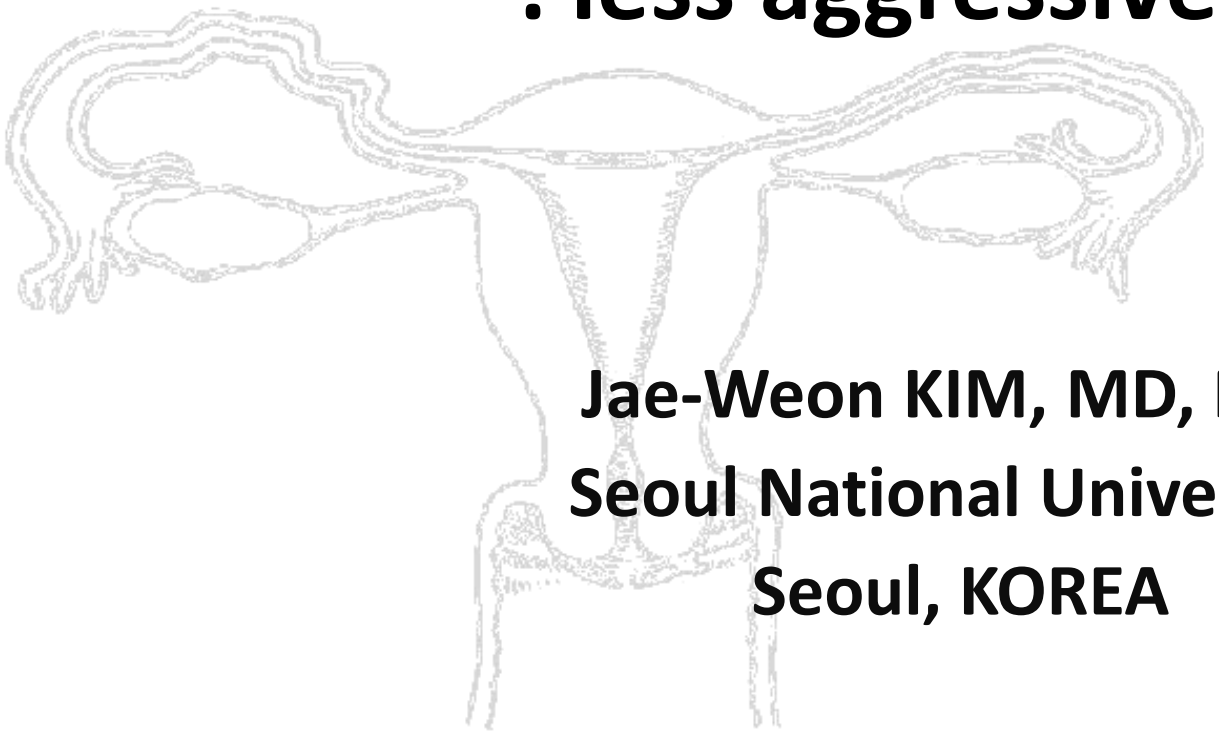
The 3rd ASGO Int'l Workshop on Gynecologic Oncology
9:25~9:50 am, 24th August 2014

# Surgery for early stage cervical cancer : less aggressive way



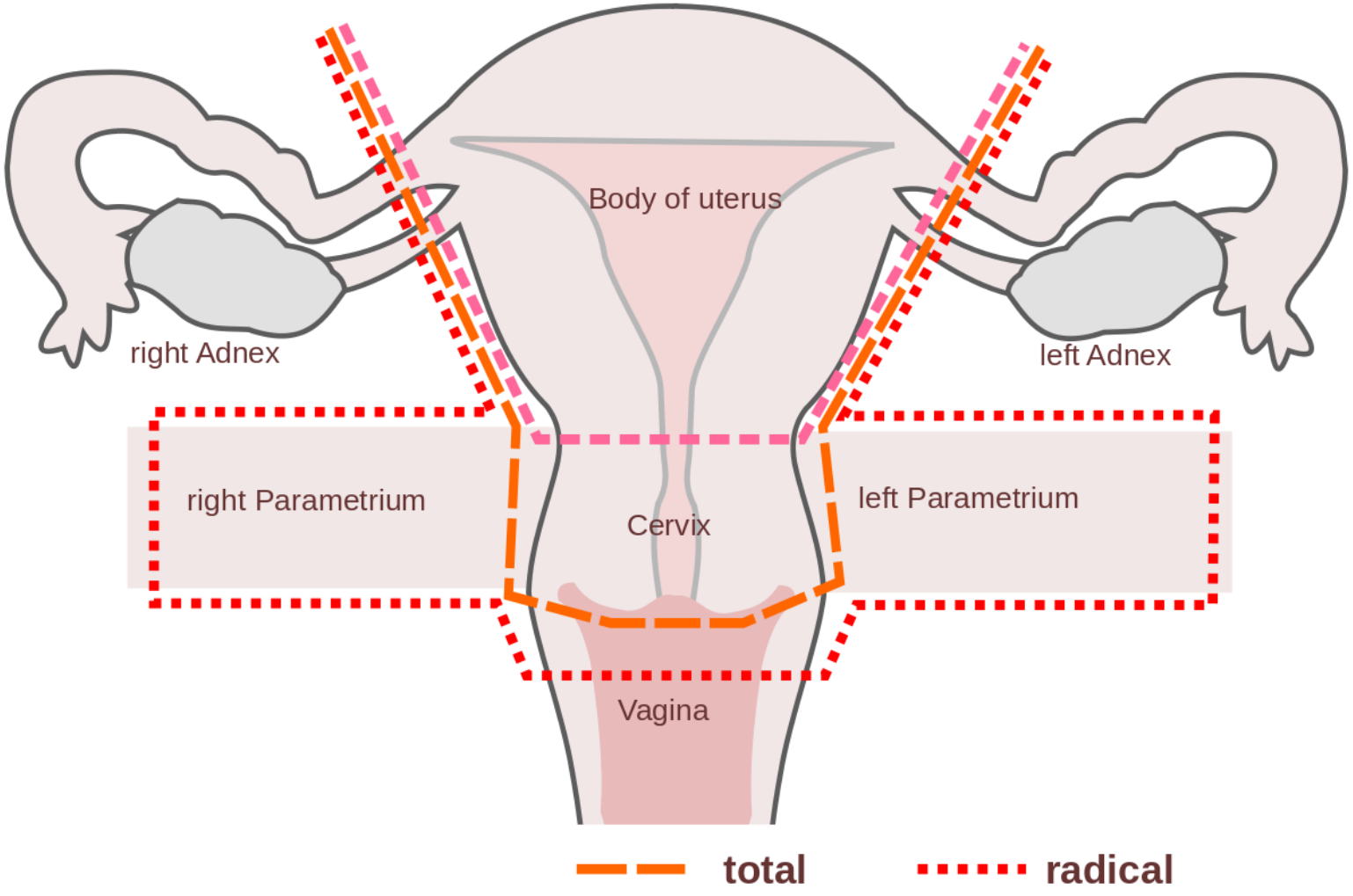
**Jae-Weon KIM, MD, PhD**
**Seoul National University**
**Seoul, KOREA**

# Verbal Disclosure

I have nothing to disclose that may pose a conflict of interest.

To assure the highest quality of educational programming, organizing committee requires individuals who have the opportunity to affect the content of an educational activity to disclose any financial relationships with any commercial entity that may result in a potential conflict of interest.

Part of slides presented in this lecture were provided by the courtesy of members of KGOG & GCIG.




# Hysterectomy

# How to describe it ..

- Less radical: SHAPE, in this talk
- Non-radical: GOG 278
- Less aggressive: I prefer this one!
- Less wide
- Less extensive
- Conservative: MDACC *ConCerv* trial
- Curtailed

# Different concept from..

1. Less-invasive surgery/MIS
2. Fertility-sparing surgery
3. Nerve-sparing rad hysterectomy

Wertheim E. The extended abdominal operation for carcinoma uteri: Based on 500 operative cases (Gradd H transl).


Am J Obstet Dis Women Children 1912:66;169-232

# Morbidity of radical hysterectomy comes from ..

- **Hysterectomy *per se***
  - Infertility
- **Lymphadenectomy**
  - Lymphocele/lymphedema
- **Parametrectomy**
  - Damage to autonomic nerve fibers
  - Bladder, rectal & sexual dysfunction

Conization

(Radical) trachelectomy

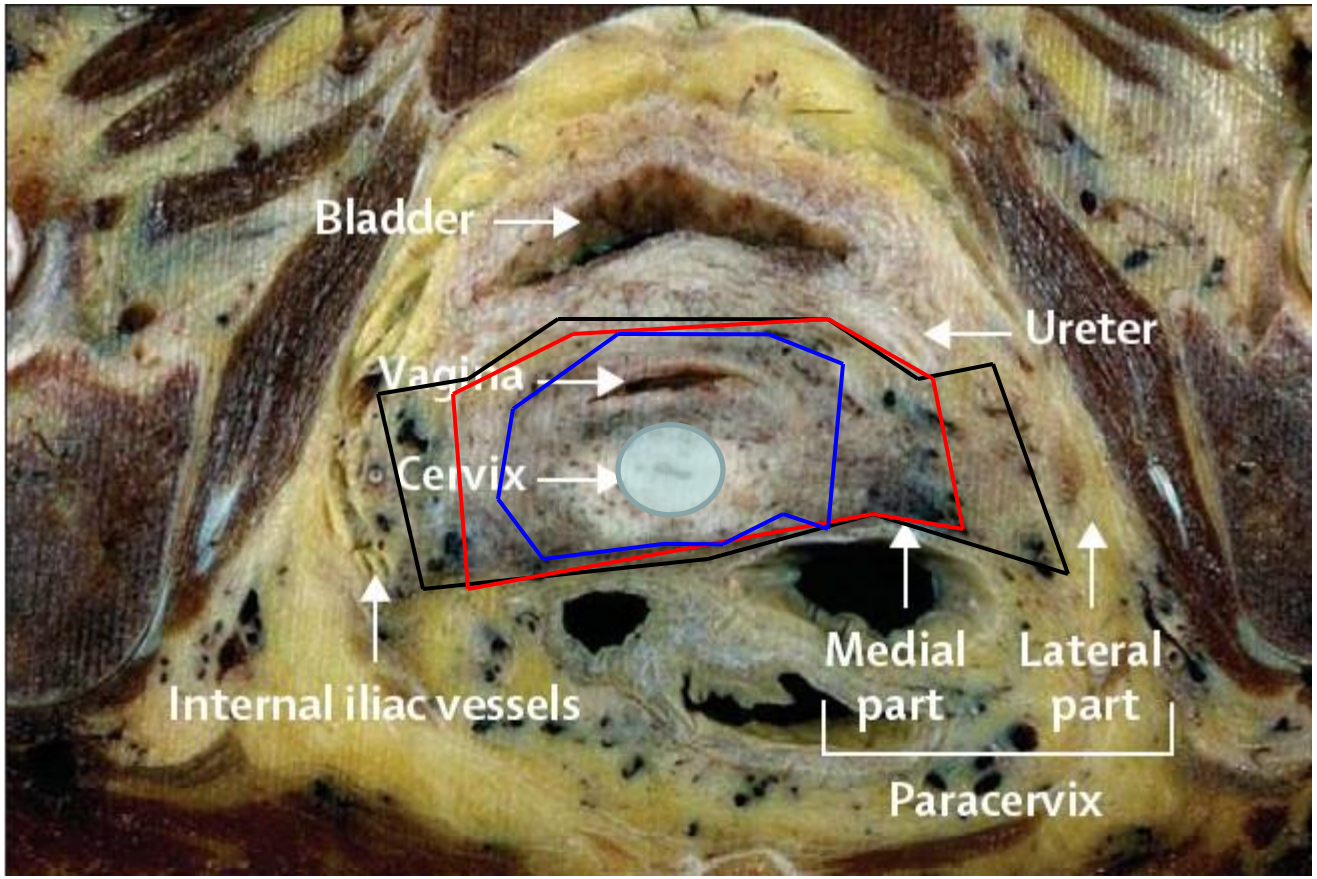
Sentinel LN

**Less radical surgery**

# Purpose of parametrectomy

1. to secure surgical margin
2. to remove potential site of spread
   - parametrial tissue & LN

