



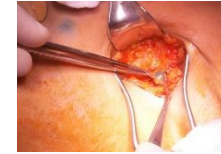
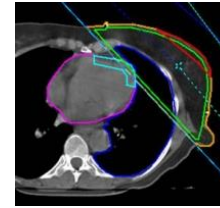
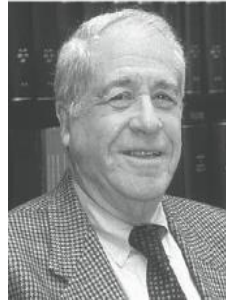
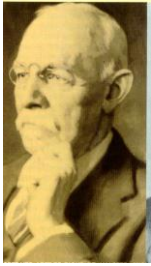
Can We Omit Surgery with Suggestion of pCR by Biopsy in Breast?

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Ke-Da Yu, M.D.**



-
- ▶ I have no relevant financial relationship with commercial interests to disclose.

Trends of breast surgery



Halsted

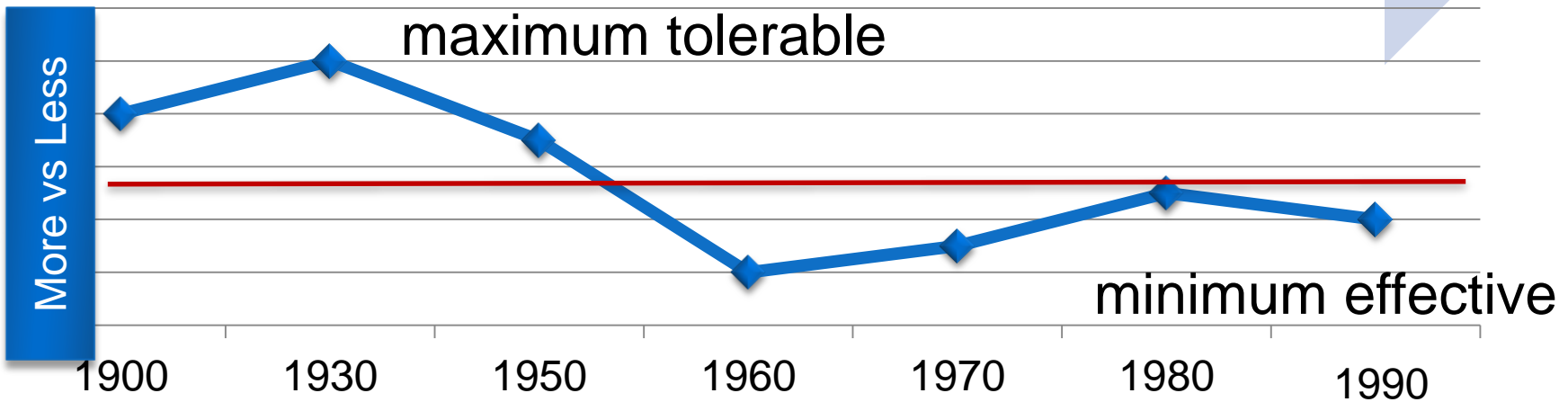
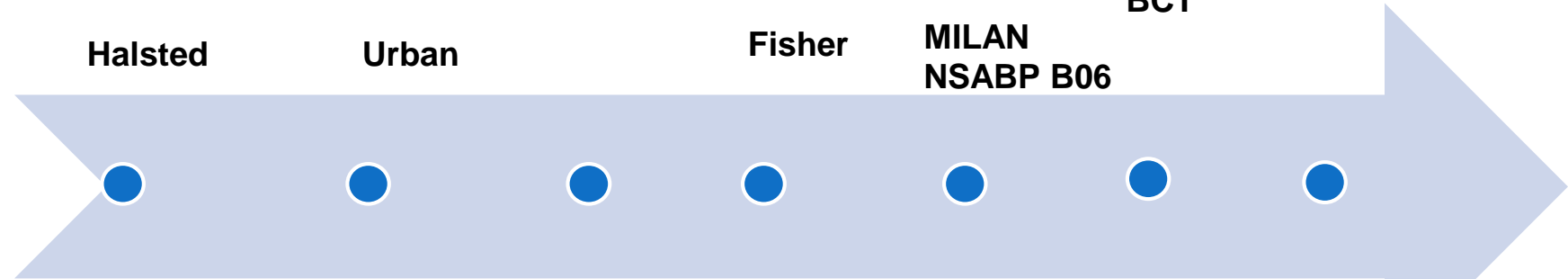
Urban

Fisher

MILAN
NSABP B06

BCT

SLNB



Omit Surgery **in Axilla** after NST?



- ▶ ALND **was** the standard approach to LN+ve pts
- ▶ Role of SLNB in LN+ve pts having response to NST is currently under review
- ▶ Feasibility studies: SLNB in pts (originally LN+) after NST (cLN- after therapy)

Study	Z1071	SN FNAC	SENTINA
Sample size	689	153	592 (cN+)
cN	cN1/2	cN1/2	cN1-2
False Negative rate	12.6%	8.4%	14.2%

Omit Surgery **in Breast** after NST?



