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Updates on the surgical management of early-stage cervix cancer

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Continuing Professional Development | Jan 21, 2026

No disclosures

Learning Objective

Understand and apply emerging data on multi-modal treatment approaches for early stage and locally advanced cervix cancer

Topics Today

- Updates on the safe de-escalation of surgical care for early-stage cervix cancer
- Refining our understanding of when minimally invasive surgery can be offered for early-stage cervix cancer
- Exploring unanswered questions about when and whether to consider neo-adjuvant chemotherapy for locally advanced cervix cancer

Cervical Cancer: A Global Problem

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United States:

- 3rd most common gynecologic cancer
- 14th most frequent cancer among women

Developing World:

- More than 80% of cases
- 1st or 2nd leading cause of cancer death among women
- Over 400,000 women die each year

Siegel *et al*, *CA Cancer J Clin*, 2014
WHO/ICO Summary Report, 2010

Presenting Symptoms

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Early-Stage Disease:

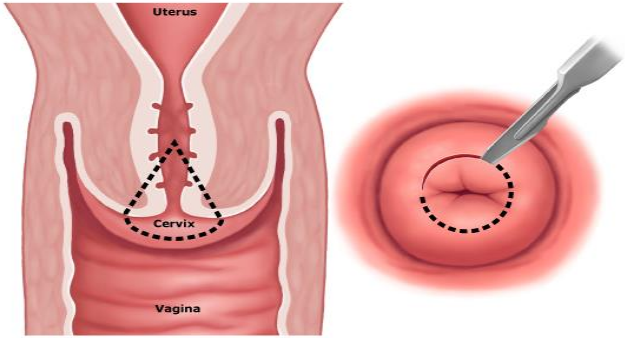
- Frequently asymptomatic
- Vaginal discharge
- Abnormal bleeding
  - Post-coital
  - Irregular menses
  - Postmenopausal bleeding

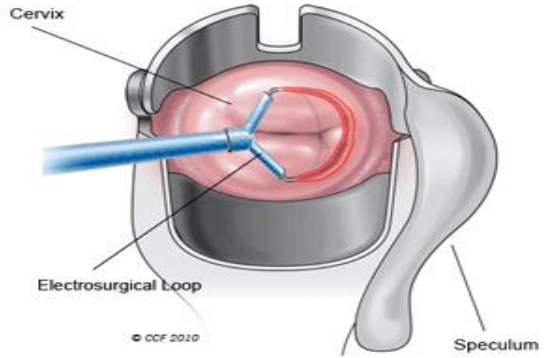
Late-Stage Disease:

- Pelvic/back pain
- Sciatica/leg swelling
- Weight loss
- Uremia
- Fistula:
  - Rectovaginal
  - Vesicovaginal

Cervical Cancer Diagnosis

- Cytology (Pap) – suspicion of cancer
- Colposcopy with biopsy is required to confirm
- If a visible lesion → directly to biopsy
- If abnormal Pap/biopsies with no visible lesion → cervical conization/LEEP is required





Cervical Cancer Survival

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FIGO Stage	5y Overall Survival	
IA1	98%	Surgery
IA2	95%	
IB1/2	89%	
IB3	76%	Chemo-radiation
IIA	73%	
IIB	66%	
IIIA	40%	
IIIB	42%	
IVA	22%	
IVB	9%	Palliative Chemotherapy

Historical Surgical Options for Early-Stage Cancer Cervical

	Stage 1A1	Stage 1A2-1B2
Non-fertility Sparing	Simple hysterectomy	Radical hysterectomy with lymphadenectomy
Fertility Sparing	Cold Knife Cone	Radical trachelectomy with lymphadenectomy

Who Needs Postoperative Radiotherapy?