# Surgical margin




A

B1

C2

New classification of radical hysterectomy

Querleu & Morrow, Lancet Oncol 2008

# Purpose of parametrectomy

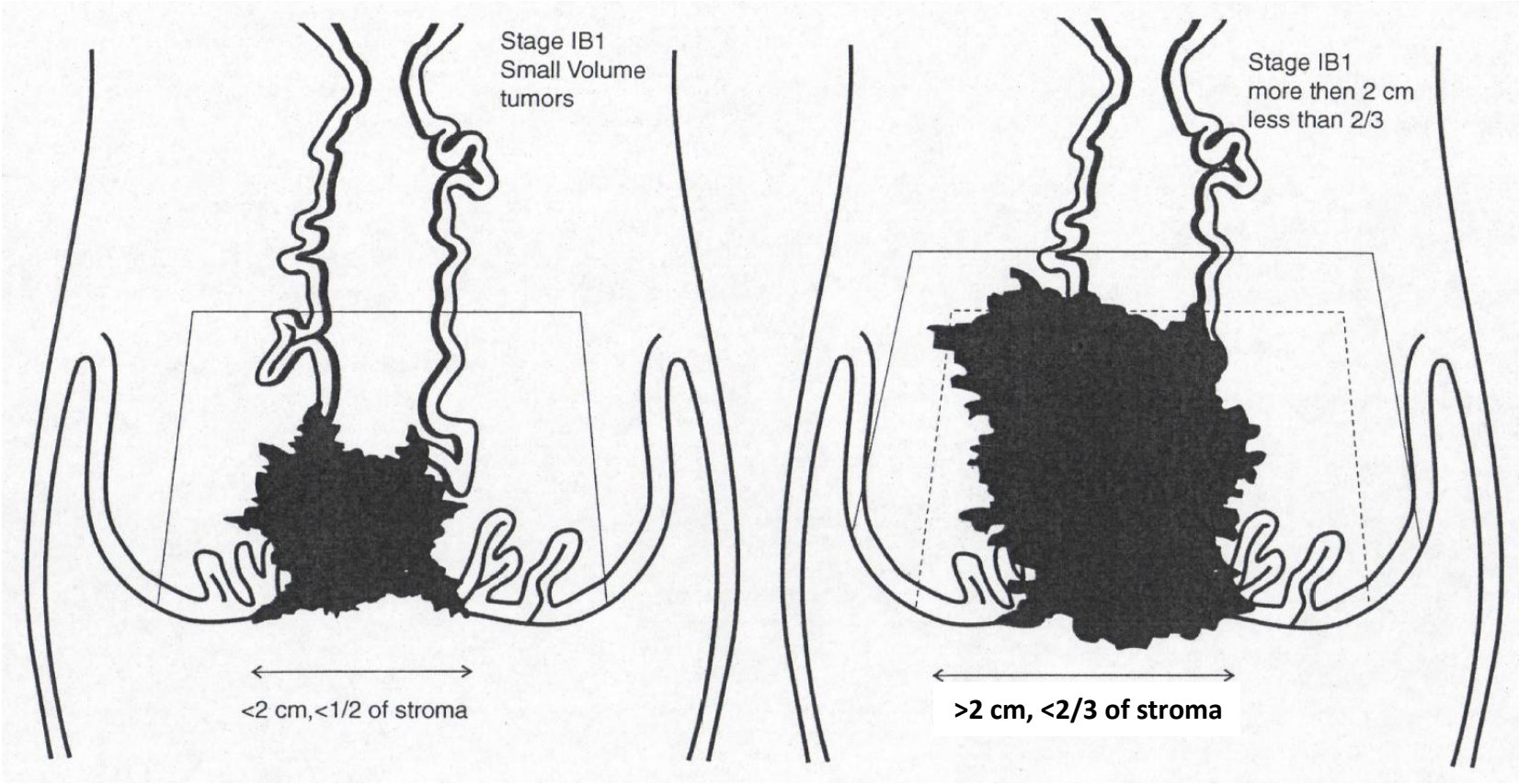
1. to secure surgical margin
2. to remove potential site of spread
   - parametrial tissue & LN

# Low incidence of parametrial involvement in small volume tumor

- **Literature review** of patients with low-risk pathological features
  - Tumor <2cm, stromal invasion <10mm, no LVSI, (-)ve pelvic nodes
  - Risk of parametrial involvement: **0.63%** (5/799)

| Authors | No. of patients | Stage | Tumor size | LVSI | Depth of invasion | PI+ PLN- |
|---|---|---|---|---|---|---|
| Kinney 1995 | 83 | IB | < 2cm | absent | 0.4-1.8 cm | 0/83 |
| Covens 2002 | 842 | IA-IB1 | ≤ 2cm vs. > 2cm | +/- | <10 mm vs. >10 mm | 3/536 |
| Sonoda 2004 | 89 | IA-IB1 | < 2cm | | | 0/77 |
| Stegeman 2007 | 103 | IA-IB1 | < 2cm | +/- | < 10mm | 2/103 |

Gynecol Oncol 2007;105:475-80




Controversies in the management of gynecological cancers
ISBN 978-0-85729-909-3; p.205

# KSGO Practice Guideline for Cervical Cancer, v2

- History & exam
- Tumor markers
- Lab. studies[b]
- Cervical Biopsy
- Pathologic Review
- Cone Biopsy as indicated

Optional
- EUA
- Cystoscopy/ proctoscopy (Sigmoidoscopy)
- Imaging studies[c]

**Stage IA1**
- Margin (-) & LVSI (-) → Observation or Extrafasical hysterectomy
- **Margin(+) or LVSI(+)** → **Repeat conization or TH or MRH or Rad trachelectomy+PLND**

**Stage IA2**
- **RH or Rad trachelectomy+PLND**
- Brachytherapy+Pelvic RT

**Stage IB1 Stage IIA1 (≤ 4 cm)**
- **RH or Rad trachelectomy+PLND** +para-aortic node sampling
- Brachytherapy+Pelvic RT

**Stage IB2 Stage IIA2 (> 4 cm)**
- Neoadjuvant chemotherapy (Class III) +RH+PLND+para-aortic LN sampling
- RH+PLND+ para-aortic LN sampling
- CCRT+Brachytherapy±adjuvant hysterectomy

Intermediate Risk Factors* (more than 2 ) → RT

High Risk Factors** → CCRT+ VBT if Vaginal Margin (+)

**Stage IB2, IIA2, IIB, IIIA,IIIB, IV**
- Imaging studies: CT / MRI / PET
- Surgical Staging : extraperitoneal or laparoscopic LN dissection

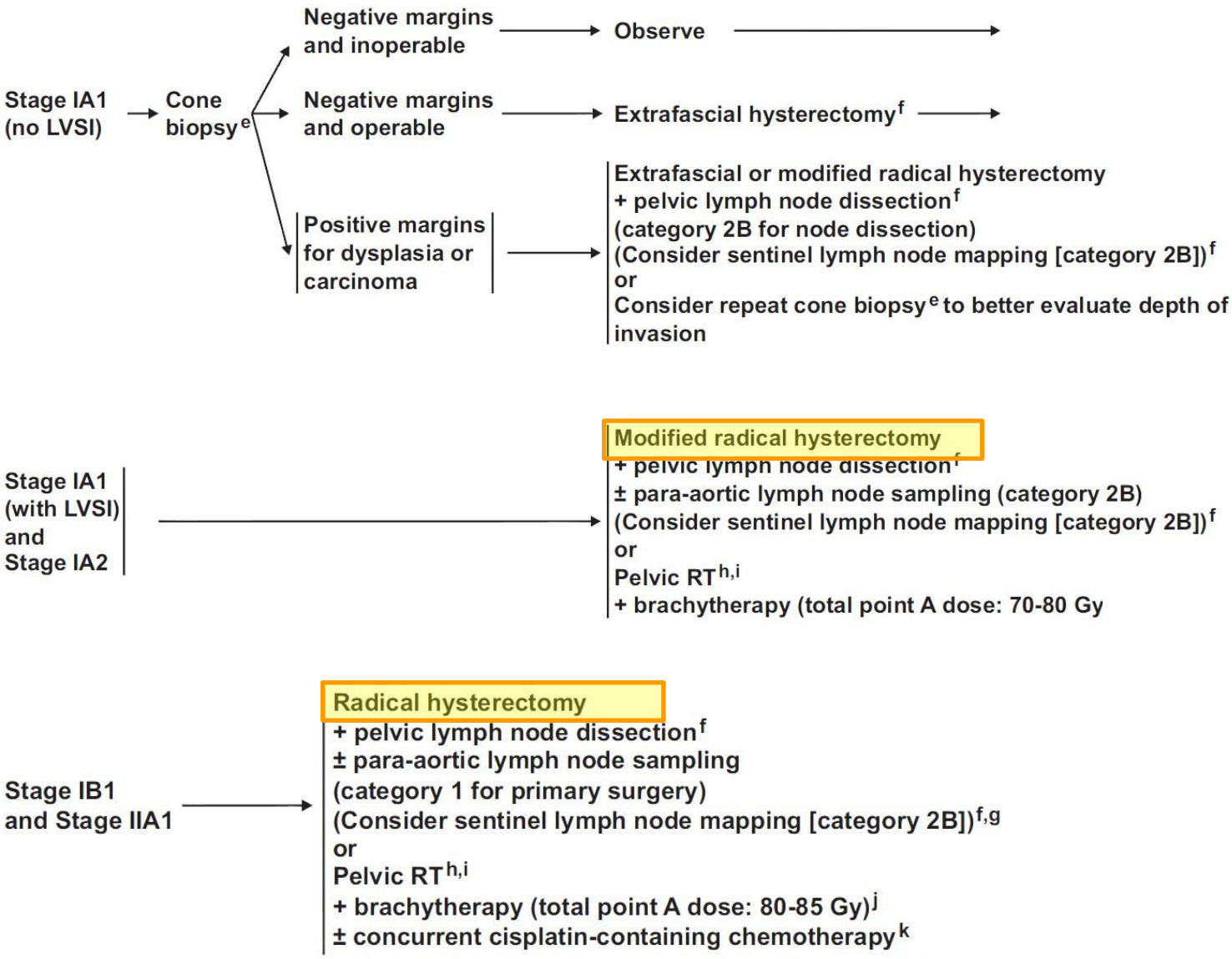
→ Para-aortic LN
- Negative → Pelvic RT+CCRT
- Positive → Pelvic RT +para-aortic LN RT+CCRT
- Positive → Systemic chemotherapy /individualized RT

[a] **Tumor markers**; SCC Ag, CEA, CA-125 if clinically indicated
[b] **Lab. studies**; CBC with platelets, chemistry profile, IVP, ECG and urine analysis
[c] **Imaging studies**; Chest X-ray, Abdomino-pelvic CT, MRI, PET if clinically indicated
* **Intermediate-risk Factors**; Larger tumor size, Cervical Stromal Invasion to the middle or deep one third, Lymph-vascular space invasion
** **High Risk factors** ; Positive margin, Positive Lymph Nodes, Microscopic parametrial Involvement

