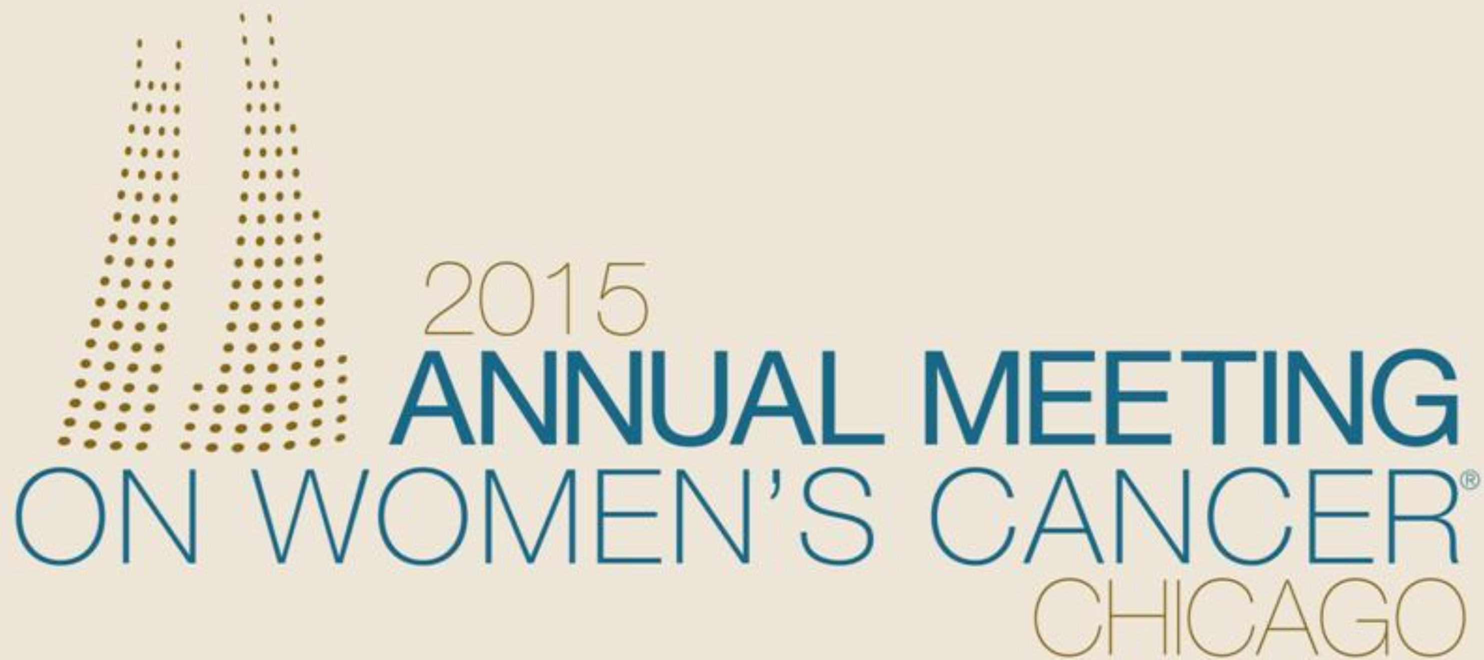
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Preoperative risk assessment for lymph node metastasis in endometrial cancer (PALME study) : results of a Korean Gynecologic Oncology Group study

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Lymph node dissection in low risk endometrial cancer patients

Cons

- No evidence of survival benefit
- Two randomized studies [1,2]
- Impaired quality of life [3,4]
- Increased cost [5]

Pros

- Criticisms of the two trial
- Preoperative and/or intraoperative tests are inaccurate – before surgery, low risk patients cannot be accurately identified [6]

1. ASTEC study group, Lancet, 2009; 2. Benedetti Panici et al. JNCI, 2008; 3. Yost et al. Obstet Gynecol, 2014; 4. Ferrandina et al. Gynecol Oncol, 2014; 5. Lee et al. Gynecol Oncol, 2014; 6. Walker, IJGC, 2011

Development of a risk model

(Kang et al. J Clin Oncol, 2012)

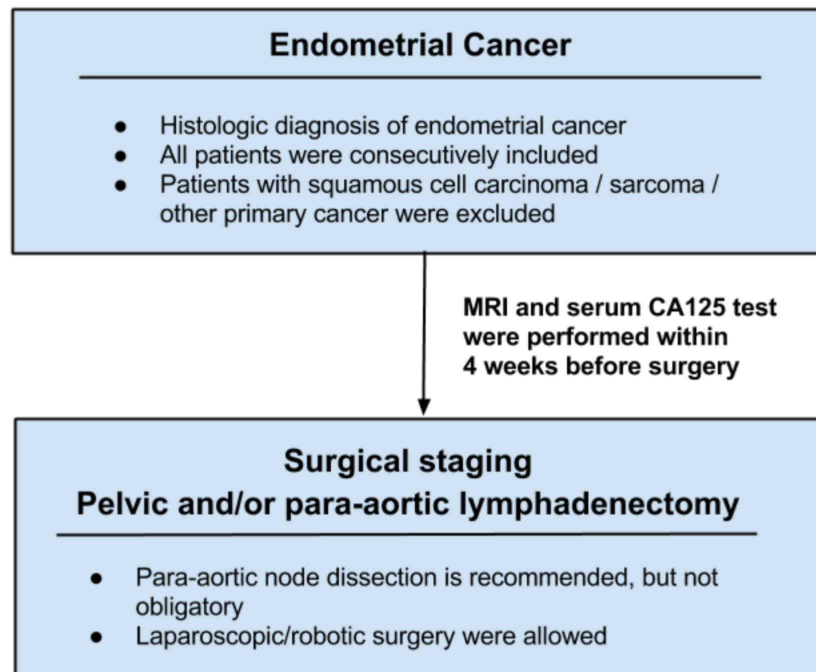
- **Included variables**
  : Preoperative MR image [1], biopsy data and serum CA125 data [2]
- **Endpoint**
  : To identify patients with risk for node metastasis less than 4% [3,4]
- **Performance**
  : The model identified 175 out of 330 patients (53%) as a low risk group
  : Only 3 out of 175 patients (1.7%) were false negatives

