

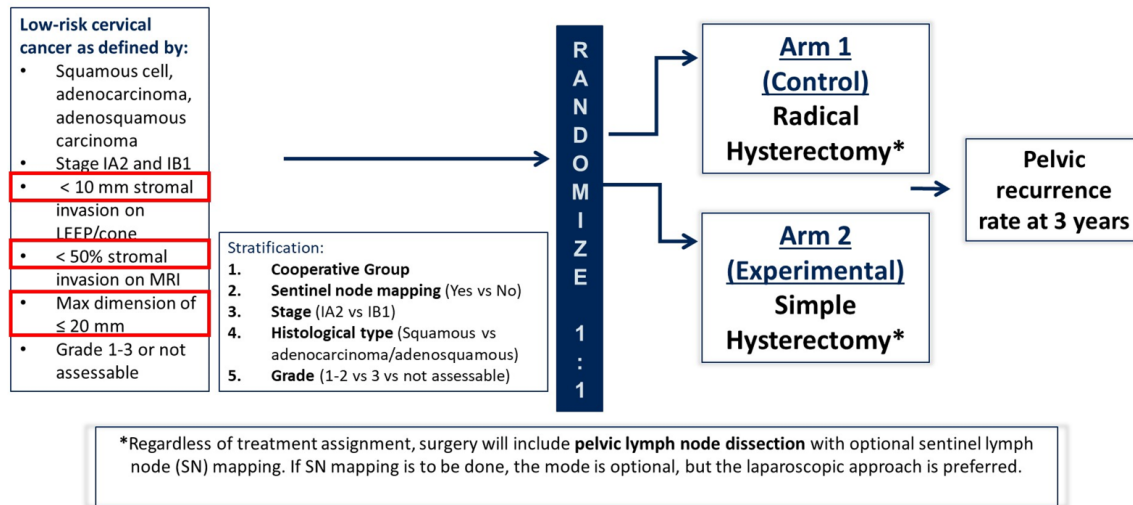
Clinicopathologic ChaRacteristics of patients with cervical
cAncer having received Simple Hysterectomy
(CRASH)

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Surgery for cervical cancer

- Standard surgery for cervical cancer
 - Type 1 hysterectomy for 1A1 LVSI-
 - Type 2 or 3 hysterectomy and lymph node evaluation (LNE) for disease more than 1A1 LVSI-
- Type 1 hysterectomy +/- LNE for disease more than 1A1 LVSI-
 - Unexpected cancer
 - Intentional (less radical surgery) : SHAPE trial showed type1 hysterectomy is safe in small cancer

Trial Schema



Recurrences

Events	Simple Hysterectomy N=350 (%)	Radical Hysterectomy N=350 (%)	Total N=700 (%)
Pelvic recurrences	11 (3.1)	10 (2.9)	21 (3.0)
• Vaginal Vault	9 (0.4)	8 (2.3)	17 (2.4)
• Parametrium	1 (0.3)	0	1 (0.1)
• Pelvic Lymph Nodes	0	0	0
• Other	1 (0.3)	2 (0.6)	3 (0.4)
Extra Pelvic recurrences	7 (2.0)	2 (0.6)	9 (1.3)
• Abdomen	2 (0.6)	0	2 (0.3)
• Para-aortic lymph nodes	2 (0.6)	2 (0.6)	4 (0.6)
• Supraclavicular L N	1 (0.3)	0	1 (0.1)
• Other	2 (0.6)	0	2 (0.3)
Pelvic and extra pelvic recurrences	3 (0.9)	2 (0.6)	5 (0.7)
Extra pelvic only recurrences	4 (1.1)	0	4 (0.6)
Pelvic or extra pelvic recurrences	15 (4.3)	10 (2.9)	25 (3.6)

Adjuvant therapy after surgery

- After type 2 or 3 hysterectomy
 - High risk factors (ANY of lymph node, parametrium or margin)
 - Intermediate risk factors (Sedlis criteria): combination of tumor size, invasion depth and LVSI
- After type 1 hysterectomy for small tumor
 - Not well studied
 - May be over-treated: 31% adjuvant therapy rate in systematic review [PMID: 33306971]
 - NCCN guideline: Same to criteria after type 2 or 3 hysterectomy
 - Incidental cervical cancer section **"No definitive data are available to guide the appropriate adjuvant treatment of these patients"**
 - GOG 278: High risk factors OR deep invasion (>10mm)
 - SHAPE: As per local center policy. Adjuvant therapy in 8-9% (LN+ 3-4%, parametrium 0-2%, margin 2-3%)
- Lack of data guiding the appropriate adjuvant therapy after type 1 hysterectomy

Objective and Study design

- Examine the recurrence pattern in women with cervical cancer who received type 1 hysterectomy to guide the appropriate adjuvant therapy after type 1 hysterectomy
- Retrospective study

Eligibility criteria

● Inclusion

- Histologically confirmed, newly diagnosed cervical cancer
- Squamous cell carcinoma or adenosquamous cell carcinoma or adenocarcinoma
- Type 1 hysterectomy +/- LNE was performed

● Exclusion

- Stage 1A1 and LVSI negative
- High risk factors present (lymph node metastasis, parametrium involvement, and resection margin involvement)
- Preoperative chemotherapy or radiotherapy
- Gross residual tumor exist after type 1 hysterectomy
- Other cancer diagnosed

Variables

- Demographics
- Conization
- Type 1 hysterectomy +- LNE
- Adjuvant therapy
- Follow up, recurrence
 - ❖ Tumor size, invasion depth and LVSI will be estimated using both conization and type 1 hysterectomy data

Analysis

Subgroup	Tumor size	Invasion depth	LVSI	LN surgically evaluated rate	Adjuvant therapy rate	PFS curve
1	<=1cm	<= 1/2	-			
2	<=1cm	<= 1/2	+			
3	<=1cm	> 1/2	-			
4	<=1cm	> 1/2	+			
5	>1cm AND <= 2cm	<= 1/2	-			
6	>1cm AND <= 2cm	<= 1/2	+			
7	>1cm AND <= 2cm	> 1/2	-			
8	>1cm AND <= 2cm	> 1/2	+			
9	> 2cm	<= 1/2	-			
10	> 2cm	<= 1/2	+			
11	> 2cm	> 1/2	-			
12	> 2cm	> 1/2	+			

*Merge subgroups with similar outcomes (adjuvant rate, PFS) into a bigger group

Plan

- 2023 4Q Study initiation at KGOG
- 2024 1Q International group participation
- 2024 3Q International group data collection initiation
- 2025 2Q Data collection completion
- 2025 4Q Analysis
- N = 500