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Comparative outcomes of simple versus radical hysterectomy in patients with and without very low-risk early-stage cervical cancer: An exploratory analysis from the Gynecologic Cancer Intergroup/Canadian Cancer Trials Group CX.5/SHAPE trial

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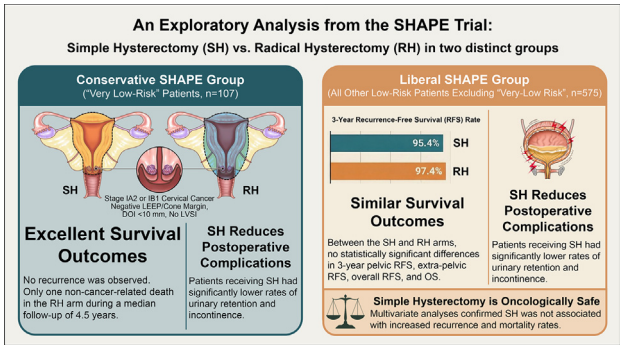
HIGHLIGHTS

- This analysis stratified patients with and without very low risk cervical cancer from the SHAPE trial.
- Very low risk (Conservative group) was similar to ConCerv; Liberal group included all others.
- In the Conservative group, no recurrence was observed after simple (SH) or radical hysterectomy (RH).
- In the Liberal group, absence of residual cancer at hysterectomy was associated with lower recurrence risk.
- In both groups, SH was associated with lower rates of urinary dysfunction than RH.

GRAPHICAL ABSTRACT



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ABSTRACT

Objective. To compare oncologic outcomes and perioperative morbidity between simple hysterectomy (SH) and radical hysterectomy (RH) in patients with and without very low-risk early-stage cervical cancer from the phase III Simple Hysterectomy And PElvic node assessment (SHAPE) trial.

Methods. Patients who underwent SH or RH in the SHAPE trial were classified into the Conservative SHAPE group (very low-risk), meeting criteria similar to the ConCerv trial, and the Liberal SHAPE group (without very low-risk), including everyone else. Between the SH and RH arms in each group, survival outcomes, including recurrence-free survival (RFS) and overall survival (OS), and intraoperative and postoperative morbidities were compared. Factors associated with recurrence and mortality rates were also investigated.

Results. In the Conservative SHAPE group ($n = 107$), no recurrence was observed in either SH or RH arms, and only one non-cancer-related death in the RH arm during a median follow-up of 4.5 years. In the Liberal SHAPE group ($n = 575$), the SH arm showed similar 3-year pelvic RFS (96.9 % vs. 97.4 %; HR, 1.15; 95 % CI, 0.49–2.70), extrapelvic RFS (97.7 % vs. 99.6 %; HR, 3.64; 95 % CI, 0.76–17.5), overall RFS (95.4 % vs. 97.4 %; HR, 1.56; 95 % CI, 0.70–3.48), and OS (98.9 % vs. 99.3 %; HR, 1.21; 95 % CI, 0.41–3.59), compared with the RH arm. In multivariate analyses, SH was not associated with recurrence and mortality rates, while absence of residual disease in the hysterectomy specimen was associated with lower recurrence. In both groups, SH was associated with a lower risk of urinary retention and incontinence.

Conclusion. There were similar recurrence and survival outcomes but less morbidity from simple hysterectomy compared to radical hysterectomy in patients with and without very low-risk early-stage cervical cancer from the SHAPE trial.

1. Introduction

Cervical cancer, the most common gynecologic malignancy, ranks as the fourth most commonly diagnosed female cancer and the fourth leading cause of female cancer death worldwide [1]. Cervical cancer is indeed a global burden, as 661,000 new cervical cancer cases and 348,000 cervical cancer deaths are estimated annually. Owing to the disease-specific early symptoms, effective screening tools, and vaccination programs, most cervical cases in developed countries are diagnosed at an early stage, and surgery remains a mainstay of treatment for patients with early-stage cervical cancer [2–4]. While radical hysterectomy (RH) with pelvic lymphadenectomy, conducted by a minimally invasive surgical (MIS) approach, had long been considered standard practice and was widely performed [5–7], the paradigm of surgical treatment for early-stage cervical cancer has undergone a major shift following the results of the recent landmark Simple Hysterectomy And PElvic node assessment (SHAPE) [8].

In the SHAPE trial, simple hysterectomy (SH) was not inferior to RH with respect to the 3-year pelvic recurrence rate, while SH was associated with a lower risk of urinary incontinence or urinary retention in patients with low-risk cervical cancer [8]. Furthermore, compared to RH, SH was associated with lower rates of sexual dysfunction [9], and less costly and more effective than RH in a cost-effectiveness analysis [10]. Based on these findings, the latest version of National Comprehensive Cancer Network (NCCN) guidelines support SH for selected patients with early-stage, low-risk cervical cancer as a surgical de-escalation strategy [11]. However, the NCCN guidelines' criteria for SH are stricter or more conservative than those of the SHAPE trial, although most of the criteria are listed as "preferred."

Historically, the criteria for SH have been developed based on previous studies that evaluated risk factors for recurrence or parametrial involvement [12–14]. Prior to the SHAPE trial, a multi-center, prospective single-arm study, ConCerv, reported that conservative surgery, consisting of SH or conization plus lymphadenectomy, was associated with a very low 2-year recurrence rate (3.5 %) in patients with early-stage, low-risk cervical cancer [15]. Both ConCerv and SHAPE trials enrolled patients with 2009 FIGO stages IA2–IB1 cervical cancer, having tumor size ≤2 cm and depth of invasion (DOI) <10 mm [8,15]. Notably, in the ConCerv trial, conization was mandatory to determine eligibility, and only those who had negative conization margins for malignancy and high-grade dysplasia and no LVSI were included. Grade 3 adenocarcinoma were also excluded. However, in the SHAPE trial, LVSI and grade 3 adenocarcinoma were not exclusion criteria. Indeed, the ConCerv trial was more conservative than the SHAPE trial. At this point, it is unknown whether oncologic outcomes of SH are similar to those of RH not only in the "conservative" population but also in the "liberal" population.

