

## JACC trial (JGOG1087)

A non-randomized confirmatory trial of minimum invasive laparoscopic radical hysterectomy (new-Japanese LRH) for patients with early stage cervical cancer:

Enrollment form 2021 Oct.

UMIN000045224

A non-randomized confirmatory trial of minimum invasive laparoscopic radical hysterectomy (new-**J**apanese LRH) for patients with early stage **c**ervical **c**ancer:JACC trial

## Purpose

To analyze  
**Non-inferiority of Revised new-Japanese laparoscopic RH**  
compared to Open RH

## Case

**Cervical cancer; FIGO stage IA2, IB, andIIA1**

## Goal

- To provide **new-Japanese LRH**
- To clarify surgical procedures related to prognosis
- To make standard evidence based procedure nationwide

**Cervical cancer**

- FIGO ; IA2/IB1/IIA1
- Tumor length  $\leq 4\text{cm}$
- PS ; 0-1
- Age; 20-70

**Patient's choice**

**MIS-  
Radical hysterectomy**

**Enrollment for  
primary analysis**

**Abdominal-  
Radical hysterectomy**

**Enrollment as  
Non-primary analysis**

- Not restricted by protocol
- Surveillance of perioperative adverse event
- Follow up

**No patient's  
consent**

**NO  
enrollment**

# LACC trial did not prove Non-inferiority of MIS-RH compared to Open-RH

The NEW ENGLAND  
JOURNAL of MEDICINE

ESTABLISHED IN 1812

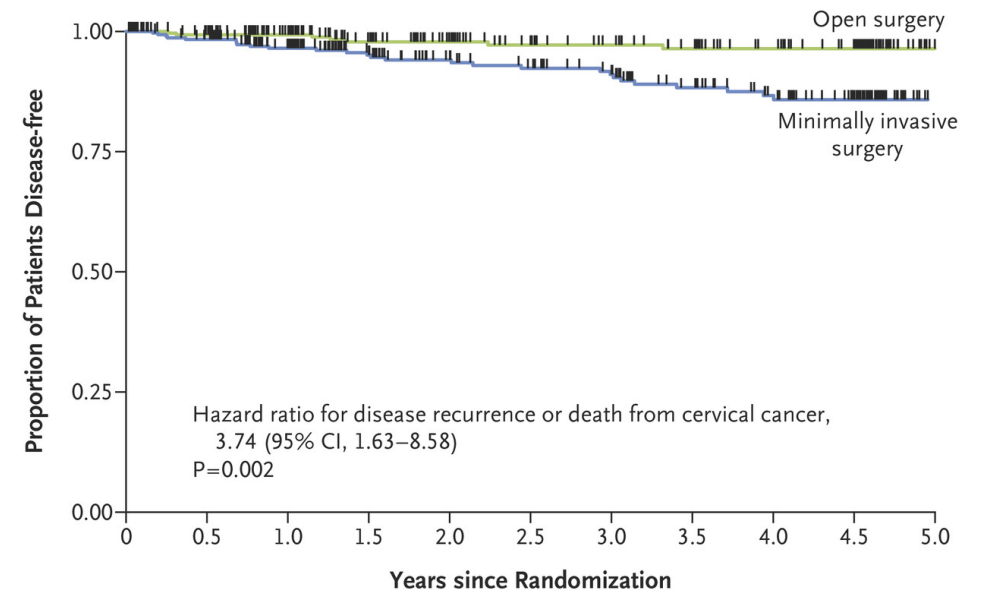
NOVEMBER 15, 2018

VOL. 379 NO. 20

## Minimally Invasive versus Abdominal Radical Hysterectomy for Cervical Cancer

Pedro T. Ramirez, M.D., Michael Frumovitz, M.D., Rene Pareja, M.D., Aldo Lopez, M.D., Marcelo Vieira, M.D.,  
Reitan Ribeiro, M.D., Alessandro Buda, M.D., Xiaojian Yan, M.D., Yao Shuzhong, M.D., Naven Chetty, M.D.,  
David Isla, M.D., Mariano Tamura, M.D., Tao Zhu, M.D., Kristy P. Robledo, Ph.D., Val GebSKI, M.Stat.,  
Rebecca Asher, M.Sc., Vanessa Behan, B.S.N., James L. Nicklin, M.D., Robert L. Coleman, M.D.,  
and Andreas Obermair, M.D.