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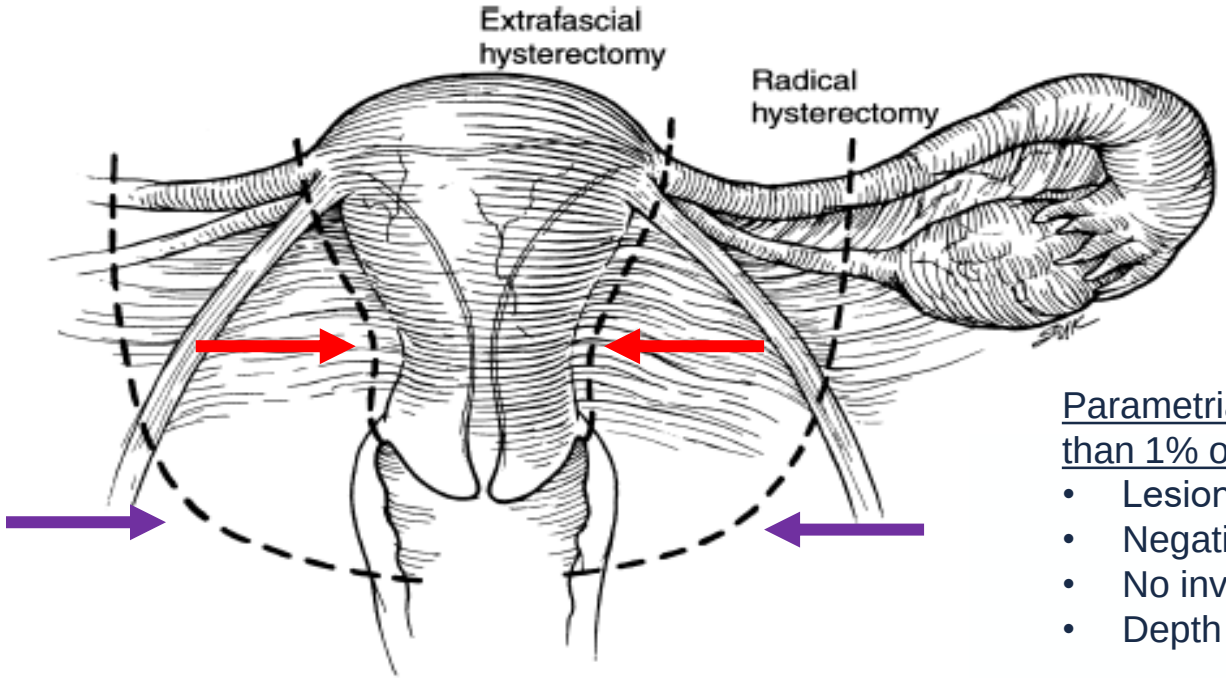
- **High-risk disease**:
  - Positive surgical margins, positive lymph nodes, parametrial involvement
  - **Combined chemo-radiation**

- **Intermediate-risk disease**:
  - Pelvic radiation
  - “Sedlis’ Criteria” (GOG 92)
  - No improvement in outcomes with combined chemo-radiation for this group (GOG 263 trial)