Therefore, the aim of this exploratory analysis study of the SHAPE trial was to evaluate whether SH is safe compared to RH within the entire SHAPE population: not only in the Conservative SHAPE group, meeting criteria similar to the ConCerv trial, but also in the Liberal SHAPE group, meeting criteria beyond the ConCerv trial.

2. Methods

2.1. Study design and population

This is an exploratory analysis study of the phase III randomized SHAPE trial, which compared SH to RH with lymphadenectomy in patients with low-risk, early-stage cervical cancer. Details of the SHAPE trial have been published in 2024 [8]. Briefly, the SHAPE trial enrolled patients who met all the following inclusion criteria: [1] 2009 FIGO stages IA2–IB1 cervical cancer with squamous-cell carcinoma, adenocarcinoma, or adenosquamous carcinoma with any histologic grade; [2] cervical lesions ≤2 cm; [3] tumors with DOI <10 mm on the sample obtained by diagnostic loop electrical excision procedure (LEEP) or conization, or invading less than 50 % of cervical stromal tissue by preoperative pelvic magnetic resonance imaging (MRI); [4] no evidence of lymph node metastasis on preoperative imaging. LVSI was not an exclusion criterion. MRI was mandatory except for patients with stage IA2 disease who underwent preoperative LEEP or conization. After providing written informed consent, patients were randomly assigned to undergo SH or RH with a 1:1 ratio. Randomization was performed with the following stratification factors: participating group, intended sentinel node mapping, stage, histologic type, and grade. Adjuvant therapy was provided at the discretion of the treating physicians in alignment with local practice. The protocol was developed by the Canadian Cancer Trials Group, and approved by each center's Institutional Review Board.

In the SHAPE trial, 700 patients were randomized between December 2012 and November 2019. Of the 350 patients assigned to the SH arm, 336 underwent the assigned procedure, while seven patients were treated by RH. Of 350 patients assigned to the RH arm, 337

underwent the assigned procedure, while two patients were treated by SH. Therefore, a total of 338 and 344 patients underwent SH and RH, respectively, and were set as the study population of the current exploratory analysis study. For the study objectives, the study population was categorized into two groups. The first group is "Conservative SHAPE," consisting of patients who received preoperative LEEP or conization and met similar eligibility criteria of the ConCerv trial. Specifically, only those who had negative conization margins, no LVSI, and tumors with DOI <10 mm were included in this group, and this would be considered very low risk. All other patients in the SHAPE trial were assigned to the second group, "Liberal SHAPE." Fig. 1 depicts comparisons of the SHAPE and ConCerv trials and the two groups assigned for the exploratory analysis study.

2.2. Statistical analysis

Primary outcome of the SHAPE trial was pelvic recurrence at 3 years. In the current exploratory analysis study, we compared oncologic outcomes and morbidities between the SH and RH arms in the Conservative and Liberal SHAPE groups, respectively.

The differences in clinicopathologic characteristics and surgical outcomes were evaluated between the SH and RH groups. Pearson's chi-square test or Fisher's exact test was used for comparisons of categorical variables, while Student's *t*-test or Mann–Whitney *U* test was used for comparisons of continuous variables. The Kaplan–Meier analysis with log-rank test was used to compare the survival outcomes between the two groups. Survival outcomes included pelvic recurrence-free survival (RFS), extrapelvic RFS, RFS, and overall survival (OS). Cox proportional hazards regression models were constructed to calculate the hazard ratios (HRs) and 95 % confidence intervals (CIs). For subsequent multivariate analyses, surgical arm (SH vs. RH) and variables with $P \leq 0.1$ in univariate analyses were used. As an exploratory analysis, *P* values were not adjusted for multiple comparisons and any difference with a *P* value of <0.05 was considered statistically significant.

3. Results

3.1. Patients' characteristics

Of 682 patients in the study population, 107 (15.7 %) and 575 (84.3 %) were categorized into Conservative and Liberal SHAPE groups, respectively. **Supplementary Table 1** summarizes patient characteristics in the two risk groups. Patient age, ethnic group, ECOG performance status, histology type, and grade were similar between the two groups. However, patients in the Conservative SHAPE group had significantly higher body mass index (median, 26.4 vs. 24.6 kg/m^2; $P = 0.01$) and greater proportion with stage IA2 disease (22.4 % vs. 5.2 %; $P < 0.0001$), compared to those in the Liberal SHAPE group. While all patients in the Conservative SHAPE group had preoperative LEEP or conization, it was performed in 77.0 % of the patents in the Liberal SHAPE group ($P < 0.0001$).

Table 1 summarizes patient characteristics according to risk group and surgical treatment. In the Conservative SHAPE group, 54 and 53 patients had SH and RH, respectively. No differences in baseline characteristics were observed between the SH and RH arms. In the Liberal SHAPE group, 284 and 291 patients underwent SH and RH, respectively. A significant difference between patients who had SH and RH was found only in histologic type ($P = 0.02$) and diagnostic procedure ($P = 0.047$). While the SH and RH arms had similar proportions of squamous cell carcinoma (61.6 % vs. 62.5 %; $P = 0.820$), that of adenosquamous carcinoma was higher in the SH arm than the RH arm (5.6 % vs. 1.4 %; $P = 0.005$). Preoperative LEEP or conization was more frequently performed in the SH arm than the RH arm (81.3 % vs. 72.9 %; $P = 0.016$) (Table 1).