Component of our low risk criteria	
MRI	Myometrial invasion < 50%
	No enlarged lymph nodes
	No suspicious extension from uterine corpus
Biopsy	Endometrioid type
Serum CA125	< 35 U/ml

1. Manfredi et al. Radiology, 2004; 2. Nicklin et al. Int J Cancer, 2011; 3. Sakuragi, J Gynecol Oncol, 2012; 4. Boronow, Gynecol Oncol, 1997

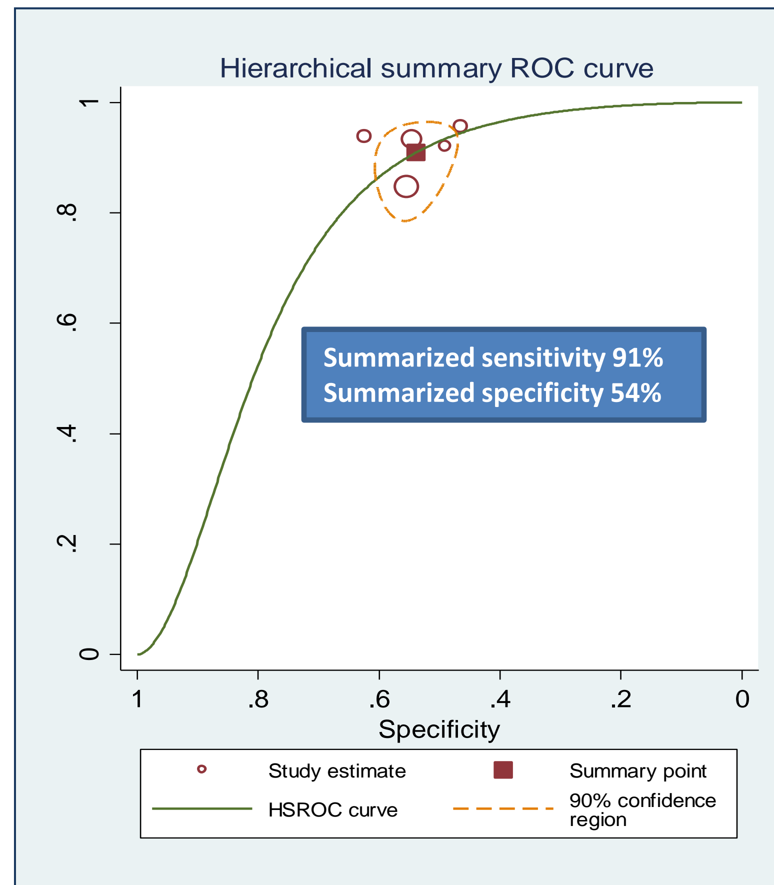
KGOG-2015
(PALME study)

- **Study design**
  : Prospective, observational study
- **End point**
  : Negative predictive value > 96%
- **Patient characteristics**
  : 529 patients from 25 hospitals,
  3 Asian countries (Korea, Japan, and China)
  : Prevalence of lymph node metastasis: 10%
  : Median tumor size: 2.5 cm
  : Median number of harvested lymph node: 23



Summary of results from the current and previous studies

	n	Estimated low risk group (n, %)	False omission rate (%) [2]
Modeling set [1]	330	175 (53%)	1.7
Validation set [1]	171	74 (43%)	1.4
External validation [2] (Japanese cohort #1)	137	57 (42%)	3.5
External validation [2] (Japanese cohort #2)	182	105 (58%)	1.0
Current study	529	272 (51%)	2.9



1. Kang et al. J Clin Oncol, 2012; 2. Kang et al. Gynecol Oncol, 2013; 2. (false negative / false negative + true negative)

Comparison of diagnostic performance

N = 529	Sensitivity	Specificity	Negative predictive value	Area of ROC curve
Our criteria	84.6%	56.5%	97.1%	0.71
Modified criteria (ca125 replaced by tumor grade)	88.5%	50.0% ↓	97.6%	0.70
Postoperative criteria #1 (myometrial invasion < 50%, endometrioid type, grade 1-2 disease in final pathology)[1-3]	86.5%	59.0%	97.6%	0.73
Postoperative criteria #2 (above criteria + tumor size < 2cm in final pathology) [4]	94.2%	25.3% ↓	97.6%	0.60 ↓

- Sensitivity and specificity were compared using McNemar chi-square test.
- Red arrows indicates statistically significant impairment of diagnostic performance.
- Areas of ROC curves were compared using an algorithm suggested by DeLong and Clarke-Pearson.

1. Queleu et al. IJGC, 2011; 2. Colombo et al. Ann Oncol, 2011; 3. Klopp et al. Pract Radiat Oncol, 2014

Summary

- Before surgery, patients with a low risk for lymph node metastasis can be reliably identified using MRI, biopsy and serum CA125 test
- Our preoperative risk model has similar accuracy to postoperative assessment in identifying low risk patients
- In our criteria, serum CA125 test can be replaced by tumor grade at the expense of slight but significant decrease of specificity
- The information from our preoperative risk assessment may be valuable in patient counseling, surgical planning, and candidates selection for surgical trials