- *RT: radiation therapy*
- *TH: total hysterectomy*
- *(M)RH: (modified) radical hysterectomy*
- *CCRT: concurrent chemoradiation*
- *VBT: Vaginal Brachytherapy*

National Comprehensive Cancer Network®

# NCCN Guidelines Version 1.2014
# Cervical Cancer



# What kind of evidence do we have?

| Level of Evidence | Information source |
|---|---|
| I | Large double blind RCTs, or meta-analyses of smaller RCTs, clinically relevant outcomes |
| II | Small RCTs, non-blinded RCTs, RCTs using valid surrogate markers |
| III | Non-randomised controlled studies, **observational (cohort) studies**, case-control studies, or cross-sectional studies |
| IV | Opinion of expert committees or respected authorities |
| V | Expert opinion |

# Only one prospective cohort study

- Outcomes of 60 patients, Pluta *et al*
  - lesions < 2cm & < 50% stromal invasion
  - sentinel node mapping followed by complete pelvic lymphadenectomy & simple vaginal hysterectomy
- No recurrences in either the 55 node-negative or the 5 node-positive patients
  - median follow-up of 47 months

Gynecol Oncol 2009;113:181-4

1

Gynecologic Oncology 119 (2010) 187–191

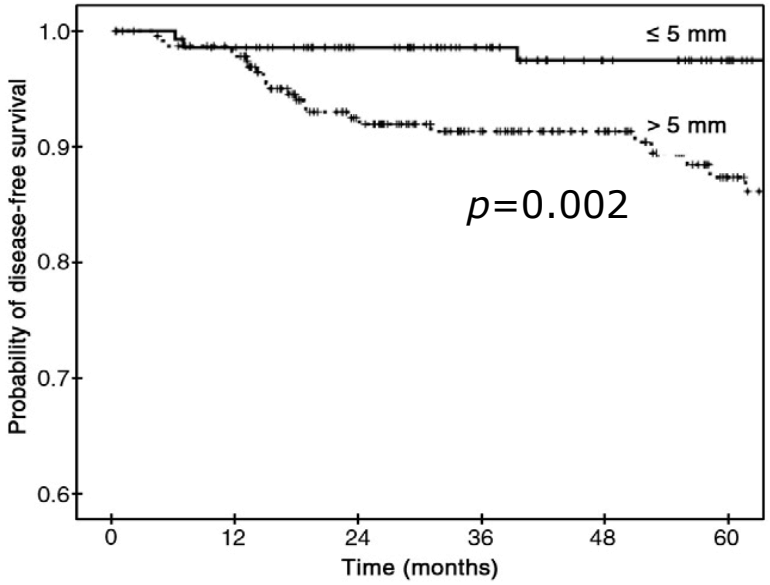
Contents lists available at ScienceDirect

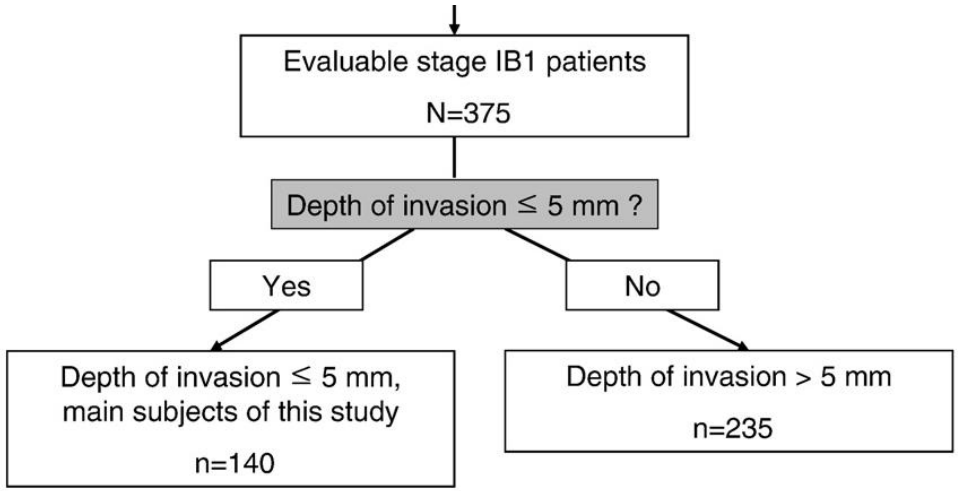
Gynecologic Oncology

journal homepage: www.elsevier.com/locate/ygyno

# Feasibility of less radical surgery for superficially invasive carcinoma of the cervix

Mi-Kyung Kim [a], Jae Weon Kim [a,b,*], Min A Kim [c], Hee Seung Kim [a], Hyun Hoon Chung [a], Noh-Hyun Park [a], In Ae Park [c], Yong-Sang Song [a,b,d], Soon-Beom Kang [a]




Gynecol Oncol 2010;119:187-191

# 2 Loop Electrosurgical Excision Procedure Findings for Identification of Patients With Early-Stage Cervical Cancer Suitable for Less Radical Surgery

*Mi-Kyung Kim, MD,* Min A Kim, MD, PhD,† Jae Weon Kim, MD, PhD,*‡ Hyun Hoon Chung, MD, PhD,*‡ Noh-Hyun Park, MD, PhD,* Yong-Sang Song, MD, PhD,*‡§ and Soon-Beom Kang, MD, PhD**

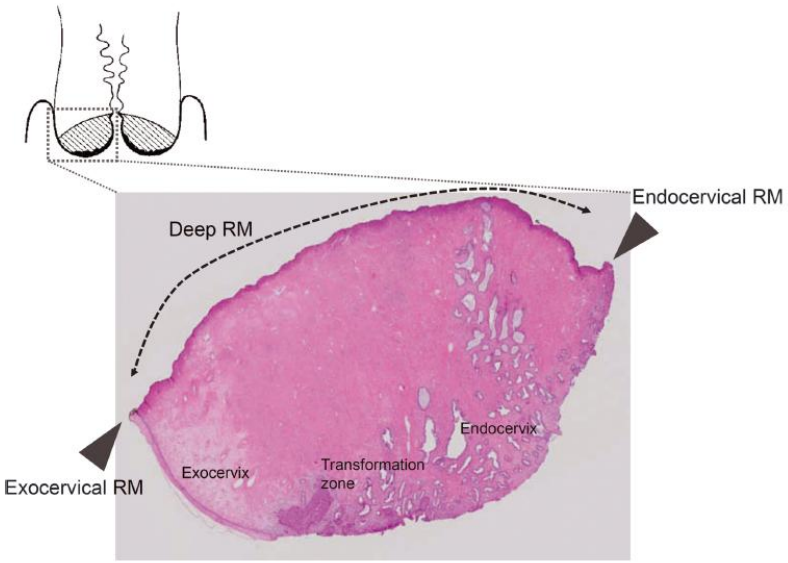



**FIGURE 1.** A gross section of a LEEP specimen illustrating the locations of resection margins.

| | Depth ≤5 mm, LEEP | Depth >5 mm, LEEP |
|---|---|---|
| **Endocervical RM -** | PM+ 0% (0/24)<br>LNM+ 0% (0/24)<br>Depth >5 mm, hyst 0% (0/24) | PM+ 0% (0/11)<br>LNM+ 0% (0/11)<br>Depth >5 mm, hyst 9.1% (1/11) |
| **Endocervical RM +** | PM+ 6.9% (5/72)<br>LNM+ 8.3% (6/72)<br>Depth >5 mm, hyst 19.4% (14/72) | PM+ 8.7% (2/23)<br>LNM+ 26.1% (6/23)<br>Depth >5 mm, hyst 52.2% (12/23) |

**FIGURE 2.** Risk of parametrial involvement according to the subgroups defined by depth of invasion and endocervical marginal status in LEEP specimens. Risks of nodal metastasis and depth of residual tumors greater than 5 mm are also indicated. PM, Parametrial involvement; LNM, lymph node metastasis; hyst, hysterectomy specimens.

Int J Gynecol Cancer 2012;22:1214-9

3

Gynecologic Oncology 134 (2014) 47–51

Contents lists available at ScienceDirect

Gynecologic Oncology

journal homepage: www.elsevier.com/locate/ygyno

# Preoperative MRI criteria for trials on less radical surgery in Stage IB1 cervical cancer

Jung-Yun Lee [a], Jina Youm [a], Tae Hun Kim [a], Jeong Yeon Cho [b], Min A Kim [c], Dong Hoon Suh [d], Myong Cheol Lim [e], Jae-Weon Kim [a,*], Noh Hyun Park [a], Yong-Sang Song [a]

[a] Department of Obstetrics and Gynecology, Seoul National University College of Medicine, Seoul, Republic of Korea
[b] Department of Radiology, Seoul National University College of Medicine, Seoul, Republic of Korea
[c] Department of Pathology, Seoul National University College of Medicine, Seoul, Republic of Korea
[d] Department of Obstetrics and Gynecology, Seoul National University Bundang Hospital, Gyeonggi-do, Republic of Korea
[e] Center for Uterine Cancer, National Cancer Center, Goyang, Gyeonggi-do, Republic of Korea

MRI-based tumor diameter, mm

| MRI-based PMI | ≤ 20 | 20-25 | 25-30 | 30-35 | >35 | Total |
|---|---|---|---|---|---|---|
| Total | 1/91 (1.1%) | 3/43(7.0%) | 3/28(10.7%) | 5/11(45.5%) | 7/17(41.2%) | 19/190(10.0%) |
| No | 0/88(0.0%) | 0/39(0.0%) | 2/25(8.0%) | 3/9(33.3%) | 2/8(25.0%) | 7/169 (4.1%) |
| Yes | 1/3(33.3%) | 3/4(75.0%) | 1/3(33.3%) | 2/2(100%) | 5/9(55.6%) | 12/21 (57.1%) |

PMI, parametrial involvement

Gynecol Oncol 2014;134:47-51

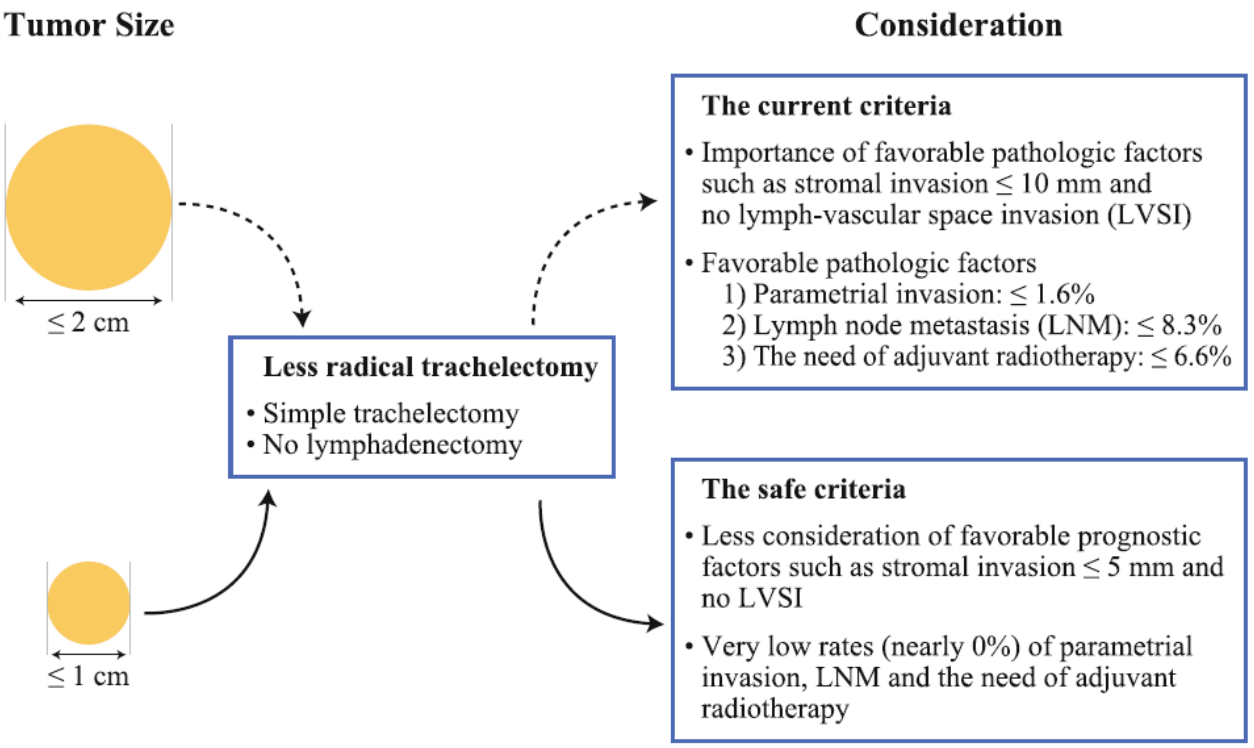
4

Annals of
SURGICAL ONCOLOGY
OFFICIAL JOURNAL OF THE SOCIETY OF SURGICAL ONCOLOGY

ORIGINAL ARTICLE – GYNECOLOGIC ONCOLOGY

# Safe Criteria for Less Radical Trachelectomy in Patients with Early-Stage Cervical Cancer: A Multicenter Clinicopathologic Study