(A)

SHAPE	ConCerv	Conservative SHAPE
① FIGO 2009 stage IA2–IB1	① FIGO 2009 stage IA2–IB1	① FIGO 2009 stage IA2–IB1
② Squamous, adenocarcinoma, or adenosquamous carcinoma	② Squamous (any grade) or adenocarcinoma (grade 1 or 2 only)	② Squamous, adenocarcinoma, or adenosquamous carcinoma
③ Tumor size ≤2 cm	③ Tumor size <2 cm	③ Tumor size ≤2 cm
④ Depth of invasion <10 mm by LEEP/conization or <50% by MRI	④ No lymphovascular space invasion	④ No lymphovascular space invasion
⑤ Tumor of any histologic grade	⑤ Depth of invasion <10 mm	⑤ Depth of invasion <10 mm by LEEP/Conization
⑥ No evidence of lymph node metastasis on preoperative imaging	⑥ Negative imaging for metastatic disease	⑥ Negative imaging for metastatic disease
	⑦ Negative conization margins	⑦ Negative conization margins
Lymphovascular invasion was not an exclusion criterion.		
MRI was mandatory except for patients with stage IA2 cancer who underwent preoperative LEEP or conization.	Cervical conization was performed to determine eligibility, with one repeat cone permitted.	Cervical conization was performed.

(B)

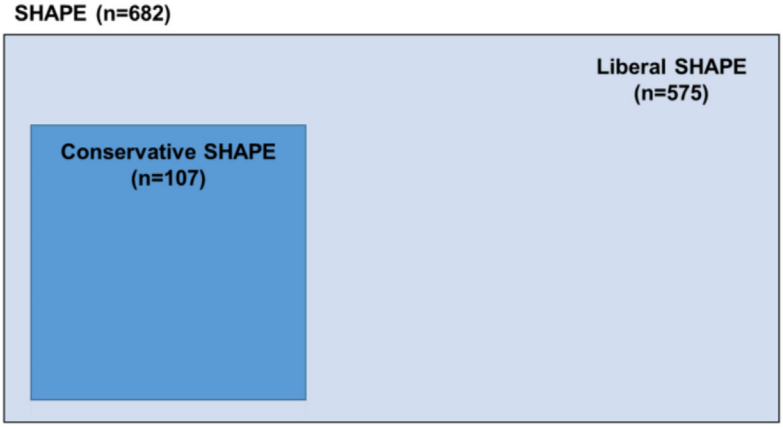

Fig. 1. Study criteria and diagram.
(A) Comparisons of eligibility criteria for the SHAPE, ConCerv, and Conservative SHAPE group.
(B) Classification of the Conservative and Liberal SHAPE groups.

Table 1
Characteristics of the patients at baseline.

	Conservative SHAPE			*Liberal SHAPE*		
	SH ($n = 54$, %)	RH ($n = 53$, %)	*P*	SH ($n = 284$, %)	RH ($n = 291$, %)	*P*
Age, years						
Median (range)	42 (26–73)	45 (24–77)	0.20	42 (28–74)	45 (24–80)	0.07
Distribution			0.25			0.02
≤50 yr	45 (83.3)	39 (73.6)		220 (77.5)	201 (69.1)	
>50 yr	9 (16.7)	14 (26.4)		64 (22.5)	90 (30.9)	
Race or ethnic group			0.32			0.99
White	44 (81.5)	41 (77.4)		212 (74.7)	216 (74.2)	
Asian	1 (1.9)	0 (0.0)		19 (6.7)	20 (6.9)	
Black	1 (1.9)	0 (0.0)		3 (1.1)	4 (1.4)	
American Indian or Alaska Native	0 (0.0)	0 (0.0)		1 (0.4)	1 (0.3)	
Not reported	7 (13.0)	7 (13.2)		38 (13.4)	41 (14.2)	
Unknown	1 (1.9)	5 (9.4)		11 (3.9)	9 (3.1)	
ECOG performance status			1.00			0.96
0	52 (96.3)	52 (98.1)		272 (95.6)	278 (95.5)	
1	2 (3.7)	1 (1.9)		12 (4.2)	11 (3.8)	
2	0 (0.0)	0 (0.0)		0 (0.0)	0 (0.0)	
3	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.3)	
Data missing	0 (0.0)	0 (0.0)		0 (0.0)	1 (0.3)	
BMI, kg/m^2			0.32			0.37
Median (range)	25.5 (18.5–53.3)	27.3 (20.2–47.9)		25.1 (16.4–51.2)	24.6 (16.7–43.7)	
Histologic type			0.82			0.02
Squamous cell carcinoma	31 (57.4)	29 (54.7)		175 (61.6)	182 (62.5)	
Adenocarcinoma	21 (38.9)	23 (43.4)		93 (32.8)	105 (36.1)	
Adenosquamous carcinoma	2 (3.7)	1 (1.9)		16 (5.6)	4 (1.4)	
Histologic grade			0.92			0.69
1	16 (29.6)	17 (32.1)		57 (20.1)	70 (24.1)	
2	19 (35.2)	16 (30.2)		105 (37.0)	106 (36.4)	
3	6 (11.1)	8 (15.1)		41 (14.4)	38 (13.1)	
Not assessable	13 (24.1)	12 (22.6)		81 (28.5)	77 (26.5)	
FIGO stage			1.00			0.84
IA2	12 (22.2)	12 (22.6)		17 (6.0)	13 (4.5)	
IB1	42 (77.8)	41 (77.4)		267 (94.0)	278 (95.5)	
Diagnostic procedure			NA			0.047
LEEP or conization	54 (100)	53 (100)		231 (81.3)	212 (72.9)	
Cervical biopsy only	0 (0.0)	0 (0.0)		50 (17.6)	73 (25.1)	
Missing	0 (0.0)	0 (0.0)		3 (1.1)	6 (2.1)	

Abbreviations. BMI, body mass index; ECOG, Eastern Cooperative Oncology Group; FIGO, International Federation of Gynecology and Obstetrics; LEEP, loop electrosurgical excision procedure; RH, radical hysterectomy; SH, simple hysterectomy; NA: Not available.