**Ramirez P. et al. *N Engl J Med* 2018**



**At least, prognosis after MIS-RH procedure in the US  
was not equivalent to those after Open RH**

# After LACC trial

## Open-RH is recommended as the gold standard



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LAPAROSCOPIC RADICAL HYSTERECTOMY: AN ESGO STATEMENT

Updated recommendation: Open approach is the gold standard

If MIS is offered and accepted by patient,

- The following factors are encouraged to be prospectively recorded
  - Detail procedure
  - Prognosis
  - Complication
  - QOL
- Every effort should be made to avoid cancer cell spillage to abdominal cavity

MIS-RH is still option for patients who are willing to receive MIS after Informed consent

# MIS-RH in Japan

MIS-RH is recommended as **Optional Treatment** to cervical cancer FIGO IA2, IB1 and IIA1 according to JSGO guideline

**As long as following some Regulations**

**# 1 Operator limitation**

Specialist on certified by JSGO

**# 1 Compliance to guidelines and national insurance restriction**

- Facility registration of MIS
- Annual report to JSOG

**# Procedure limitation**

Every effort to avoid cancer cell spillage

**# Case limitation**

Tumor size should be considered

**# Informed consent**

Prognosis at each facility should be proposed to patients

# Some criticism remains for LACC trial

- **Statistically, sample power is not enough**
  - **Ten percent** of Change operation approach, Drop out, and Operation cancel
  - **Early stopping of the clinical trial**
- **Problematic Surgical procedure**
  - **Tube or similar uterine mobilization is inserted trans-vaginally**
- **Undefined procedures**
  - **Uterine recovery method**
  - **Step to avoid cancer cell spillage**



**LACC trial protocol**

# Clinical trial for **new-Japanese** Laparoscopic RH

## JACC trial (JGOG1087)

A non-randomized confirmatory trial of minimum invasive laparoscopic radical hysterectomy (new-**J**apanese LRH) for patients with early stage **c**ervical **c**ancer:

**#1 Procedures influencing to prognosis**

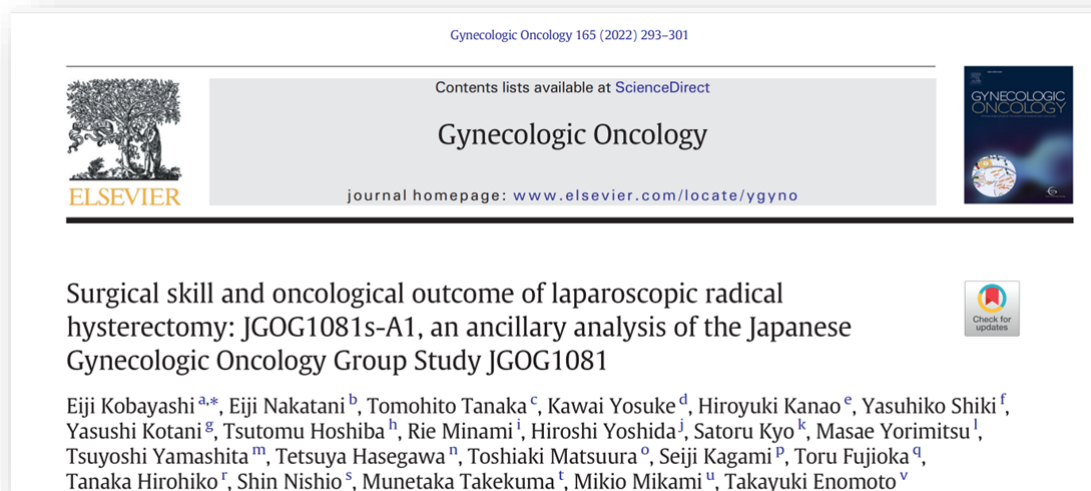
**#2 Quality control of surgery during ongoing trial**



# Clinical trial for **new-Japanese** Laparoscopic RH

## JACC trial (JGOG1087)

### Procedures influencing to prognosis



JGOG1081s-A1

- LN recovery method
- Procedure to avoid cancer cell spillage

Operation **time** and operative **proficiency** Did Not influence prognosis.