Hee Seung Kim, MD[1,2], Chel Hun
Yong Beom Kim, MD, PhD[6], Min
Byoung-Gie Kim, MD, PhD[3], Yong
and Jae Weon Kim, MD, PhD[1,2]




Ann Surg Oncol 2012;19:1973-9

# CALL for PAPERS

JGO Journal of Gynecologic Oncology

WWW.EJGO.ORG

Journal of Gynecologic Oncology (JGO) invites authors, especially from Asia, to submit high quality original research w… d to the advancement of care of the patients with gynecologic cancer.

2012 Impact Facto…

*Source: apps.webofknowle…

JGO now indexed in MEDLINE

… the official journal of the *Asian Society of …necologic Oncology*; **JGO** distributed to …ynecologic oncologists in over 40 countries, …nd has a printed circulation of over 1,500.

**JGO** is indexed in **SCIE, PubMed (Central), EmBase, & Scopus.**

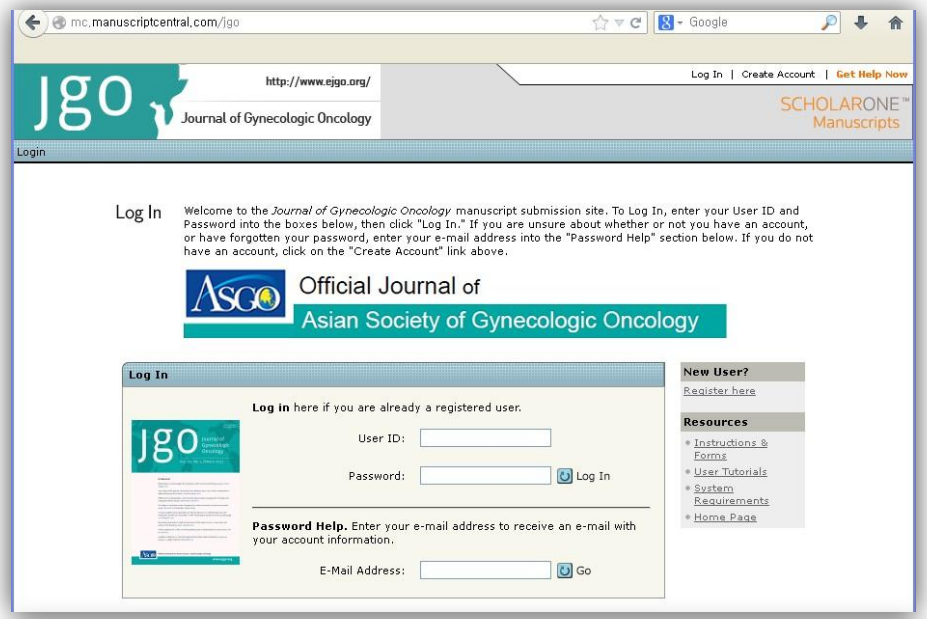
Open access to full text article at **EJGO.ORG** web site.

We hope JGO will be a gynecologic oncology platform for the researchers in this field, especially from Asian region.

Online submission is available at

**Manuscript Submission Site: mc.manuscriptcentral.com/jgo**

Asian Society of Gynecologic Oncology


Asian Society of Gynecologic Oncology

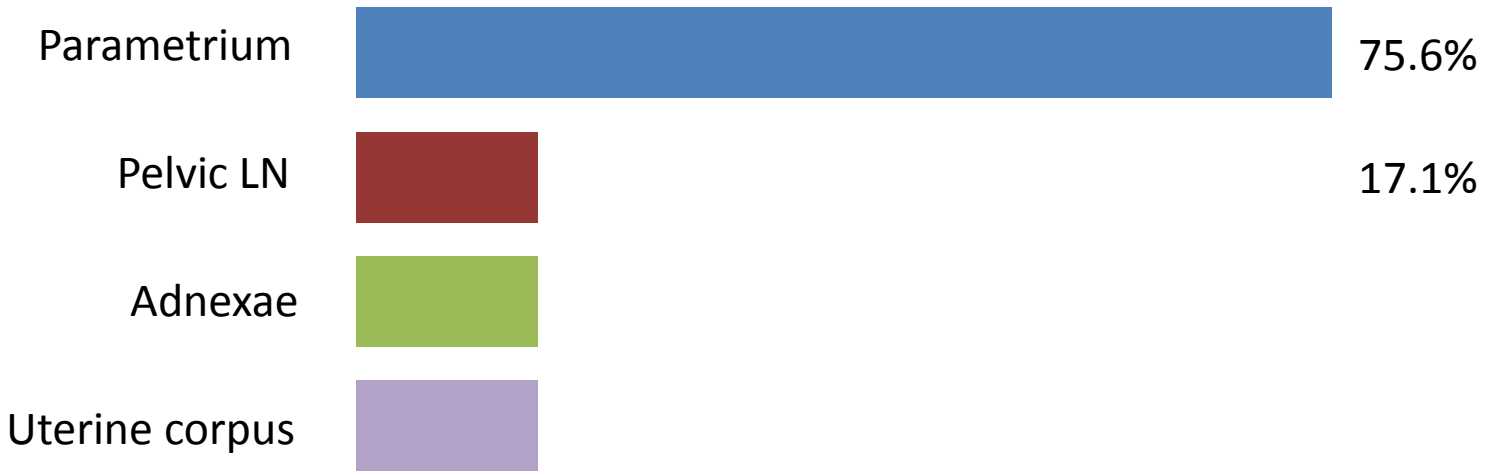
Korean Gynecologic Oncology Group

# Findings of an survey by the Korean Society of Gynecologic Oncology (KSGO)

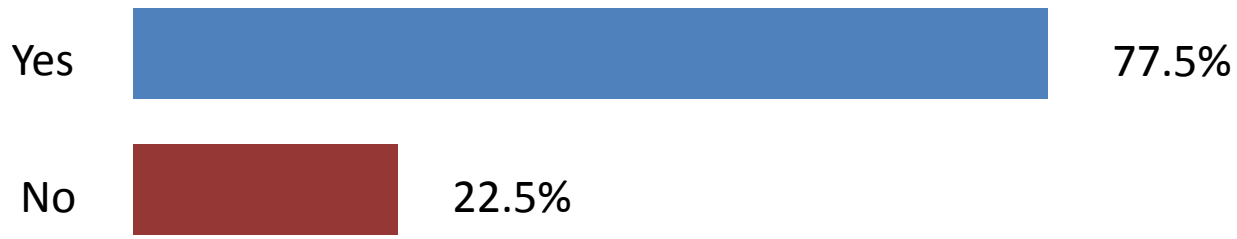
# Level of evidence in less-radical surgery for early-stage cervical cancer.