Surgical outcomes and adjuvant treatment are summarized in Table 2. In both the Conservative and Liberal SHAPE groups, MIS was more frequently performed in the SH arm than the RH arm (87.0 % vs. 67.9 %; $P = 0.02$ and 82.4 % vs. 71.1 %; $P = 0.003$, respectively). In the Conservative SHAPE group, pathologic examination of the hysterectomy specimen revealed LVSI in one patient in the RH arm and residual tumors in 6 (11.1 %) and 6 (11.3 %) in the SH and RH arms, respectively, without statistical significance ($P = 1.00$). Cervical lesions >2 cm on final pathology, lymph node involvement, and parametrial involvement were identified in one case each, and all of them had undergone RH, rather than SH. After surgery, only two patients in the Conservative SHAPE group received adjuvant treatment. In the Liberal SHAPE group,

Table 2
Surgical outcomes and adjuvant treatment.

	Conservative SHAPE			*Liberal SHAPE*		
	SH ($n = 54$, %)	RH ($n = 53$, %)	*P*	SH ($n = 284$, %)	RH ($n = 291$, %)	*P*
Surgical approach			0.02			0.003
Open	7 (13.0)	17 (32.1)		50 (17.6)	82 (28.2)	
MIS	47 (87.0)	36 (67.9)		234 (82.4)	207 (71.1)	
LVSI in conization specimen	0 (0.0)	0 (0.0)	1.00	67/212 (31.6)	83/231 (35.9)	0.37
Positive surgical margins in conization specimen	0 (0.0)	0 (0.0)	1.00	173/212 (81.6)	168/231 (72.7)	0.03
LVSI in hysterectomy specimen	0 (0.0)	1 (1.2)	0.50	45 (15.9)	44 (15.1)	0.82
Positive surgical margins in hysterectomy specimen	6 (11.1)	6 (11.3)	1.00	8 (2.8)	10 (3.4)	0.81
Residual disease in hysterectomy specimen	6 (11.1)	6 (11.3)	1.00	148 (52.1)	157 (54.0)	0.68
Lesions >2 cm on final pathology	0 (0.0)	1 (1.9)	0.50	14 (4.9)	14 (4.8)	1.00
Lymph node involvement	0 (0.0)	1 (1.9)	0.50	11 (3.9)	14 (4.8)	0.68
Parametrial involvement	0 (0.0)	1 (1.9)	0.50	0 (0.0)	5 (1.7)	0.06
Adjuvant treatment						
No	54 (100.0)	51 (96.2)	0.24	253 (89.1)	264 (90.7)	0.58
Chemotherapy only	0 (0.0)	0 (0.0)	1.00	1 (0.4)	0 (0.0)	0.49
Radiotherapy only	0 (0.0)	0 (0.0)	1.00	15 (5.3)	11 (3.8)	0.43
Both chemotherapy and radiotherapy	0 (0.0)	2 (3.8)	0.24	15 (5.3)	16 (5.5)	1.00

Abbreviations. CI, confidence interval; MIS, minimally invasive surgery, RH, radical hysterectomy; SH, simple hysterectomy.

443 patients had preoperative LEEP or conization, and 150 (33.9 %) had LVSI on the conization specimen, while 341 (77.0 %) had positive conization margins, which were more frequent in the SH arm than the RH arm (81.6 % vs. 72.7 %; $P = 0.03$). On pathologic examination of the hysterectomy specimen, the SH and RH arms showed similar rates of LVSI, positive resection margins, and residual disease. Cervical lesions >2 cm on final pathology, lymph node involvement, and parametrial involvement were identified in 28 (4.9 %), 25 (4.3 %), and 5 (0.9 %), respectively. While no differences in cervical lesions >2 cm on final pathology and lymph node involvement were observed between the SH and RH arms, parametrial involvement was more frequent in the RH arm than the SH arm with marginal statistical significance (1.7 % vs. 0 %; $P = 0.06$). After surgery, 10.1 % of patients in the Liberal SHAPE group received adjuvant treatment, which was similar between the SH and RH arms (10.9 % vs. 9.3 %; $P = 0.58$) (Table 2).

3.2. Survival outcomes

During a median follow-up of 4.5 years (range, 3–10 years), no patient relapsed and only one died in the Conservative SHAPE group; this patient underwent RH and died from medical conditions unrelated to cervical cancer. Among patients in the Liberal SHAPE group, recurrence occurred in 15 of 284 (5.3 %) who underwent SH as compared with 10 of 291 (3.4 %) who underwent RH ($P = 0.278$). In terms of recurrence patterns, pelvic recurrence occurred in 11 (3.9 %) patients in the SH arm and 10 (3.4 %) patients in the RH arm. The most common recurrence site was the vaginal vault in both arms. Recurrences outside the pelvis occurred in 7 (2.5 %) patients in the SH arm and 2 (0.7 %) in the RH arm. In the Liberal SHAPE group, 13 (2.3 %) patients died: 7 (2.5 %) and 6 (2.1 %) in the SH and RH arms, respectively. Of 13 deaths, five were related to cervical cancer: 4 (1.4 %) and 1 (0.3 %) in the SH and RH arms, respectively (**Supplementary Table 2**).