PMID: 10329031
PMID: 10764420

Simple vs. Radical Hysterectomy



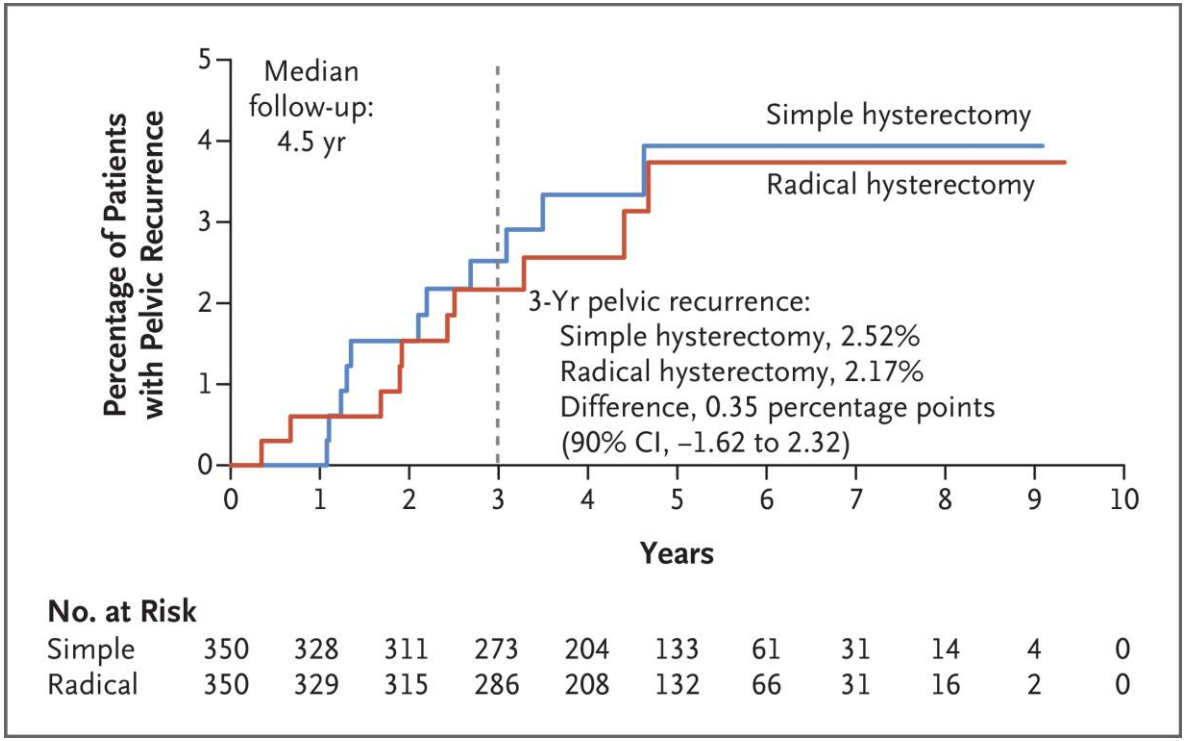
Parametrial involvement is present in less than 1% of tumors:

- Lesions of ≤2 cm
- Negative nodes
- No invasion of the lymphovascular space
- Depth of stromal invasion of <10 mm

Is radical hysterectomy superior to simple hysterectomy for well selected patients?

PMID: 17654664
PMID: 19546764
PMID: 21320670

Simple versus Radical Hysterectomy in Women with Low-Risk Cervical Cancer (SHAPE Trial, NEJM 2024)



Reduced urinary morbidity:

- Early urinary incontinence (2.4% vs 5.5%)
- Late urinary incontinence (4.7% vs 11.0%)
- Urinary retention (0.6% vs 11.0%)

PMID: 38416430

Simple Hysterectomy: A New Standard of Care for Early-Stage Cervix Cancer

- Fewer urinary complications were seen following **simple hysterectomy**
- **“SHAPE criteria”**
  - Stage 1A2-1B1 ≤ 2cm
  - < 10 mm stromal invasion (LEEP/cone)
  - < 50% depth on invasion (MRI)
- Still need to evaluate lymph nodes, either sentinel lymph node procedure or full lymphadenectomy

Open vs Minimally Invasive Radical Hysterectomy

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When compared to open radical hysterectomy, laparoscopic approach is associated with:

- less intraoperative blood loss
- shorter length of hospital stay
- lower risk of postoperative complications

After years of growing adoption for laparoscopy, prospective randomized non-inferiority LACC trial compared laparoscopic radical hysterectomy to open approach