# 1. Do you know the concept of ‘less radical surgery’?

## 2. Which of the following part could be omitted in less radical surgery?

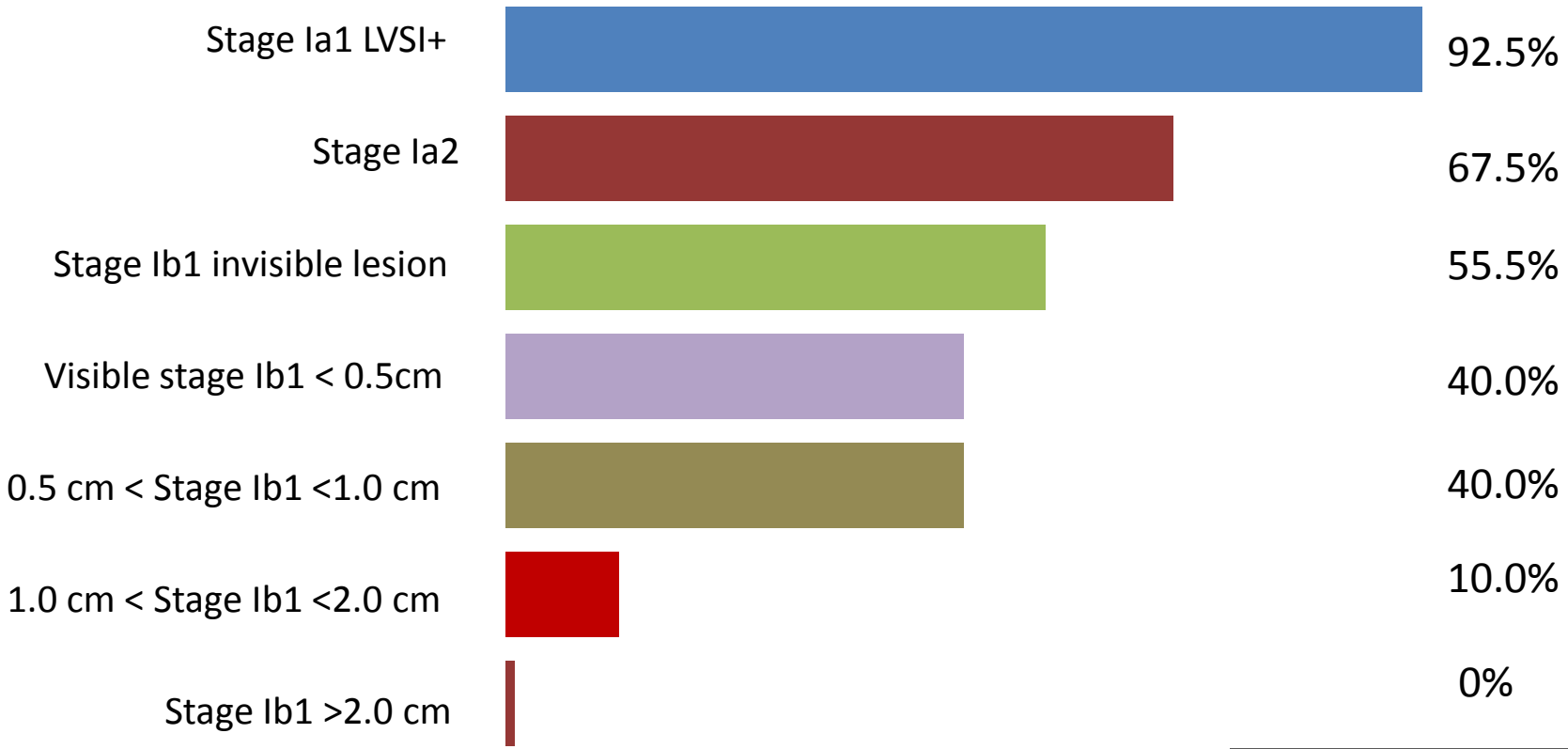


## 3. Have you ever performed less radical surgery in your clinical practice?



# 4. Please define the criteria for less radical surgery.

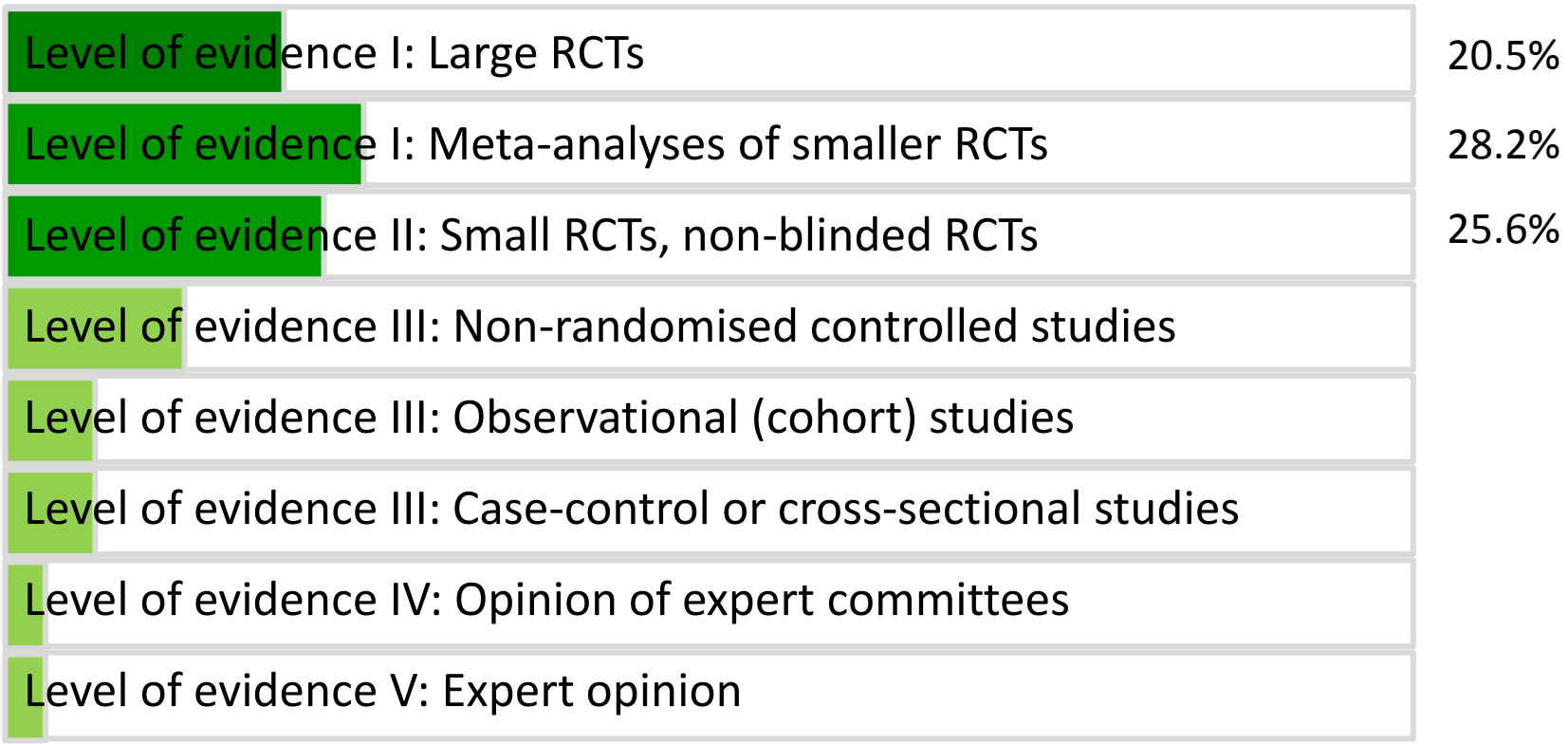
(plural response permitted)



## 5. Up to date, what is your opinion about the level of evidence for less radical surgery?

| | |
|---|---|
| Level of evidence I: Large RCTs | |
| Level of evidence I: Meta-analyses of smaller RCTs | |
| Level of evidence II: Small RCTs, non-blinded RCTs | |
| Level of evidence III: Non-randomised controlled studies | 30.8% |
| Level of evidence III: Observational (cohort) studies | 20.5% |
| Level of evidence III: Case-control or cross-sectional studies | 10.3% |
| Level of evidence IV: Opinion of expert committees | |
| Level of evidence V: Expert opinion | 10.3% |

## 6. In order to perform less radical surgery in practice, which level of evidence is required?



ASGO 2015

# The 4th Biennial Meeting of Asian Society of Gynecologic Oncology

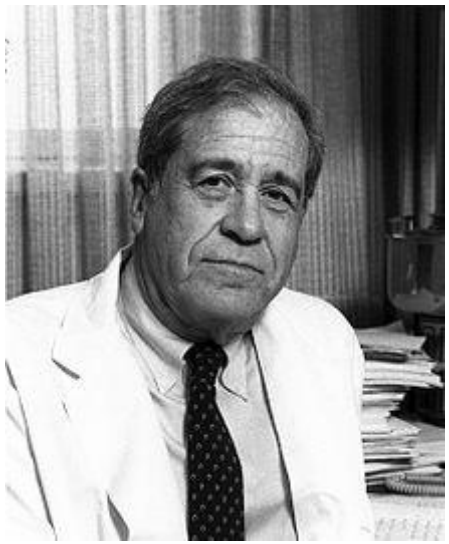
**Date** · Nov 12(Thu) - 14(Sat), 2015

**Venue** · Seoul, Korea

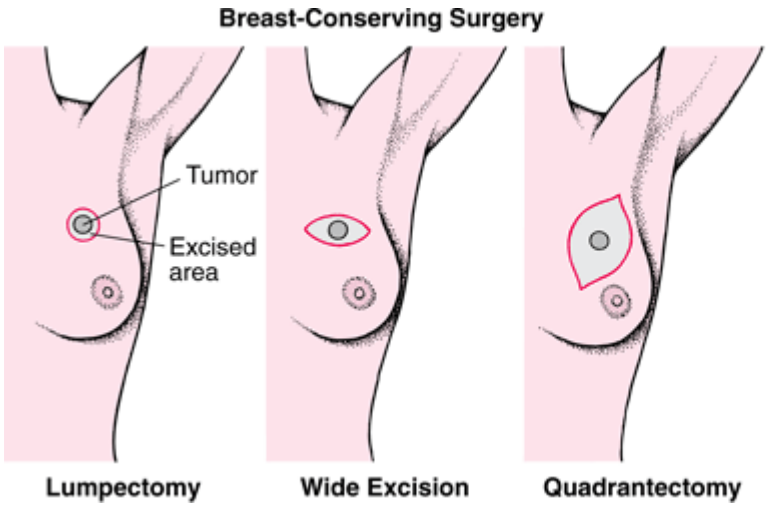
Asian Society of Gynecologic Oncology

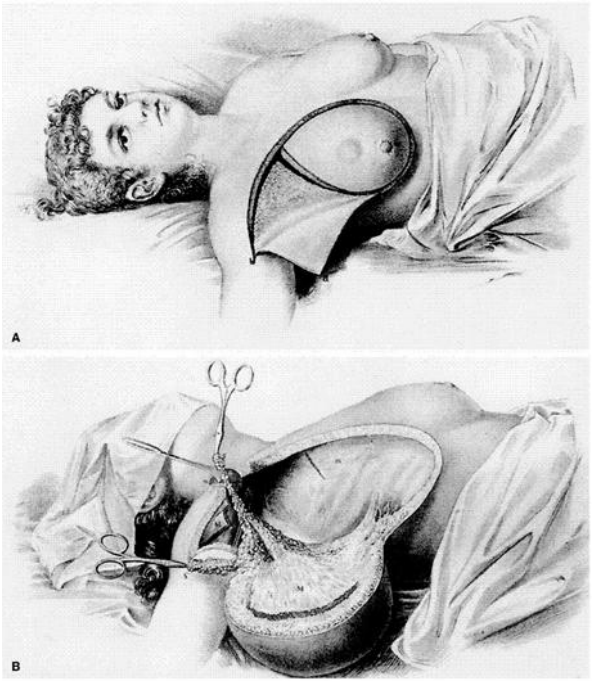
asgo2015.org

# William Stewart Halsted (1852 - 1922)



Bernard Fisher (1918 - )



# National Surgical Adjuvant Breast and Bowel Project (NSABP)

**1958**
The first patient was enrolled in the first NSABP randomized clinical trial.

**1967**
Dr. Bernard Fisher was appointed the chairman of the Surgical Adjuvant Chemotherapy Breast Project. Dr. Fisher moved the Operations and Biostatistical Centers to Pittsburgh, Pennsylvania.

**1971**
Up until this time, physicians thought that breast cancer was a local disease that could only be treated with the complete removal of the breast, chest wall muscle, and underarm lymph nodes (radical mastectomy). Protocol B-04 was one of the first studies that indicated that the total mastectomy was just as effective as the more extensive operation. This landmark study gave way to future breast-conserving procedures.

**1976**
The era of lumpectomy begins with Protocol B-06. This study was based on the results of Protocol B-04, and showed that removing just the tumor and the underarm lymph nodes plus adding radiation therapy was just as effective as a mastectomy, but was far less disfiguring.

**1977**
Protocols C-01 and R-01 were launched as the NSABP's first colorectal cancer treatment trials.

**1982**
Protocol B-14 was one of the first studies that evaluated tamoxifen therapy in women with negative axillary nodes who were estrogen-receptor positive (ER+). Results showed that women in the tamoxifen group had fewer recurrences of cancer and improved survival compared to the women who received placebo. This study later determined that there was no additional advantage for continuing tamoxifen therapy for more than five years.

