

What is the best surgical management for early cervical cancer less than 2 cm?

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ASGO Webinar
Disclosure of Conflict of Interest

Name of first author: Hiroaki Komatsu

I have no COI

With regard to our presentation.

New findings in JAPAN

A confirmatory trial of modified radical hysterectomy for FIGO Stage IB1 cervical cancer patients with tumor diameter preoperatively estimated 2 cm or less: Japan Clinical Oncology Group study, JCOG1101

Takahide Arimoto, Takahiro Kasamatsu, Takafumi Toita, Hiroaki Kobayashi, Ryunosuke Machida, Haruhiko Fukuda, Takashi Onda, Toru Nakanishi, Haruhige Yokota, Shoji Kamiura, Kazuhiro Takehara, Hirokuni Takano, Toshiaki Saito, Ikuo Konishi, Satoshi Yamaguchi, Toshiaki Nakamura, Kimio Ushijima, Daisuke Aoki, Nobuo Yaegashi, Toyomi Satoh, Gynecologic Cancer Study Group of Japan Clinical Oncology Group (JCOG), Japan

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JCOG
Japan Clinical Oncology Group
(www.jcog.jp/en/)

#5532

Endpoints & Statistical considerations

Primary endpoint:

- 5-year overall survival (OS)

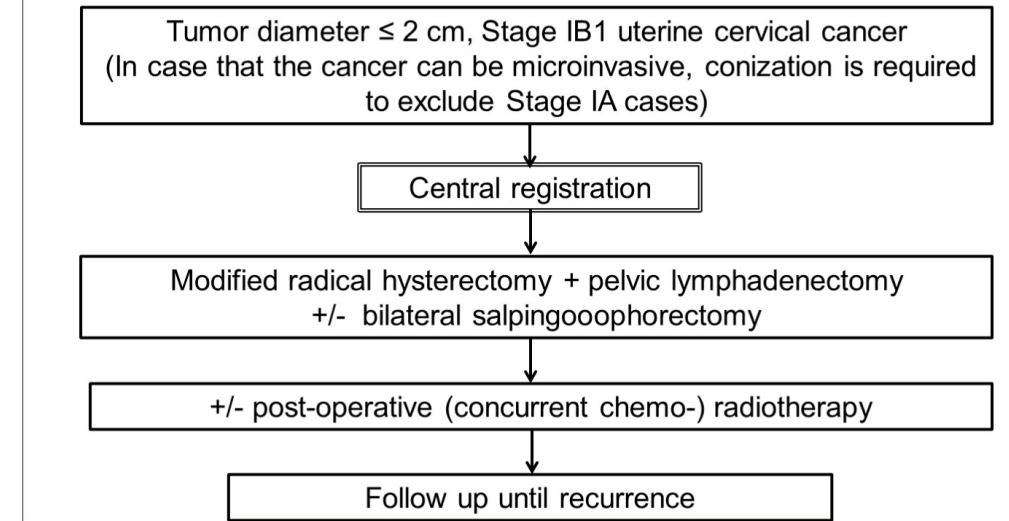
Secondary endpoints:

- Relapse-free survival, local relapse-free survival
- % completion of MRH
- % local relapse
- % pathological parametrial involvement
- Days until self-urination and residual urine disappearance
- Blood loss, Operation time
- % post-operative RT
- Adverse event (AE)s (CTCAE ver.4.0), serious AEs

Study hypothesis: MRH is more useful if the 5-year OS of MRH is not inferior to that of RH