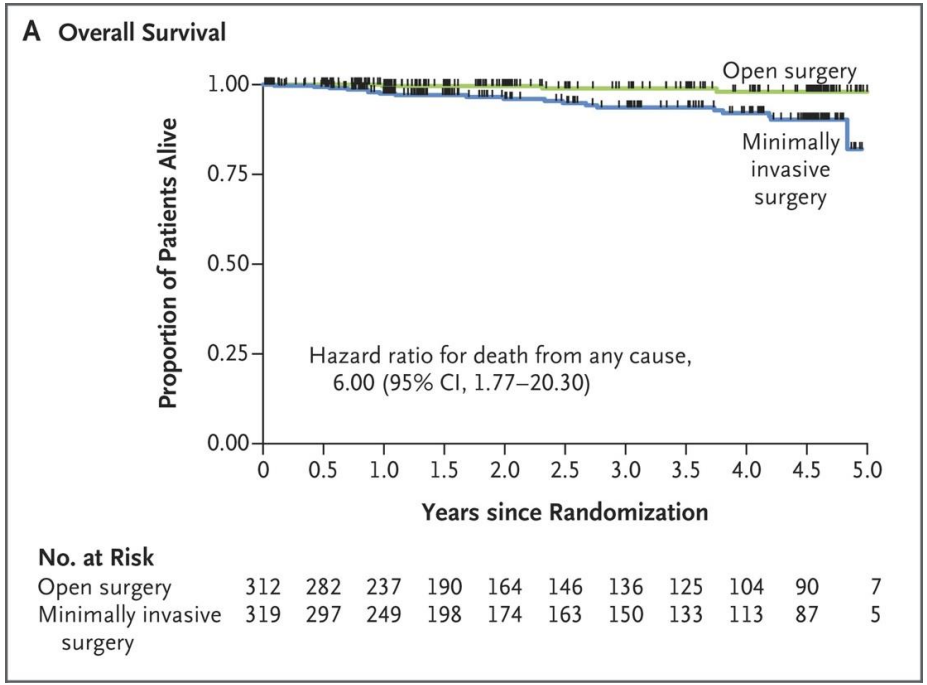
PMID: 30380365

Open vs Minimally Invasive Radical Hysterectomy

Disease-free survival at 4.5 years:

- 86.0% with minimally invasive surgery
- 96.5% with open surgery

A difference of −10.6 percentage points (95% confidence interval [CI], −16.4 to −4.7)



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Adoption of Open Radical Hysterectomy

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Publication of LACC in 2018 led to widespread shift in practice to open radical hysterectomy.

SHAPE trial of surgical de-escalation was ongoing. Exploratory analysis showed no difference:

- MIS simple: pelvic recurrence 3.2%
- Open simple: pelvic recurrence 3.5%

- MIS radical: pelvic recurrence 2.9%
- Open radical: pelvic recurrence 3.0%

UNANSWERED QUESTIONS:

- If performing simple hysterectomy based on SHAPE criteria, should this be done via laparotomy?
- Is there ever a situation where laparoscopy is appropriate for definitive management?

PMID: 30380365
PMID: 38416430

Ongoing Trial: ROCC GOG-3043

Randomized trial of open vs robotic minimally invasive hysterectomy for early-stage cervix cancer

Primary Outcome: 3-year disease-free survival

Incorporates rigorous patient selection and surgical tumor containment techniques.

Is there a role for additional chemotherapy?

EORTC-55994 trial (2023) & Gupta et al (2018)

Stage 1A2-1B2

Simple or Radical Hysterectomy

INTERLACE trial (2024)

Stage 2-4A

Chemo-radiation

OUTBACK trial (2023)

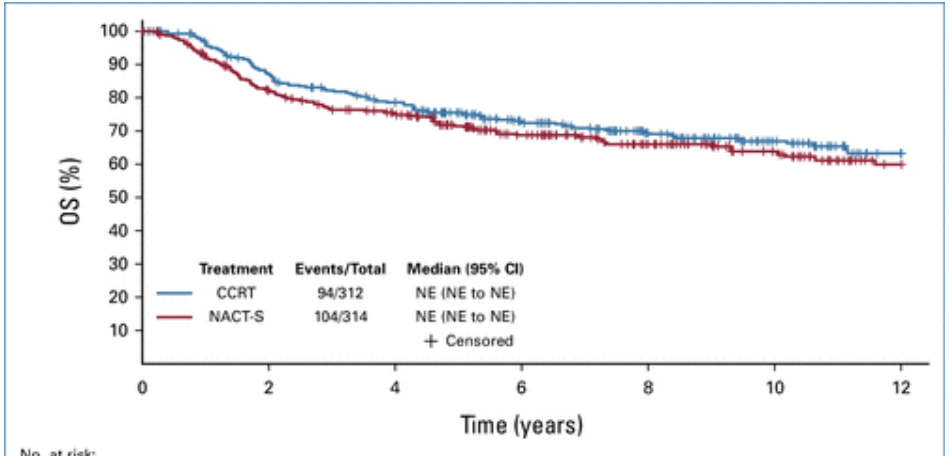
Randomized Phase III Study Comparing Neoadjuvant Chemotherapy Followed by Surgery Versus Chemoradiation in Stage IB2-IIB Cervical Cancer: EORTC-55994