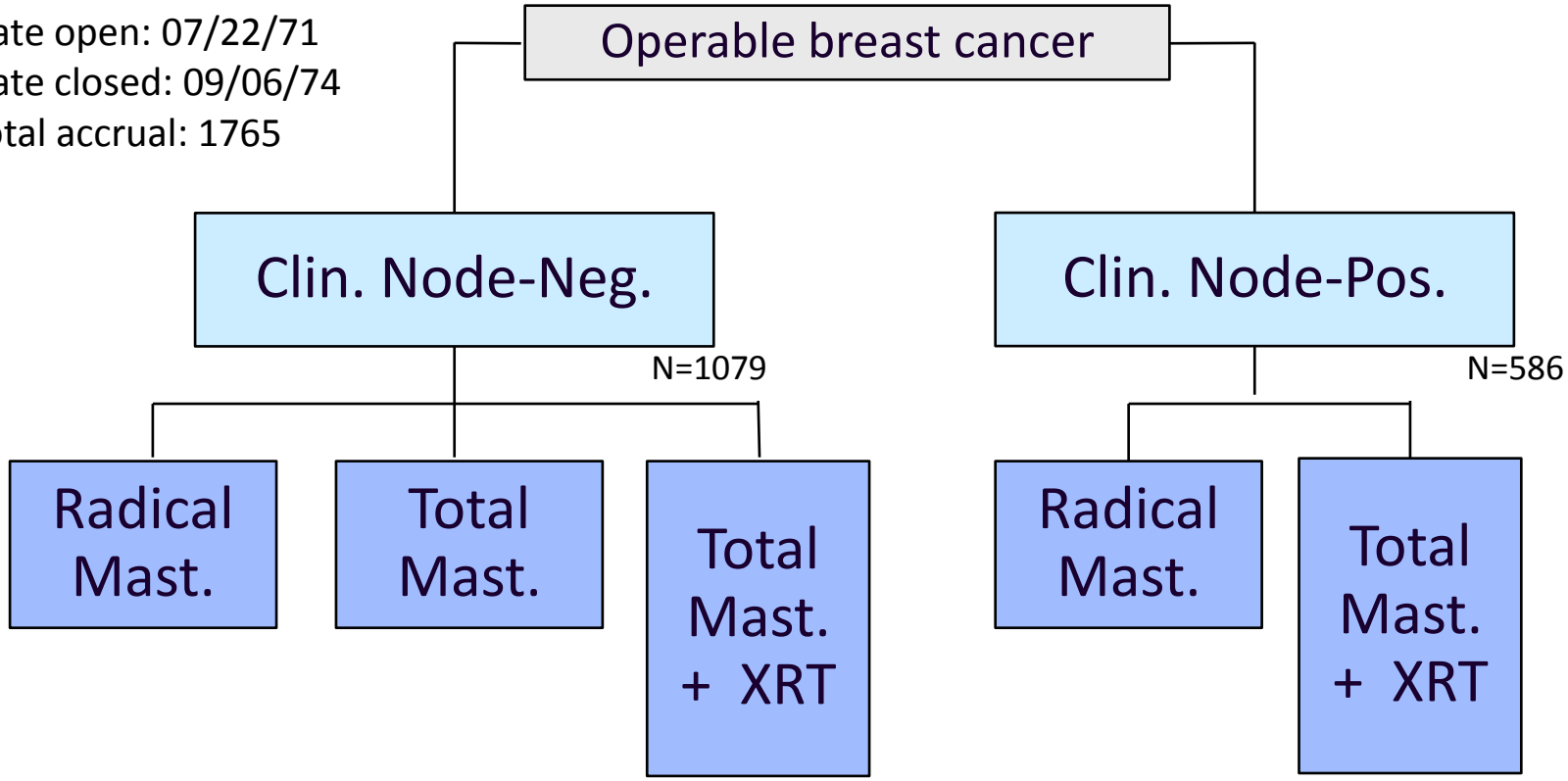
**1988**
Protocol B-18 demonstrated that therapy prior to surgery reduced the size of breast tumors in 80% of patients, decreased the spread of the tumor to the lymph nodes and increased the number of women able to undergo lumpectomy.

**1989**
Protocol C-04 assessed 2,151 patients who underwent a "curative" resection of a Dukes' B or C carcinoma of the colon and demonstrated that the use of adjuvant 5-FU+ leucovorin is an acceptable therapeutic standard for such patients.

# B-04 study scheme

Evaluation of Radical Mastectomy and Total Mastectomy c/s Radiation in the Primary Treatment of Cancer of the Female Breast

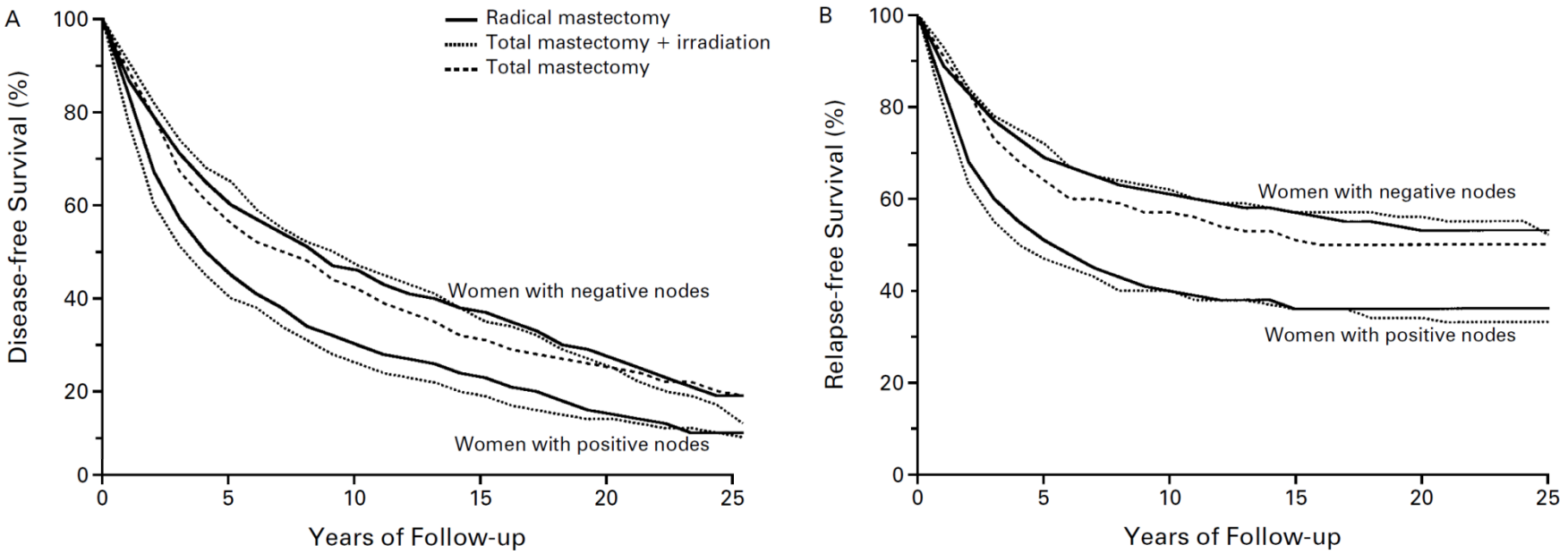
5 arm
Date open: 07/22/71
Date closed: 09/06/74
Total accrual: 1765




Cancer 1977;39:2827-39

# TWENTY-FIVE-YEAR FOLLOW-UP OF A RANDOMIZED TRIAL COMPARING RADICAL MASTECTOMY, TOTAL MASTECTOMY, AND TOTAL MASTECTOMY FOLLOWED BY IRRADIATION

BERNARD FISHER, M.D., JONG-HYEON JEONG, PH.D., STEWART ANDERSON, PH.D., JOHN BRYANT, PH.D., EDWIN R. FISHER, M.D., AND NORMAN WOLMARK, M.D.

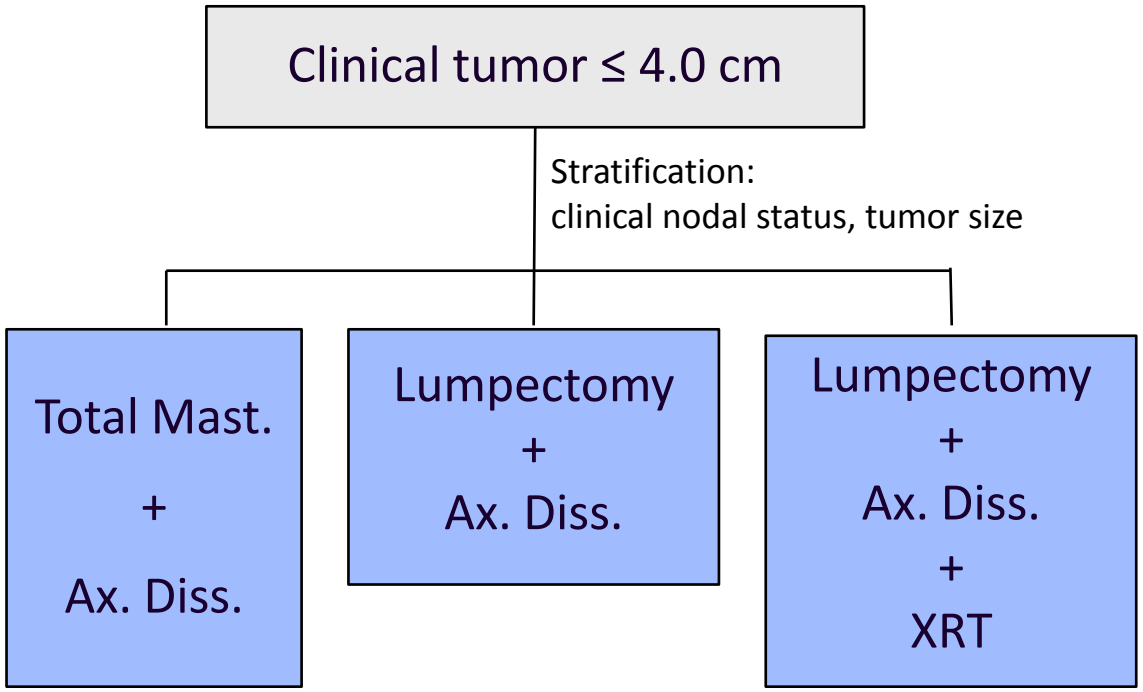



N Engl J Med 2002;347:567-75

# B-06 study scheme

A Protocol to Compare Segmental Mastectomy and Axillary Dissection With and Without Radiation of the Breast and Total Mastectomy and Axillary Dissection

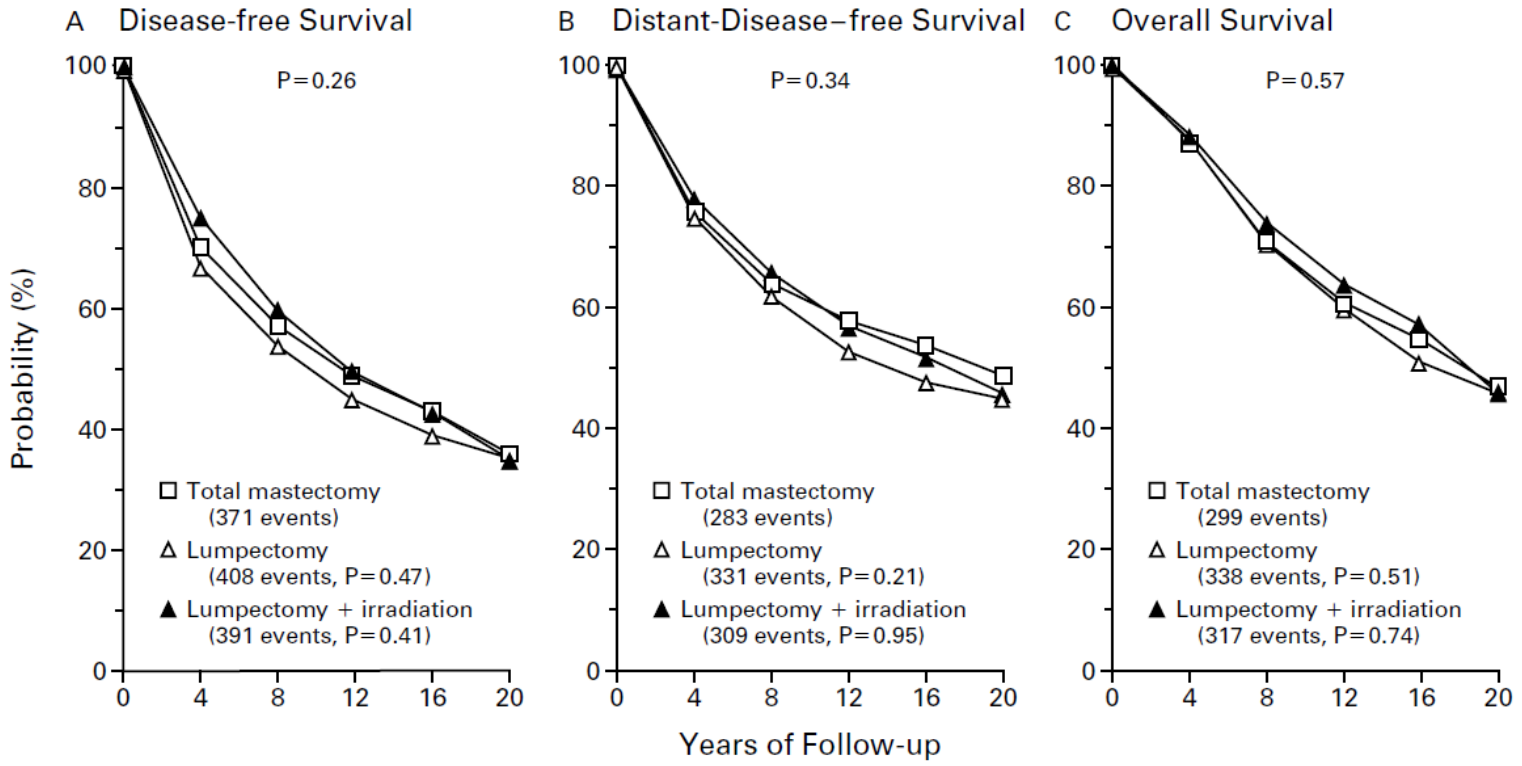
3 arm
Date open: 04/08/76
Date closed: 01/31/84
Total accrual: 2163