In the Conservative SHAPE group, pelvic RFS, extrapelvic RFS, RFS, and OS were not estimatable, therefore further multivariate analysis could not be performed. In the Liberal SHAPE group, between the SH and RH arms, no statistically significant differences in survival outcomes were observed: 3-year pelvic RFS (96.9 % vs. 97.4 %; HR, 1.15; 95 % CI, 0.49–2.70), extra-pelvic RFS (97.5 % vs. 99.6 %; HR, 3.64; 95 % CI, 0.76–17.5), RFS (95.4 % vs. 97.4 %; HR, 1.56; 95 % CI, 0.70–3.48), and OS (98.9 % vs. 99.3 %; HR, 1.21; 95 % CI, 0.41–3.59) (Fig. 2). In multivariate analysis adjusting for pathologic factors, SH was not associated with patients' RFS (aHR, 1.45; 95 % CI, 0.64–3.26; $P = 0.37$). Meanwhile, absence of residual disease in the hysterectomy specimen was associated with a lower risk of recurrence (aHR, 0.21; 95 % CI, 0.06–0.77; $P = 0.02$) (Table 3). Multivariate analysis adjusting for patient age, pathologic factors, and adjuvant treatment revealed that SH was not associated with OS (aHR, 1.44; 95 % CI, 0.45–4.67; $P = 0.54$). Meanwhile, negative surgical margins in the hysterectomy specimen (aHR, 0.22; 95 % CI, 0.05–1.09; $P = 0.06$) and cervical lesions ≤2 cm on final pathology (aHR, 0.31; 95 % CI, 0.08–1.21; $P = 0.09$) showed trends toward favorable OS (**Supplementary Table 3**).

3.3. Adverse events

Intraoperative and postoperative morbidities are presented in Table 4. Intraoperative surgical complications occurred in 4.7 % of the patients in the Conservative SHAPE group as compared with 7.1 % of the patients in the Liberal SHAPE group ($P = 0.352$). In both groups, no differences in detailed intraoperative injuries were observed between the SH and RH arms.

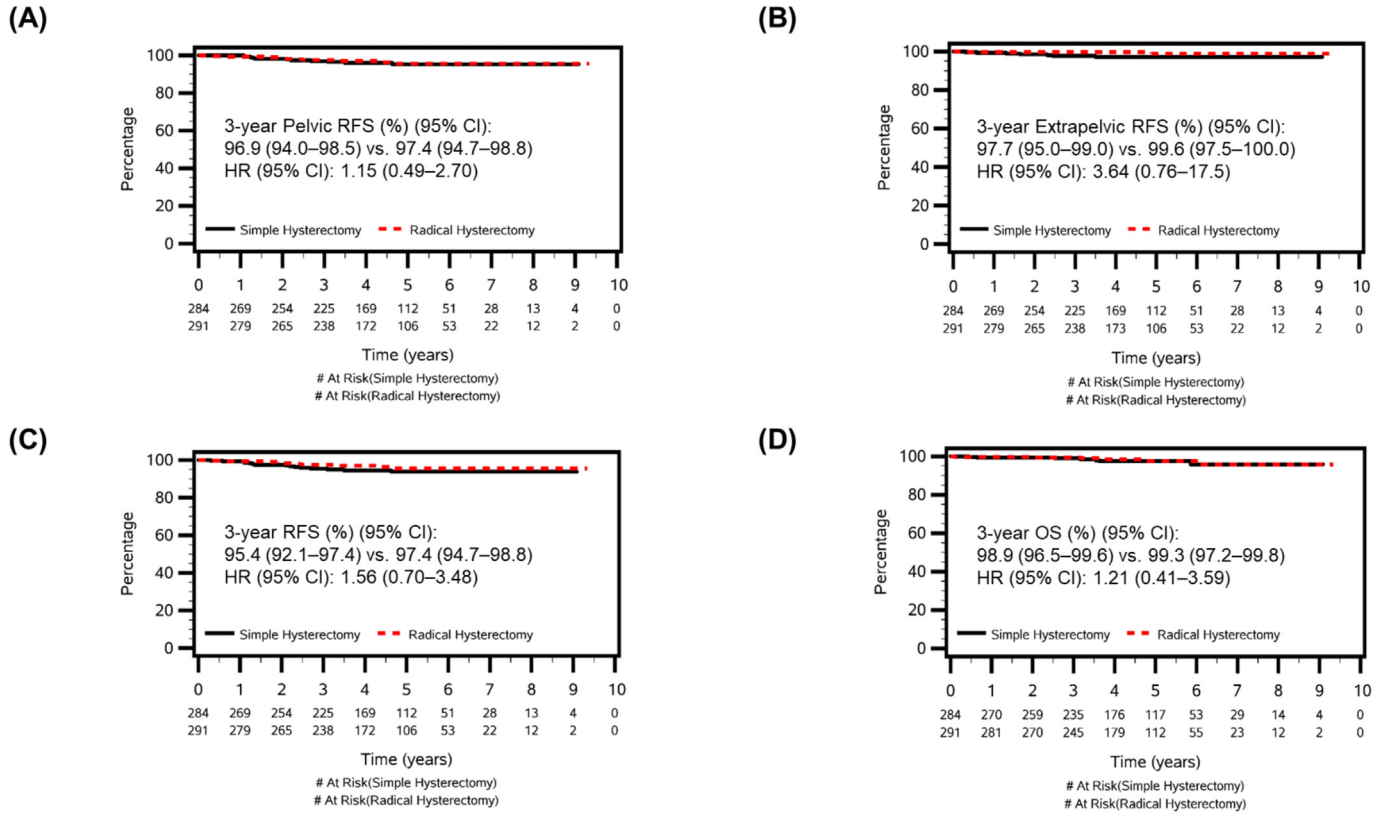

Fig. 2. Survival analysis in the Liberal SHAPE group.
Comparisons of survival outcomes between simple hysterectomy (black line) versus radical hysterectomy (red dotted line).
(A) Pelvic recurrence-free survival; (B) Extra-pelvic recurrence-free survival; (C) Recurrence-free survival; (D) Overall survival. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

Table 3
Factors associated with recurrence-free survival in the Liberal SHAPE group.