Randomized, prospective multi-center trial

Chemo regimen not specified, most received 3 weekly doses of cisplatin

5-year OS was 72% in the NACT-S arm compared with that 76% in the CCRT arm (4%; 95% CI, 4 to 11; *P* = .291)

No difference



	Event/Total	Median (95% CI)[a]	Hazard Ratio (95% CI)[b]	Survival Estimates (95% CI)[a]	*P*
Treatment					.240[c]
CCRT	94/312	NE (NE to NE)	0.84 (0.64 to 1.12)	5: 75.5 (70.2 to 80.0)	
NACT-S	104/314	NE (NE to NE)	Reference	5: 71.7 (66.2 to 76.5)	

PMID: 37656948

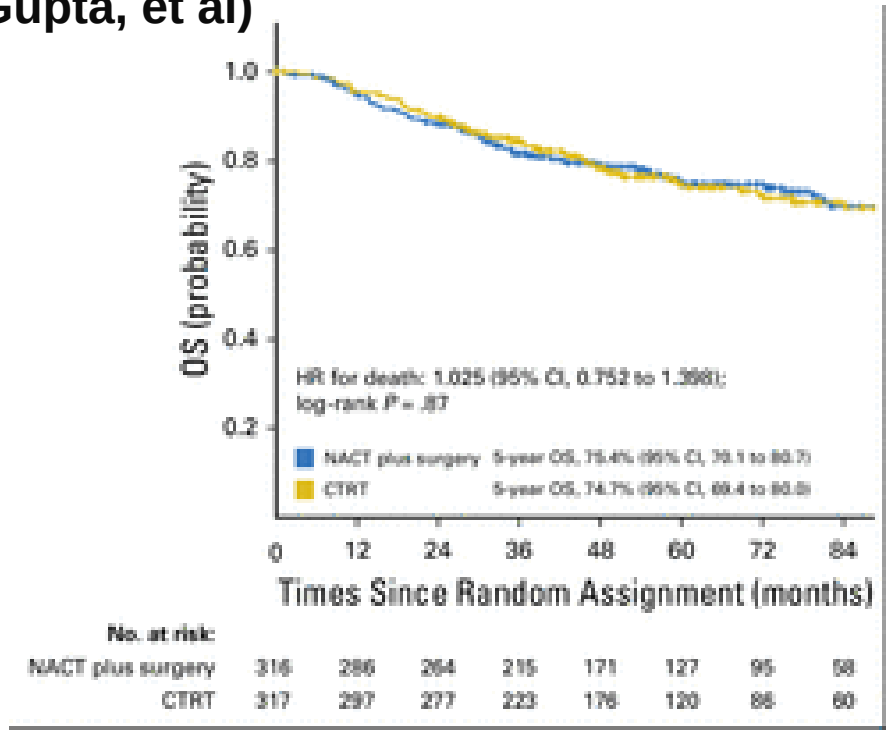
Neoadjuvant Chemotherapy Followed by Radical Surgery Versus Concomitant Chemotherapy and Radiotherapy in Patients With Stage IB2, IIA, or IIB Squamous Cervical Cancer: A Randomized Controlled Trial (Gupta, et al)

Randomized, prospective single institution trial

Carboplatin and paclitaxel every 3 weeks for three cycles in neo-adjuvant arm

5-year OS 75.4% for chemo plus surgery vs 74.7% chemoradiation (HR 1.025, p = .87)

No difference



PMID: 29432076

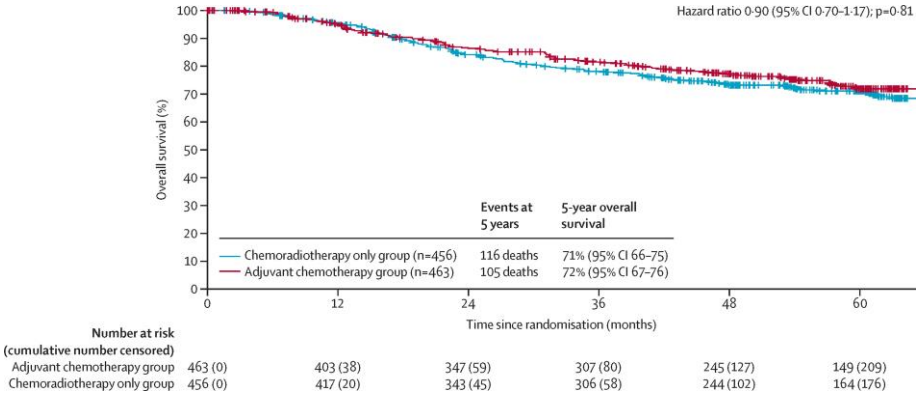
Adjuvant chemotherapy following chemoradiotherapy as primary treatment for locally advanced cervical cancer versus chemoradiotherapy alone (OUTBACK): an international, open-label, randomised, phase 3 trial