N Engl J Med 1985;312:665-73

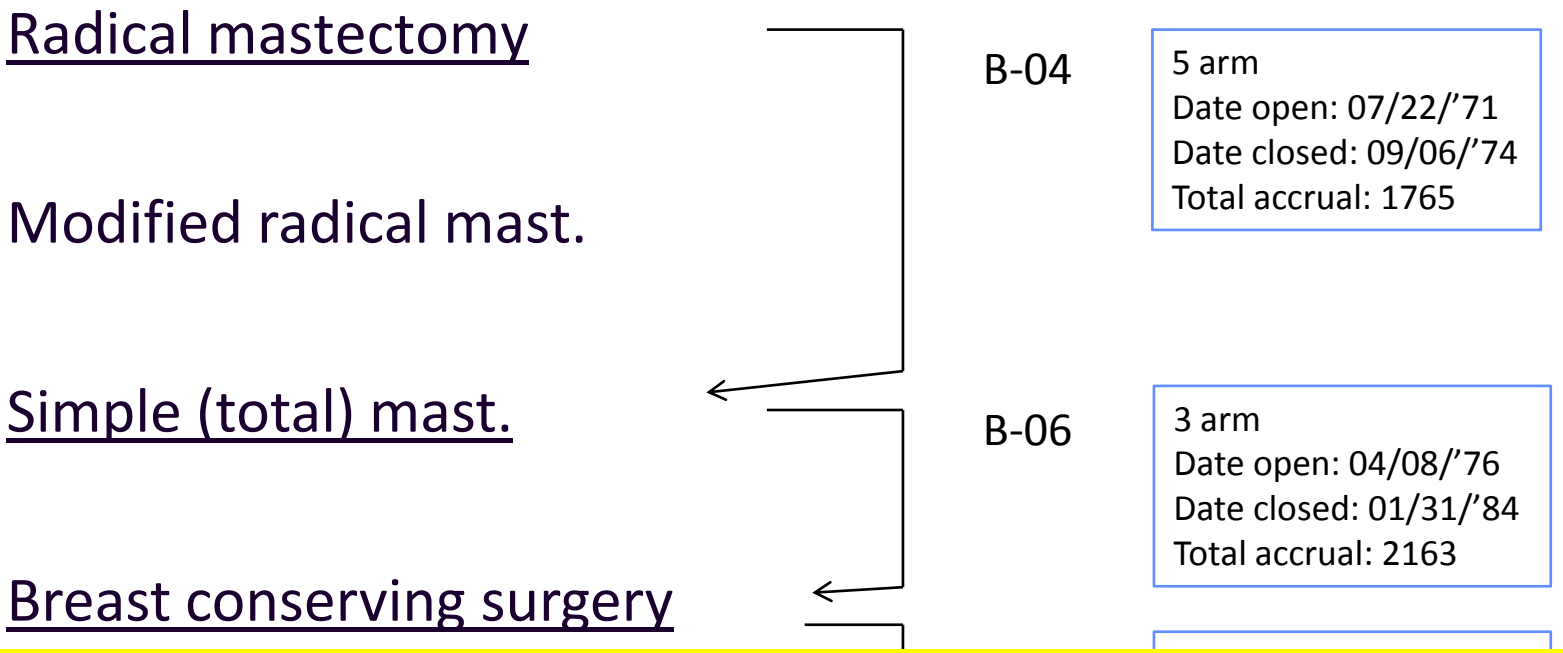
# TWENTY-YEAR FOLLOW-UP OF A RANDOMIZED TRIAL COMPARING TOTAL MASTECTOMY, LUMPECTOMY, AND LUMPECTOMY PLUS IRRADIATION FOR THE TREATMENT OF INVASIVE BREAST CANCER

BERNARD FISHER, M.D., STEWART ANDERSON, PH.D., JOHN BRYANT, PH.D., RICHARD G. MARGOLESE, M.D., MELVIN DEUTSCH, M.D., EDWIN R. FISHER, M.D., JONG-HYEON JEONG, PH.D., AND NORMAN WOLMARK, M.D.




N Engl J Med 2002;347:1233-41

# History of mastectomy after Halsted




**From radical to simple mastectomy to lumpectomy + radiation**

# 2009 State of the State of Gynecologic Cancers

*Seventh Annual Report to the Women of America*

**New surgical approaches are uniformly recommended and adopted after Phase III trials demonstrate superior safety, tolerability and/or effectiveness.**

**Larry J. Copeland, MD**

**Vice Chairman of GOG**

GCF Gynecologic Cancer Foundation

# How to evaluate the role of less radical surgery in the low-risk cervical cancer?

- **Single arm prospective cohort study (registry)**
  - to be compared with similar sized contemporaneous cohort of pts treated by Modified rad H: ~160 pts
  - All pts should undergo a cone or LEEP prior to H

- **Two arms randomized trial**
  - Modified rad H/nodes *vs*. Simple H/nodes
  - Survival as primary endpoint: ~1500 pts

    (80% power, difference of 2% in 2-yr pelvic relapse, i.e, 2 vs 4%)

# Currently, 3 prospective studies are ongoing

Two prospective single arm cohort studies

1. GOG 278 (n=200~)
2. MDACC *ConCerv* study: NCT01048853 (n=100)

One randomized controlled phase III trial

3. SHAPE (n=700)

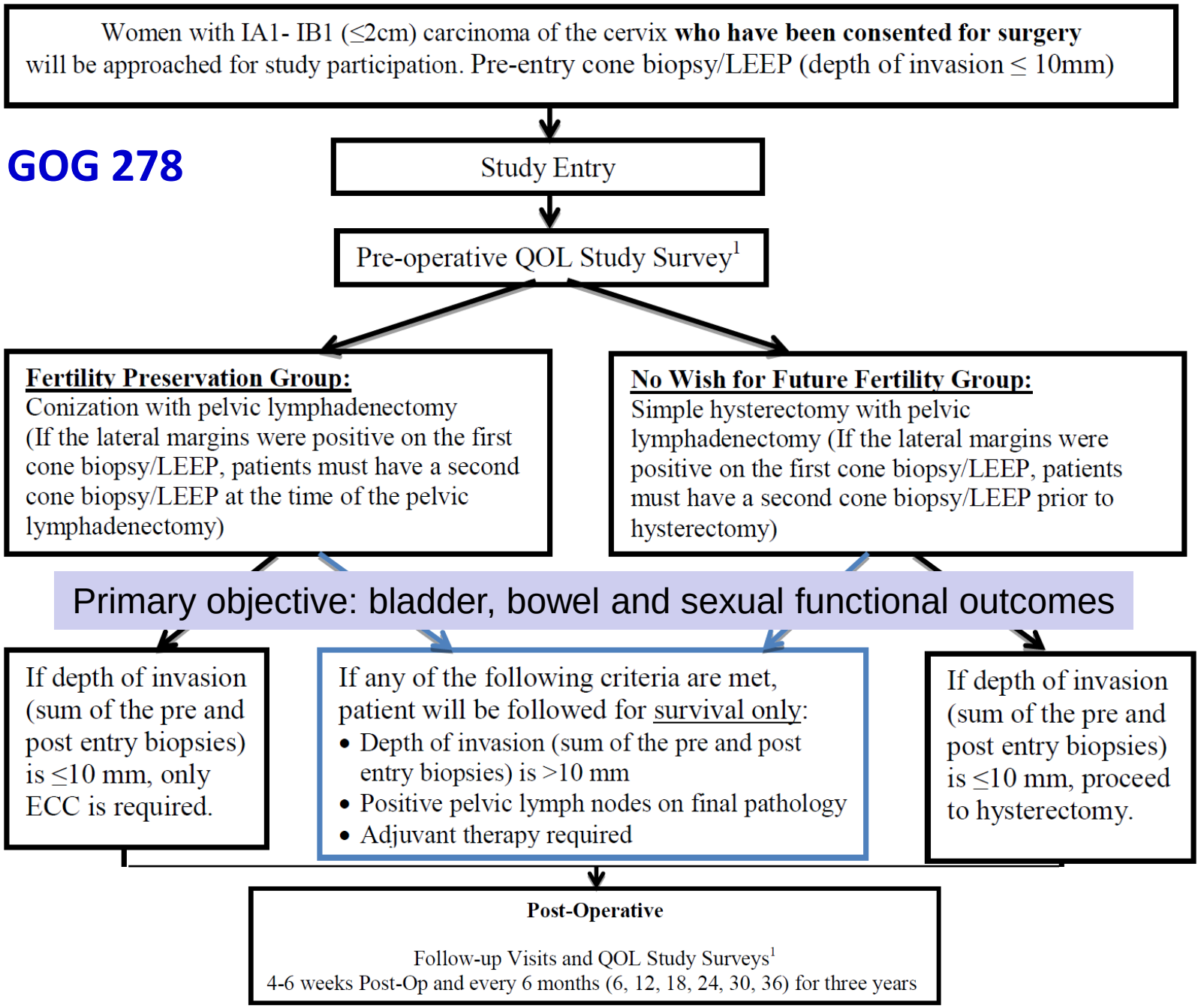

Women with IA1- IB1 (≤2cm) carcinoma of the cervix **who have been consented for surgery** will be approached for study participation. Pre-entry cone biopsy/LEEP (depth of invasion ≤ 10mm)
GOG 278
Study Entry
Pre-operative QOL Study Survey[1]
**Fertility Preservation Group:**
Conization with pelvic lymphadenectomy
(If the lateral margins were positive on the first cone biopsy/LEEP, patients must have a second cone biopsy/LEEP at the time of the pelvic lymphadenectomy)
**No Wish for Future Fertility Group:**
Simple hysterectomy with pelvic lymphadenectomy (If the lateral margins were positive on the first cone biopsy/LEEP, patients must have a second cone biopsy/LEEP prior to hysterectomy)
Primary objective: bladder, bowel and sexual functional outcomes
If depth of invasion (sum of the pre and post entry biopsies) is ≤10 mm, only ECC is required.
If any of the following criteria are met, patient will be followed for survival only:
• Depth of invasion (sum of the pre and post entry biopsies) is >10 mm
• Positive pelvic lymph nodes on final pathology
• Adjuvant therapy required
If depth of invasion (sum of the pre and post entry biopsies) is ≤10 mm, proceed to hysterectomy.
**Post-Operative**
Follow-up Visits and QOL Study Surveys[1]
4-6 weeks Post-Op and every 6 months (6, 12, 18, 24, 30, 36) for three years