			Univariate		*Multivariate*	
	Events/N	3-year RFS rate (%) (95 % CI)	HR (95 % CI)	*P*	Adjusted HR (95 % CI)	*P*
Surgical group						
Simple hysterectomy	15/284	95.4 (92.1–97.4)	1.56 (0.70–3.48)	0.27	1.45 (0.64–3.26)	0.37
Radical hysterectomy (Ref.)	10/291	97.4 (94.7–98.8)				
Surgical approach						
Open	6/132	95.9 (90.4–98.3)	1.16 (0.46–2.92)	0.75		
MIS (Ref.)	19/441	96.6 (94.3–98.0)				
Age, years						
<50	16/408	96.8 (94.5–98.2)		0.70		
≥50 (Ref.)	9/167	95.6 (90.9–97.9)	0.71 (0.31–1.60)			
Histologic type						
Squamous cell carcinoma	16/357	96.6 (94.0–98.1)	1.09 (0.48–2.48)	0.83		
Non-squamous cell carcinoma (Ref.)	9/218	96.1 (92.4–98.1)				
FIGO stage						
IA2	1/30	100 (100—100)	0.77 (0.10–5.69)	0.80		
IB1 (Ref.)	24/545	96.3 (94.2–97.6)				
LVSI in conization specimen						
No	11/337	97.2 (94.6–98.5)	0.44 (0.20–0.99)	0.047	0.50 (0.17–1.48)	0.21
Yes (Ref.)	13/180	94.6 (89.9–97.2)				
Positive surgical margins in conization specimen						
No	2/67	98.4 (89.3–99.8)	0.67 (0.15–2.93)	0.59		
Yes (Ref.)	15/341	96.2 (94.0–97.6)				
LVSI in hysterectomy specimen						
No	16/486	97.1 (95.1–98.3)	0.31 (0.14–0.69)	0.005	1.05 (0.32–3.48)	0.94
Yes (Ref.)	9/89	92.7 (84.3–96.6)				
Positive surgical margins in hysterectomy specimen						
No	23/557	96.7 (94.8–98.0)	0.34 (0.08–1.44)	0.14		
Yes (Ref.)	2/18	88.1 (60.2–96.9)				
Residual disease in hysterectomy specimen						
No	3/270	98.8 (96.4–99.6)	0.14 (0.04–0.48)	0.002	0.21 (0.06–0.77)	0.02
Yes (Ref.)	22/305	94.3 (90.9–96.5)				
Lesions > 2 cm on final pathology						
No	21/547	96.7 (94.7–97.9)	0.24 (0.08–0.71)	0.01	0.43 (0.14–1.33)	0.14
Yes (Ref.)	4/28	91.5 (0.70–0.98)				
Lymph node involvement						
No	25/550	96.3 (94.2–97.6)	NA (NA-NA)	0.99		
Yes (Ref.)	0/25	100 (100–100)				
Parametrial involvement						
No	25/570	96.4 (94.5–97.7)	NA (NA-NA)	0.99		
Yes (Ref.)	0/5	100 (100–100)				
Adjuvant treatment						
No	21/517	96.7 (94.6–98.0)	0.63 (0.22–1.83)	0.39		
Yes (Ref.)	4/58	94.6 (84.2–98.2)				

Abbreviations. CI, confidence interval; FIGO, International Federation of Gynecology and Obstetrics; HR, hazard ratio; Ref., reference; MIS, minimally invasive surgery; RFS, recurrence-free survival; NA: Not available.

Between the Conservative and Liberal SHAPE groups, there were no differences in the incidence of surgery-related adverse events within 4 weeks after surgery (52.3 % vs. 45.6 %; $P = 0.197$) and beyond 4 weeks after surgery (59.8 % vs. 56.5 %; $P = 0.528$).

In the Conservative SHAPE group, the incidence of surgery-related adverse events within 4 weeks after surgery (42.6 % vs. 62.3 %; $P = 0.053$) and beyond 4 weeks after surgery (50.0 % vs. 69.8 %; $P = 0.04$) was less common in the SH arm than in the RH arm. In particular, the incidence of urinary retention was 0 % in the SH arm as compared with 15.1 % in the RH arm within 4 weeks after surgery ($P = 0.003$) and 1.9 % vs. 13.2 % beyond 4 weeks after surgery ($P = 0.03$). Urinary incontinence occurred significantly less in the SH arm than in the RH arm beyond 4 weeks after surgery (3.7 % vs. 17.0 %; $P = 0.03$) (Table 4).

In the Liberal SHAPE group, the incidence of surgery-related adverse events within 4 weeks after surgery (42.6 % vs. 48.5 %; $P = 0.18$) and beyond 4 weeks after surgery (54.2 % vs. 58.8 %; $P = 0.28$) was similar between the SH and RH arms. Nevertheless, the incidence of urinary retention was significantly less in the SH arm than in the RH arm: 0.7 % vs. 10.3 % within 4 weeks after surgery ($P = 0.0001$) and 0.4 % vs. 9.3 % beyond 4 weeks after surgery ($P = 0.0001$). Urinary incontinence was also less common in the SH arm than in the RH arm beyond 4 weeks after surgery (4.9 % vs. 10.0 %; $P = 0.03$) (Table 4**).**

4. Discussion

In this exploratory analysis of the SHAPE trial, survival outcomes and morbidities were compared between the SH and RH arms, stratified by very low-risk (Conservative group) and everyone else who qualified for SHAPE (Liberal group) but without very low-risk disease as defined by the Conservative group criteria. In the Conservative SHAPE group, no recurrence was observed in either SH or RH arms, and only one non-cancer related death in the RH arm during a median follow-up of 4.5 years. In the Liberal SHAPE group, the SH arm showed similar 3-year pelvic RFS, extrapelvic RFS, RFS, and OS, compared with the RH arm. However, both in the Conservative and Liberal SHAPE groups, SH was associated with a lower risk of urinary retention or incontinence. The current study results are consistent with those from the original SHAPE trial [8].

The Conservative SHAPE group represents patients with very low-risk, early-stage cervical cancer, similar to the ConCerv trial. As each clinical trial had different inclusion and exclusion criteria, the characteristics of the study populations are inevitably different, leading to limitations in direct comparisons between the trials and requiring careful interpretation of the study results. Nevertheless, from the SHAPE population, we could successfully identify patients who received

Table 4
Intraoperative and postoperative morbidities.