Randomized, prospective multi-institution trial – adding additional chemo following chemo-radiation

Carboplatin and paclitaxel every 3 weeks for four cycles following chemo-radiation

5-year OS 72% in the adjuvant chemotherapy group vs 71% in the chemoradiotherapy only group (HR 0·90, p=0·81)

No difference



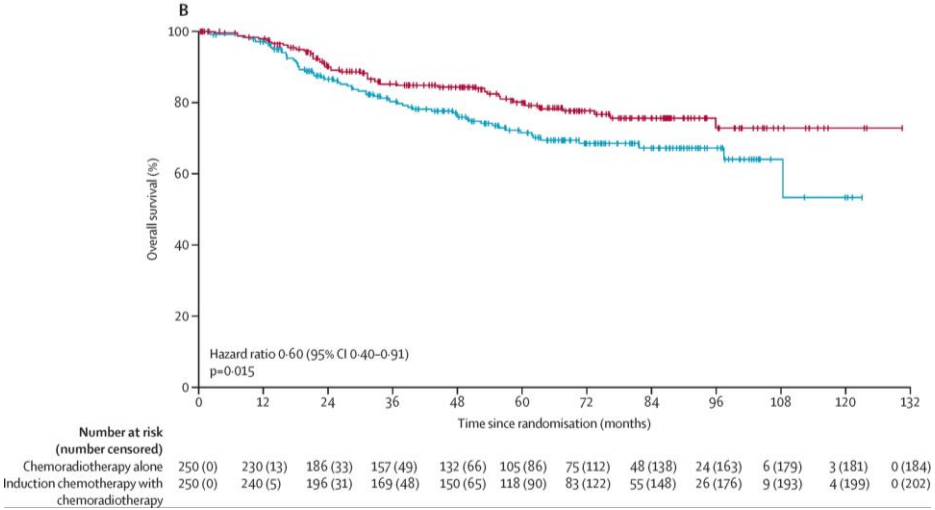
PMID: 37080223

Induction chemotherapy followed by standard chemoradiotherapy versus standard chemoradiotherapy alone in patients with locally advanced cervical cancer (GCIG INTERLACE): an international, multicentre, randomised phase 3 trial

Randomized, prospective multi-institution trial – induction chemotherapy before chemo-radiation

Carboplatin and paclitaxel weekly for 6 weeks before chemo-radiation

5-year OS 80% in the induction chemotherapy with chemoradiotherapy group vs 72% in the chemoradiotherapy alone group (HR of 0·60, p=0·015)



Number at risk (number censored)												
Chemoradiotherapy alone	250 (0)	230 (13)	186 (33)	157 (49)	132 (66)	105 (86)	75 (112)	48 (138)	24 (163)	6 (179)	3 (181)	0 (184)
Induction chemotherapy with chemoradiotherapy	250 (0)	240 (5)	196 (31)	169 (48)	150 (65)	118 (90)	83 (122)	55 (148)	26 (176)	9 (193)	4 (199)	0 (202)

PMID: 39419054

Is there a role for additional chemotherapy?

EORTC-55994 trial (2023)

Gupta et al (2018)

Stage 1A2-1B2

Simple or Radical Hysterectomy

INTERLACE trial (2024)

Stage 2-4A

Chemo-radiation

OUTBACK trial (2023)

Summary

- Significant progress in de-escalation of surgical treatment of early-stage cervix cancer
- Defining a population who can safely have minimally invasive surgery for early-stage cervix cancer is an unmet need
- No clearly defined benefit with the addition of systemic chemotherapy before surgery or chemo-radiation

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Thank you!

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