Table 1. Current ongoing studies and new simplified criteria for less radical surgery

| Study | Stage | Selection Criteria | Histology |
|---|---|---|---|
| ConCerv [11] | IA2, or IB1 | tumor size ≤ 2cm, No LVSI, and negative margin on cone | SCC, or AC[a] |
| GOG-278 [12] | IA1(LVSI+), IA2, or IB1 | tumor size ≤ 2cm, negative lateral margins, and depth of invasion ≤ 10 mm on cone | SCC, AC, or ASC |
| SHAPE [13] | IA2, or IB1 | tumor size ≤ 2cm and <50% stromal invasion on MRI, and depth of invasion < 10 mm on cone (if performed) | SCC, AC, or ASC |
| MRI | microscopic IB1 | No demonstrate lesion on postconization MRI | SCC, AC, or ASC |

Table 4. Performance of the criteria used in ongoing trials and MRI criteria

| Study | No. of less radical surgery candidate (%) | No. of PMI in less radical surgery candidate (%) | Sensitivity | Specificity | NPV | PPV |
|---|---|---|---|---|---|---|
| ConCerv | 11 (8.8%) | 0 (0%) | 100.00% | 9.32% | 100% | 6.14% |
| GOG-278 | 14 (11.2%) | 0 (0%) | 100.00% | 11.86% | 100% | 6.31% |
| SHAPE | 78 (62.4%) | 1 (1.3%) | 85.71% | 65.25% | 98.72% | 12.77% |
| MRI | 74 (59.2%) | 1 (1.4%) | 85.71% | 61.86% | 98.65% | 11.76% |

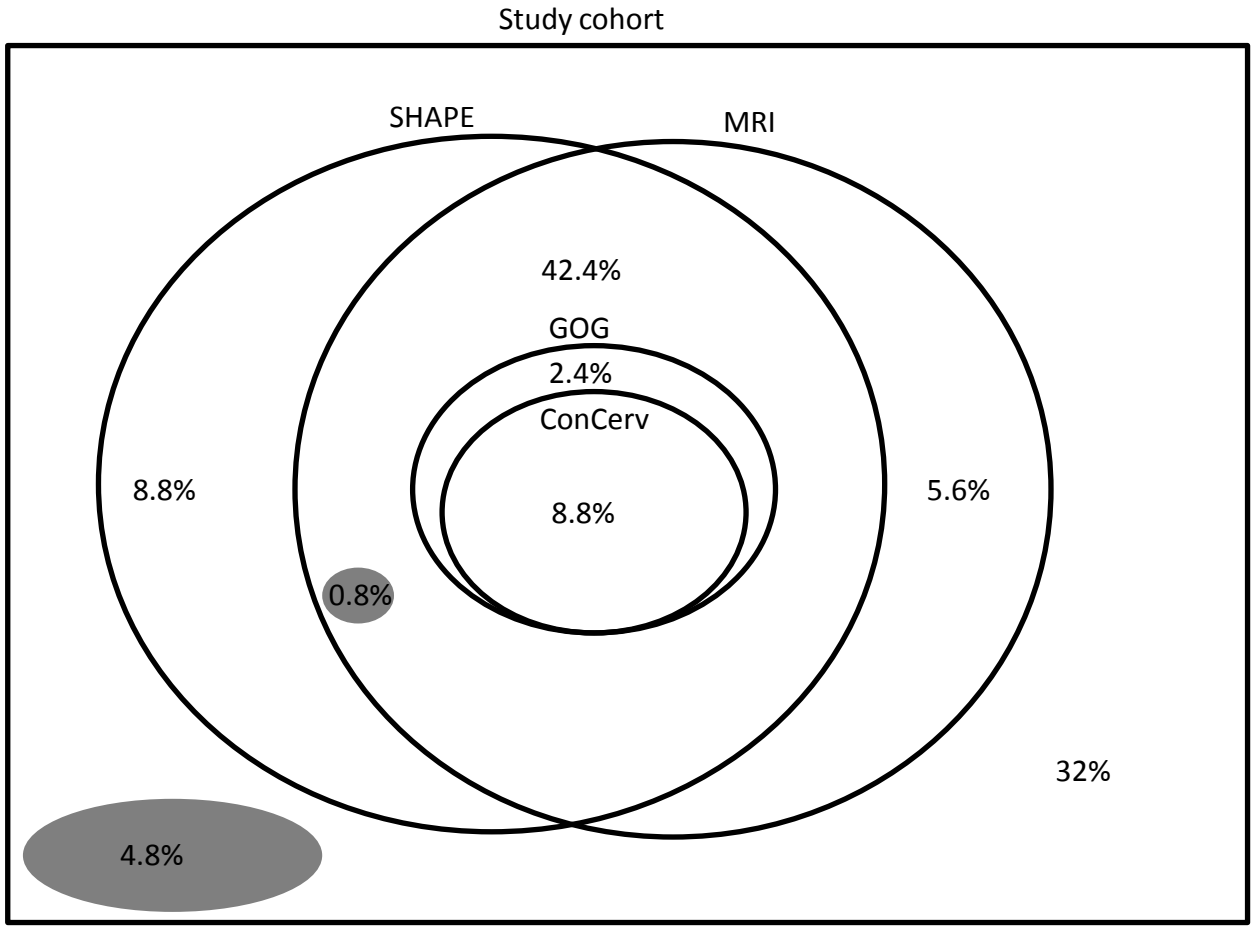
PMI, parametrial involvement; PPV, positive predictive value; NPV, negative predictive value

Unpublished data

Figure 2. Venn diagram for less radical surgery candidates.

Study cohort = 100% (n=125)

ConCerv = 8.8% (n=11)
GOG 278 = 11.2% (n=14)
SHAPE = 62.4% (n=78)
MRI = 59.2% (n=74)




Gray colored area is proportional to the rate of pathologic PMI

Unpublished data

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# A model for prediction of parametrial involvement and feasibility of less radical resection of parametrium in patients with FIGO stage IB1 cervical cancer ☆

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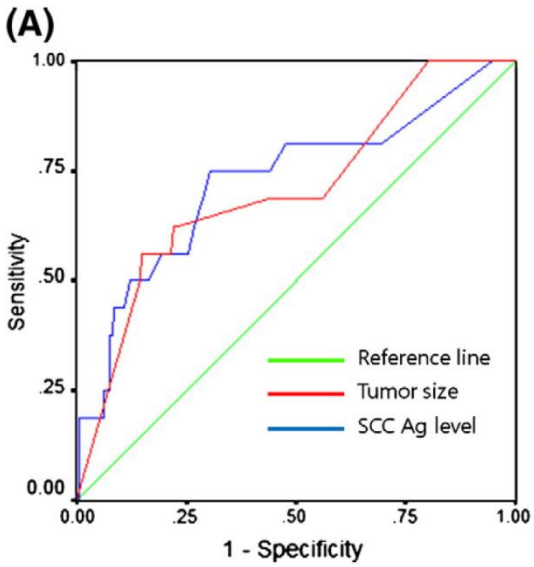


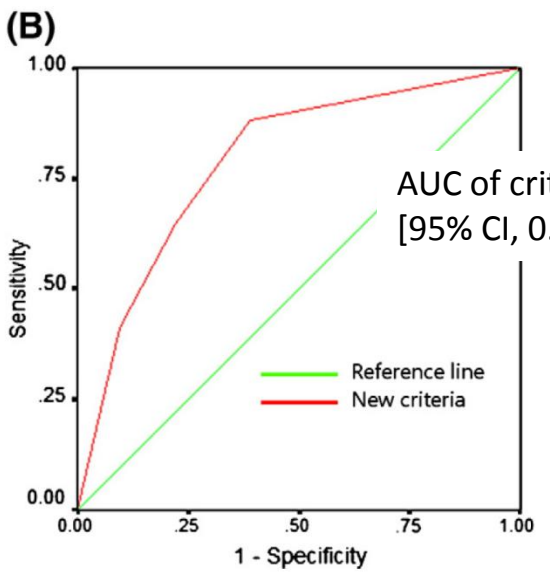


AUC of criteria=0.789
[95% CI, 0.683–0.895], p<0.01

National Cancer Institute of Canada
Institut national du cancer du Canada
Clinical Trials Group
Groupe des essais cliniques

GYNECOLOGIC CANCER INTERGROUP
An Organization of International Cooperative Groups for Clinical Trials in Gynecologic Cancers

# **SHAPE** Trial

**S**imple **H**ysterectomy **A**nd **P**elvic node dissection in **E**arly cervix cancer

## Radical *versus* Simple Hysterectomy and Pelvic Node Dissection in Patients With Early Stage Cervical Cancer

A prospective, randomized, international, multi-center trial, led by the NCIC-CTG Study Group

# SHAPE Trial : scheme

SHAPE
Simple Hysterectomy And Pelvic node dissection in Early-stage, low-risk cervical cancer
NCIC CTG CX.5 / GCIG SHAPE

**Patient Population**
Stage IA2, modified IB1 cervix cancer
Squamous, adeno & adenosquamous ca
<10mm stromal invasion (SI) on LEEP/cone
< 2cm and < 50% SI on MRI
Grades 1-3 or not assessable

**RANDOMIZATION**

**Radical Hysterectomy & PLND +/- SLN Mapping***

**Stratification**
Centers (performing SN mapping vs not)
Mode of surgery (abd vs non-abd route)
Stage (IA2 vs IB1)
Histology (squamous vs adenoca)
Grade (1-2 vs 3)

Post surgical QoL & disease outcomes measured 3 monthly X 2 years, and 6 monthly for further 3 years

**Simple Hysterectomy & PLND +/- SLN Mapping***

**Primary endpoint: pelvic relapse-free survival, 3 years**

*SI, stromal invasion; PLND, pelvic lymph node dissection; SLN, sentinel lymph node mapping

# **SHAPE** Trial : criteria

SHAPE
Simple Hysterectomy And Pelvic node dissection in Early-stage, low-risk cervical cancer
NCIC CTG CX.5 / GCIG SHAPE

## Inclusion criteria

-Stage IA2~IB1< 2cm cervix cancer pts

-< 50% stromal invasion (MRI) or <1cm depth of invasion on LEEP/cone

-Squamous, adeno or adenosquamous

-Grade 1, 2, 3

-Radiologically (MRI or CT) node negative

## Exclusion criteria

-High risk histology: clear/small cell

-Stage IA1

-Neoadjuvant chemotherapy

-Pregnancy

-Desire to preserve fertility

# **SHAPE** Trial : status

Simple Hysterectomy And Pelvic node dissection in Early-stage, low-risk cervical cancer
NCIC CTG CX.5 / GCIG SHAPE

- This trial was activated on Aug 2012.
- Currently, as of Aug 2014, 40 patients have been randomized to this trial in Canada (33), Korea (5) and Austria (2).
- France, Germany, The Netherlands, Belgium, Ireland, UK and the Nordic countries will join this study.

# My conclusion/suggestion are...

- Too much is as bad as too little.
- Join the crowd!
- At least one, preferable 2 (non-inferiority) phase III trials
- Action points
  - Join SHAPE trial.
  - Develop another SHAPE on the ASGO platform.


**Thank you for your time & attention.**

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