	Conservative SHAPE			*Liberal SHAPE*		
	SH ($n = 54$, %)	RH ($n = 53$, %)	*P*	SH ($n = 284$, %)	RH ($n = 291$, %)	*P*
Intraoperative injury						
Any intraoperative injury	2 (3.7)	3 (5.7)	0.68	22 (7.8)	19 (6.5)	0.63
Bladder	1 (1.9)	1 (1.9)	1.00	2 (0.7)	8 (2.7)	0.11
Ureter	0 (0.0)	2 (3.8)	0.24	3 (1.1)	3 (1.0)	1.00
Nerve	0 (0.0)	0 (0.0)	1.00	5 (1.8)	2 (0.7)	0.28
Bowel	0 (0.0)	0 (0.0)	1.00	2 (0.7)	2 (0.7)	1.00
Vein	0 (0.0)	0 (0.0)	1.00	4 (1.4)	1 (0.3)	0.21
Other	1 (1.9)	0 (0.0)	1.00	6 (2.1)	3 (1.0)	0.33
Surgery-related adverse event ≤ 4 weeks after surgery*						
Any adverse event	23 (42.6)	33 (62.3)	0.053	121 (42.6)	141 (48.5)	0.18
Abdominal pain	5 (9.3)	9 (17.0)	0.27	28 (9.9)	33 (11.3)	0.59
Constipation	4 (7.4)	3 (5.7)	1.00	12 (4.2)	19 (6.5)	0.27
Nausea	3 (5.6)	2 (3.8)	1.00	10 (3.5)	10 (3.4)	1.00
Vomiting	3 (5.6)	2 (3.8)	1.00	1 (0.4)	3 (1.0)	0.63
Fatigue	2 (3.7)	3 (5.7)	0.68	17 (6.0)	20 (6.9)	0.74
Urinary tract infection	2 (3.7)	4 (7.5)	0.44	5 (1.8)	12 (4.1)	0.14
Paresthesia	2 (3.7)	4 (7.5)	0.44	12 (4.2)	18 (6.2)	0.35
Peripheral sensory neuropathy	0 (0)	3 (5.7)	0.12	14 (4.9)	8 (2.7)	0.20
Urinary incontinence	1 (1.9)	3 (5.7)	0.36	7 (2.5)	16 (5.5)	0.09
Urinary retention	0 (0)	8 (15.1)	0.003	2 (0.7)	30 (10.3)	0.0001
Urinary tract pain	2 (3.7)	3 (5.7)	0.68	11 (3.9)	9 (3.1)	0.65
Pelvic pain	2 (3.7)	0 (0.0)	0.50	17 (6.0)	9 (3.1)	0.11
Vaginal discharge	3 (5.6)	3 (5.7)	1.00	8 (2.8)	10 (3.4)	0.81
Hot flashes	0 (0.0)	3 (5.7)	0.12	9 (3.2)	8 (2.7)	0.81
Surgery-related adverse event > 4 weeks after surgery*						
Any adverse event	27 (50.0)	37 (69.8)	0.049	154 (54.2)	171 (58.8)	0.28
Abdominal pain	4 (7.4)	10 (18.9)	0.09	32 (11.3)	37 (12.7)	0.61
Bloating	3 (5.6)	2 (3.8)	1.00	9 (3.2)	6 (2.1)	0.44
Constipation	5 (9.3)	4 (7.5)	1.00	8 (2.8)	15 (5.2)	0.20
Fecal incontinence	0 (0.0)	3 (5.7)	0.12	0 (0.0)	1 (0.3)	1.00
Fatigue	2 (3.7)	5 (9.4)	0.27	17 (6.0)	23 (7.9)	0.41
Muscle weakness lower limb	1 (1.9)	3 (5.7)	0.36	2 (0.7)	3 (1.0)	1.00
Paresthesia	3 (5.6)	3 (5.7)	1.00	14 (4.9)	19 (6.5)	0.47
Peripheral sensory neuropathy	2 (3.7)	3 (5.7)	0.68	19 (6.7)	10 (3.4)	0.09
Urinary frequency	0 (0.0)	5 (9.4)	0.03	5 (1.8)	12 (4.1)	0.14
Urinary incontinence	2 (3.7)	9 (17.0)	0.03	14 (4.9)	29 (10.0)	0.03
Urinary retention	1 (1.9)	7 (13.2)	0.03	1 (0.4)	27 (9.3)	0.0001
Urinary tract pain	0 (0.0)	4 (7.5)	0.06	9 (3.2)	10 (3.4)	1.00
Other renal and urinary disorders	1 (1.9)	6 (11.3)	0.06	6 (2.1)	7 (2.4)	1.00
Dyspareunia	3 (5.6)	3 (5.7)	1.00	18 (6.3)	16 (5.5)	0.73
Pelvic pain	3 (5.6)	1 (1.9)	0.62	20 (7.0)	16 (5.5)	0.49
Vaginal discharge	2 (3.7)	3 (5.7)	0.68	8 (2.8)	7 (2.4)	0.80
Lymphedema	1 (1.9)	6 (11.3)	0.06	34 (12.0)	30 (10.3)	0.60
Hot flashes	1 (1.9)	7 (13.2)	0.03	13 (4.6)	13 (4.5)	1.00

* Data include adverse events of grade 1 or higher that occurred in at least 5 % in either group. Grading was performed according to the Common Toxicity Criteria of the National Cancer Institute, version 4.0. Abbreviations. RH, radical hysterectomy; SH, simple hysterectomy.

preoperative LEEP or conization and met similar eligibility criteria to the ConCerv trial [15].