# Clinical trial for **new-Japanese** Laparoscopic RH

## JACC trial (JGOG1087)

### Regulations for surgery Procedure

**1) Uterine manipulator is prohibited**

**2) Lymph nodes and uterus are collected trans-vaginally in bag**

**3) Avoiding cancer cell spillage**

Ex. Vaginal cuff, Gut clumper, Automatic anastomosis machine

**4) Wash with saline**

Vagina; 100ml before and after uttering collection

Abdominal cavity after vaginal closure

**5) Vaginal cut from abdominal cavity**

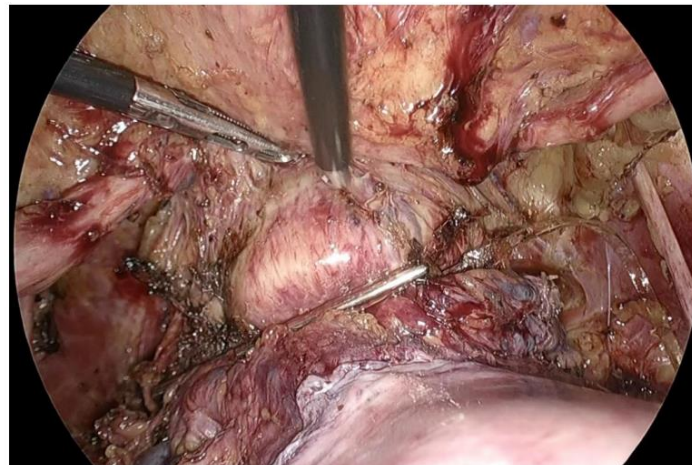
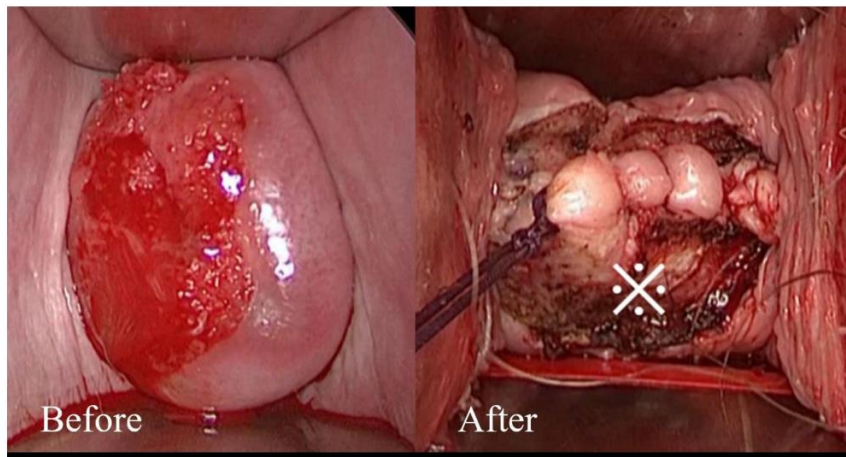
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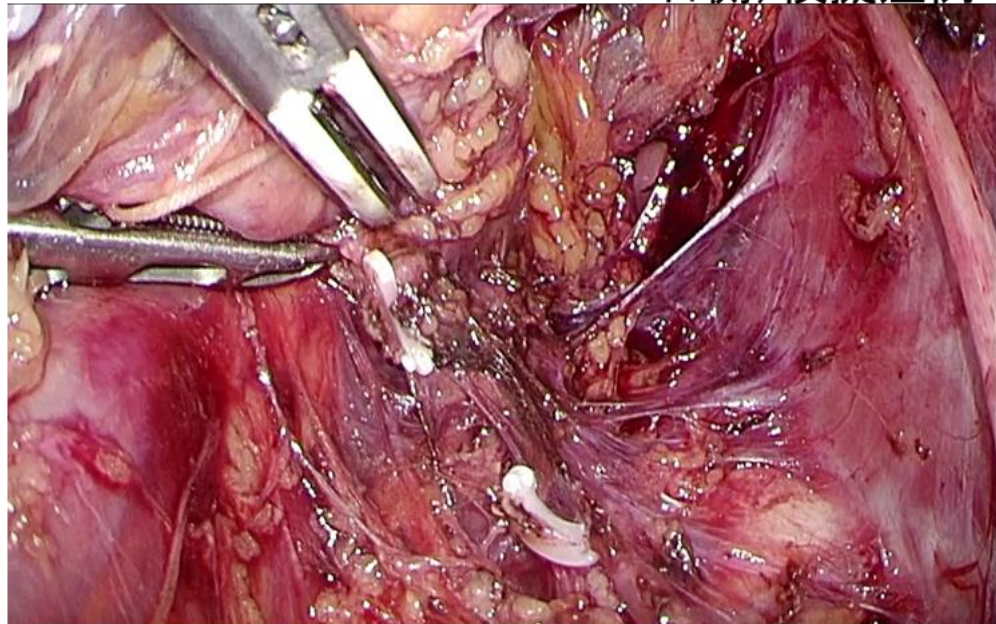
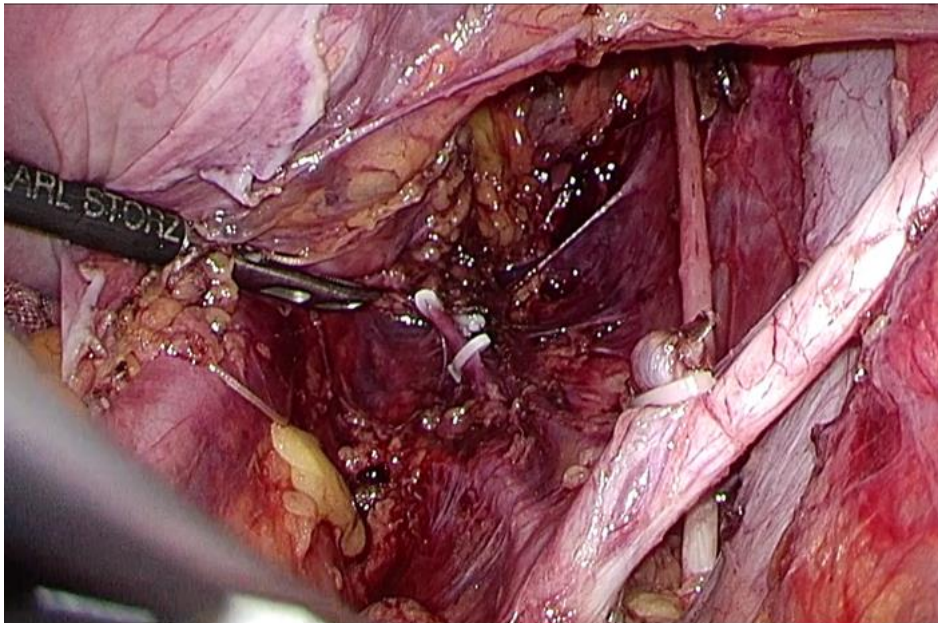


# Clinical trial for **new-Japanese** Laparoscopic RH

**JACC trial (JGOG1087)**

**Central control of surgical procedure**

Example; Deep uterine veins are cut at internal iliac vein bifurcation.



# Clinical trial for **new-Japanese** Laparoscopic RH

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### Regulations to Facility and operator

#### Facility

- ✓ Member of JGOG
- ✓ Experience of Laparoscopic RH  $\geq 10$  cases
- ✓ **Participating in** Gynecologic oncology Registration JSOG
- ✓ Surgery can be performed under insurance coverage
- ✓ "Laparoscopic Extensive Total Hysterectomy Facility" certified by JSOG

#### Operator in charge

- ✓ Gynecological oncologist certified by JSOG
- ✓ Laparoscopic Technical Certified Physician
- ✓ Experience of Laparoscopic RH  $\geq 15$  cases

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