurrence and high survival of Stage IA1 cervical cancer patients after conization

Table 3. — *Pathological characteristics after cone excision and definitive surgical approach.*

Pathological characteristics			Surgical approach (number of patients)				Total
Pathology	Margin		C	AH	BH	CH	
Dysplasia	Benign			2	1		3
	LVSI	-		2	1		3
	Dysplasia			4	1	1	6
	LVSI	-		4	1	1	6
	Total			6	2	1	9
	LVSI	-		6	2	1	9
Invasive	Benign		13	276	20	5	314
	LVSI	+	0	0	1	1	2
		-	13	276	19	4	312
	Dysplasia		4	221	72	57	354
	LVSI	+	1	3	3	8	15
		-	3	218	69	49	339
	Invasive			7	5	3	15
	LVSI	-		7	5	3	15
	Total		17	504	97	65	683
	LVSI	+	1	3	4	9	17
		-	16	501	93	56	666
Total	Benign		13	278	21	5	317
	LVSI	+	0	0	1	1	2
		-	13	278	20	4	315
	Dysplasia		4	225	73	58	360
	LVSI	+	1	3	3	8	15
		-	3	222	70	50	345
	Invasive			7	5	3	15
	LVSI	-		7	5	3	15
	Total		17	510	99	66	692
	LVSI	+	1	3	4	9	17
		-	16	507	95	57	665

C: conization; AH: type A hysterectomy, simple hysterectomy; BH: type B hysterectomy, modified radical hysterectomy; CH: type C hysterectomy, radical hysterectomy; LVSI: lymphovascular space invasion.

were comparable to those after three types of hysterectomy. Conization, however, took the position of advantage over type A, B, and C hysterectomies in respect of shorter operative time, less blood loss, shorter hospital stay, and urinary catheterization time.

In the present study, type B and C hysterectomies were performed in 107 (14.8%) and 68 (9.4%) women with Stage IA1 cervical cancer, which were characterized by great variation in definitive surgery in the previous studies [7-10]. There is no difference in overall survival and relapse of disease among conservative conization and three types of hysterectomy. In a past report, none of the patients with early-stage cervical cancer underwent simple hysterectomy or cone biopsy had a recurrence during a median follow-up period of 21 months [7]. Even if patients with cervical adenocarcinoma Stage IA1, hysterectomy and only surgical conization to preserve fertility were effective approaches [11]. Non-radical surgery seemed to be an appropriate choice in selected early-stage cervical cancer patients. There was a universal idea in Chinese patients that survival from the disease was more important than quality of life after treatment. Of these Stage IA1 cervical cancer patients, 89.5% women were premenopausal and 34.5%

women were less than 40 years of age. It showed a high incidence of micro-invasive cervical cancer in young women. With improving living conditions and loosening of the "birth control" policy, there will be a new trend of fertility in China. The increasing young patients with early-stage cervical cancer will prefer conservative surgical approach, thus its safety should be evaluated repeatedly.

The margin status of conization should be considered when making management choices (NCCN Guidelines for Cervical Cancer version 1. 2017). The positive margin of conization specimen may be a cue of residual disease. It was reported that residual disease could be found in 44% to 84% of repeat operation specimens after conization with positive surgical margins [12-14]. Patients with positive margins in cone biopsy specimens have an increased risk of residual disease at radical hysterectomy and require careful evaluation before conservative surgery [15]. Residual disease in women who underwent secondary surgery was significantly related to positive margins on the primary cone excision [9, 16], which was consistent with the present findings. In this study, residual disease rate of patients with positive conization margins for intraepithelial lesion and micro-invasive cervical cancer was 25.4%, lower than that

Table 4. — *Pathological characteristics after cone excision and residual disease.*

Pathological characteristics			Residual disease (number of patients)			Total
Pathology	Margin		Benign	Dysplasia	Invasive	
Dysplasia	Benign				3	3
	LVSI	-			3	3
	Dysplasia				6	6
	LVSI	-			6	6
	Total				9	9
	LVSI	-			9	9
Invasive	Benign		280	21	4	305
	LVSI	+	2	0	0	2
		-	278	21	4	303
	Dysplasia		267	78	8	353
	LVSI	+	7	7	1	15
		-	260	71	7	338
	Invasive		12	2	1	15
	LVSI	-	12	2	1	15
	Total		559	101	13	673
	LVSI	+	9	7	1	17
		-	550	94	12	656
Total	Benign		280	21	7	308
	LVSI	+	2	0	0	2
		-	278	21	7	306
	Dysplasia		267	78	14	359
	LVSI	+	7	7	1	15
		-	260	71	13	344
	Invasive		12	2	1	15
	LVSI	-	12	2	1	15
	Total		559	101	22	682
	LVSI	+	9	7	1	17
		-	550	94	21	665

LVSI: lymphovascular space invasion.

of other reports. The lower residual disease rate in this study may be due to cauterization of wound edge by electrosurgical conization. It was reported that cold knife conization with electrocauterization was a safe treatment option for Stage IA1 cervical carcinoma patients even if with CIN 3 exocervical resection margins under careful follow-up [17]. Nevertheless, the residual disease was also found in 9% patients with a negative conization margin in the present study. With the weakness of non-prospective, non-randomized analysis for thus research, Stage IA1 cervical cancer patients who had cone excision as primary treatment should be closely followed even if the margin is clear. The lead colposcopists of the United Kingdom believe that women with Stage IA cervical cancer who managed conservatively should be followed up for at least five years [4].

LVSI as well as margin status of conization was significantly associated with residual disease in the cervix uteri. LVSI is not a staging criterion of FIGO classification, but may be a risk factor of lymph node metastasis. There was no positive pelvic lymph nodes found in patients who underwent pelvic lymphadenectomy in this study, which coincided with the previous study [10]. Nevertheless, the other report summarized a few cases of Stage 1a1 cervical cancer with pelvic lymph node metastasis [18]. It was estimated that the incidence of lymph node metastasis in Stage 1a1 was as low as 0.8% [19]. In few cases, patients with lymph node metastasis even showed no LVSI. There were 20 patients in this study with positive LVSI. There appears to be no evidence of pelvic lymph node metastasis in all 721 Stage 1a1 cervical cancer patients by radiologic or pathological examination. Whether positive LVSI indicates an increased risk of lymph node metastasis is still controversial. Conization with sentinel lymph node (SLN) mapping/lymphadenectomy might be a reasonable strategy in cases of Stage IA1 with LVSI and negative margins [20]. The present study also found that LVSI had significantly positive correlation with residual disease in specimens of three types of hysterectomy, which was in agreement with previous research [9]. There was a different report demonstrating that residual disease in women who underwent subsequent surgery had no correlation with LVSI emerged [16]. The diversity of conclusions from previous researches led to variable management and follow-up strategies of Stage IA1 cervical cancer patients with positive LVSI at present. The larger number of patients and more radical surgical approaches in the present study provided more precise information to evaluate the necessity and efficacy of

the management approach.

In summary, conization, rather than three types of hysterectomy, proved to be the alternative optimization of surgical approach for Stage IA1 cervical cancer patients. Positive margin status of conization and LVSI significantly prompted the residual disease in the cervix uteri, which might result in palindromia of disease. Thus, margin status and LVSI should be taken into account when conservative treatment is requested.

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Corresponding Author:
XISHI LIU, M.D.
Shanghai Obstetrics and Gynecology Hospital
Fudan University
128 Shenyang Road
Shanghai 200090 (China)
e-mail: lxsdoc@sina.com