The ConCerv trial was a multi-center, prospective single-arm study, and included 100 patients with 2009 FIGO stages IA2–IB1 cervical cancer having squamous carcinoma (any grade) or adenocarcinoma (grade 1 or 2 only), tumor size ≤2 cm, no LVSI, DOI ≤10 mm and negative conization margins. Conization was mandatory to determine eligibility except women who had undergone an "inadvertent" SH with an unexpected post-operative diagnosis of cancer and met the inclusion criteria ($n = 16$). Excluding inadvertent SH cases, all patients had conservative surgery, consisting of conization ($n = 44$) or SH ($n = 40$) plus lymphadenectomy. During a median follow-up of 36.3 months, three patients relapsed within 2 years, resulting in a very low 2-year recurrence rate (3.5 %) [15].

In the Conservative SHAPE group, all patients received preoperative LEEP or conization, followed by SH or RH plus lymphadenectomy. On pathologic examination, residual disease in the hysterectomy specimen was noted in 11.2 %, which was higher than that of the ConCerv trial (2.5 %) [15]. This could be attributed to the fact that ConCerv permitted one repeat conization if required to meet the inclusion criteria (negative margins) and this was not necessarily done in SHAPE. Nevertheless, the survival outcomes of the Conservative SHAPE were excellent, as there was no recurrence and only one death unrelated to cervical cancer, after a median follow-up of 4.5 years. Such favorable RFS is consistent with another single-arm prospective study of GOG-0278 [16]. Considering similar survival outcomes but lower risk of surgery-related adverse events in the SH arm compared with the RH arm, indeed, SH is justified in the patients with very low-risk, early-stage cervical cancer.

Meanwhile, the Liberal SHAPE group represents patients who meet the SHAPE criteria but are beyond criteria of the ConCerv trial. This is a novel attempt to focus on patients excluded as "very low-risk" to provide some assurance that when patients with very low-risk disease were excluded, the risk of recurrence is still no different between RH and SH. In the current study, 575 of 682 (84.3 %) were classified in the Liberal SHAPE group, representing a significant proportion of patients *without* "very low-risk" disease who are likely to be encountered in real-world clinical practice.

As expected, in the Liberal SHAPE group, patients frequently had FIGO stage IB1 disease (94.8 %) and residual disease in the hysterectomy specimen (53.0 %). On pathologic examination, lymph node involvement and parametrial involvement were observed in 4.3 % and 0.9 % of patients. Nevertheless, patients' clinicopathologic characteristics

and surgical outcomes were well balanced between the SH and RH arms, except for MIS, which was more frequently performed in the SH arm than the RH arm. Survival analysis revealed that the SH and RH arms showed similar 3-year pelvic RFS, extrapelvic RFS, RFS, and OS. Notably, 3-year RFS in the SH arm was 95.4 %, which was comparable with ConCerv [15], LESSER [17], a phase II non-inferiority randomized trial that included 40 patients with 2009 FIGO stages IA2–IB1 cervical cancer, and JCOG1101 [18], another confirmatory trial that evaluated the effectiveness of less invasive surgery for stage IB1 cervical cancer. In the multivariate analysis adjusting for confounders, SH was not associated with higher recurrence and mortality rates in the Liberal SHAPE group. Therefore, SH might also be applicable to patients who meet the Liberal SHAPE criteria, as it offers similar survival outcomes and a lower risk of surgery-related adverse events compared to the RH arm.

In early-stage cervical cancer, the criteria for less radical surgery or SH have been developed based on previous studies that evaluated risk factors for recurrence or parametrial involvement [12–14]. Herein, it is stressed that all preoperative data should be used to predict risk as accurately as possible. In this regard, MRI and conization before hysterectomy are expected to play crucial roles. First, MRI enables tumor delineation and precise assessment of its local extent, such as parametrial involvement, in cervical cancer. Furthermore, when considering imaging studies, MRI is known to provide the highest level of accuracy in the assessment of cervical tumor size [19–22]. Second, conization not only provides precise pathologic diagnosis prior to the administration of primary treatment but also provides pathological information on histological type, LVSI status, depth of invasion, tumor size, and margin status, which is very essential for the selection of patients suitable for SH, rather than RH [23]. Furthermore, recent retrospective studies suggest conization before RH, especially for MIS, was associated with improved survival outcomes in patients with early-stage cervical cancer by minimizing tumor breakdown and dissemination [24–26]. In addition, the absence of residual disease in the hysterectomy specimen was associated with a lower risk of recurrence rate in the Liberal SHAPE group of the current study. Therefore, both preoperative MRI and cervical conization may be offered as a part of conservative or less radical surgery in patients with low-risk, early-stage cervical cancer.

Although the current study has its merit in using data from a landmark phase III clinical trial, there are several limitations. In the original SHAPE trial, preoperative conization and LVSI were not considered stratification factors. Second, owing to the small number of events in the Conservative SHAPE group (no recurrence, only one death), further multivariate analyses could not be performed. A longer duration of observation is needed. Third, details on the treatment after the first relapse were not reported. Considering the most common recurrence site in the Liberal SHAPE group was the vaginal vault, the role of salvage RT or secondary surgery should be evaluated, as well as post-recurrence survival. Lastly, the impact of MIS on survival outcomes should be re-evaluated. In a recent exploratory analysis study of the SHAPE trial, MIS was not associated with worse survival outcomes for patients meeting the SHAPE criteria who underwent SH [27]. However, as the surgical approach was not stratified at the time of randomization in the SHAPE trial, more robust evidence is needed, and the currently ongoing ENGOT-cx23/ MITO/ LASH trial might answer the key question of whether MIS SH is oncologically safe in patients with low-risk, early-stage cervical cancer [28].

In conclusion, this exploratory analysis of the SHAPE trial demonstrated similar survival outcomes but lower incidence of morbidities from SH compared to RH both in patients with and without very low-risk early-stage cervical cancer. Based on the study results, even when patients with very low-risk disease (lowest risk of recurrence) are excluded, the recurrence and survival outcomes are comparable in the remainder of patients. This implies that simple hysterectomy with nodal assessment is suitable for all patients who fulfil SHAPE criteria.

CRediT authorship contribution statement

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Declaration of competing interest

None declared.

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Appendix A. Supplementary data

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