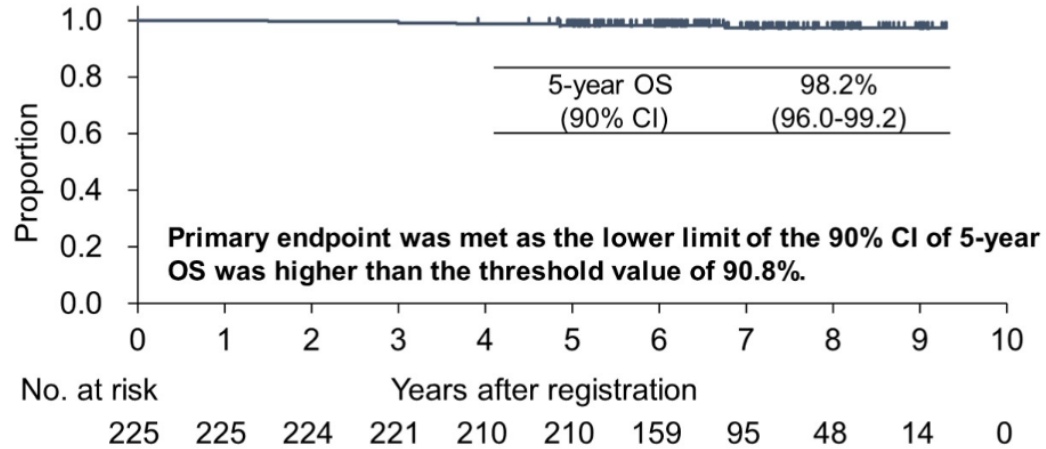
- Expected 5-year OS of MRH: 95.8% (5-year OS of RH in JCOG0806-A: retrospective observational study)
- Threshold 5-year OS: 90.8%
- Alpha error: 0.05 (one-sided), beta error: 0.1
- **Planned sample size: 240**
- Planned accrual: 5 years, follow-up period: 5 years
- Actual accrual: 1/8/2013 – 8/25/2017

Study design

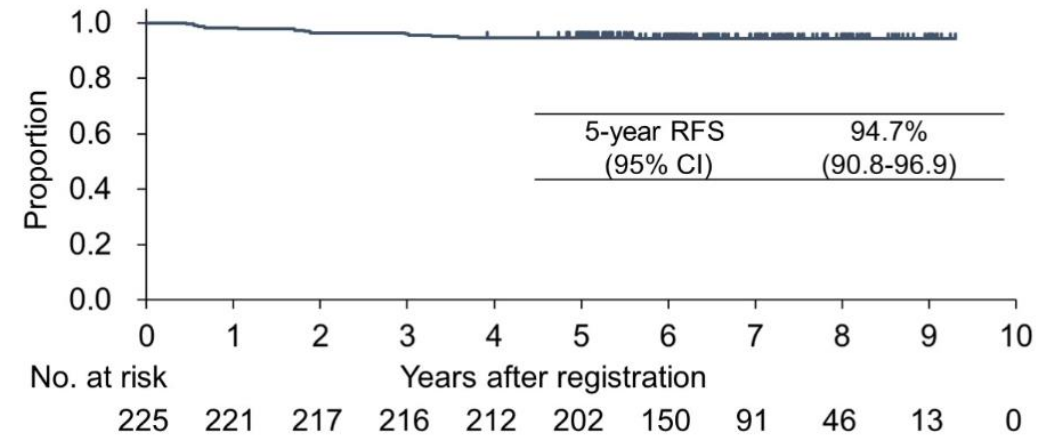


Survival

Overall survival (n=225)



Relapse-free survival (n=225)



	SH N = 350 (%)	RH N = 350 (%)
Pelvic recurrence at 3 years	2.52%	2.17%

MRH was as effective as RH and less invasive.

MRH can be considered a standard surgery for tumor \leq 2cm Stage IB1 cervical cancer.

Discussion point

invasiveness



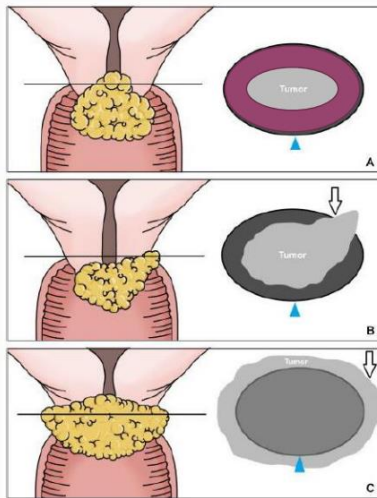
SH vs MRH vs RH

SHAPE

JCOG1101



Is pelvic lymph node dissection necessary?



→ MIS OK?

} Open surgery OK?