- ▶ **Safety is the top priority**
 - ▶ Low locoregional recurrence (LRR) rate (annual ~1%)
 - ▶ No survival (RFS, DFS and OS) compromise
- ▶ Assess lesion accurately and find suitable pts



Omit Surgery in Breast after NST?



cCR as indicator for “no surg”?

- Assessed by imaging and/or physical examination

pCR as indicator for “no surg”?

- How to assess pCR?
- Who will likely obtain pCR?
- Relapse and survival data?

cCR in breast indicates low LRR?



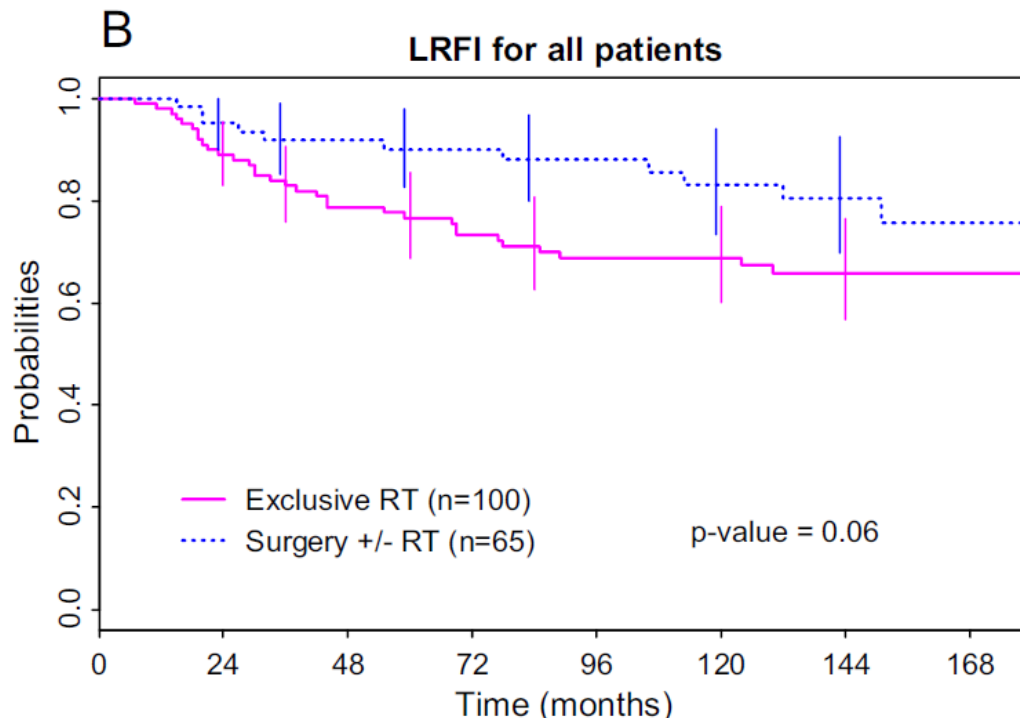
- ▶ Two retrospective studies (N>100)
- ▶ **UK study**, 453 NCT (1986-1999)
 - ▶ 136 cCR: 67 surg, 69 no surg but RT alone
 - ▶ cCR definition: no residual palpable disease

	No. of Patients	
	Surgery	No Surgery
Patients	67	69
Relapses	10%	21%
Locoregional only		
Breast	7	15
Axilla	0	0
Breast and axilla	0	1
Local and metastatic	4	4

cCR in breast indicates low LRR?



- ▶ Two retrospective studies (N>100)
- ▶ **France study**, 1477 NCT (1985-1999)
 - ▶ 165 cCR: 65 surg, 100 no surg but RT alone
 - ▶ Evaluation by imaging and physical examination



31% no surg vs.
17% surg

Int J Radiat Oncol Biol Phys.
2011;79:1452-9.

cCR as indicator for “no surg”?



- ▶ LRR rate after cCR is **NOT** acceptable
 - ▶ Surg **10-15%**; No Surg but RT only **20-30%**
- ▶ cCR is not highly consistent with pCR

False negative rates (Imaging vs. pathological)	MMG	Ultrasound	MRI
Schott et al (N=43)	9	9	6
Schaefgen et al (N=143)	13	24	4
Croshaw et al (N=61)	70	67	56

Omit Surgery in Breast after NST?



cCR as indicator for “no surg”?

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pCR as indicator for “no surg”?

- How to assess pCR?
- Who will likely obtain pCR?
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1. How to assess pCR w/o surg?



- ▶ Minimally invasive biopsy methods
 - ▶ Using core-cut (CC) or vacuum-assisted (VA) biopsy
 - ▶ pCR: absence of invasive and non-invasive tumor cells
 - ▶ All molecular subgroups enrolled

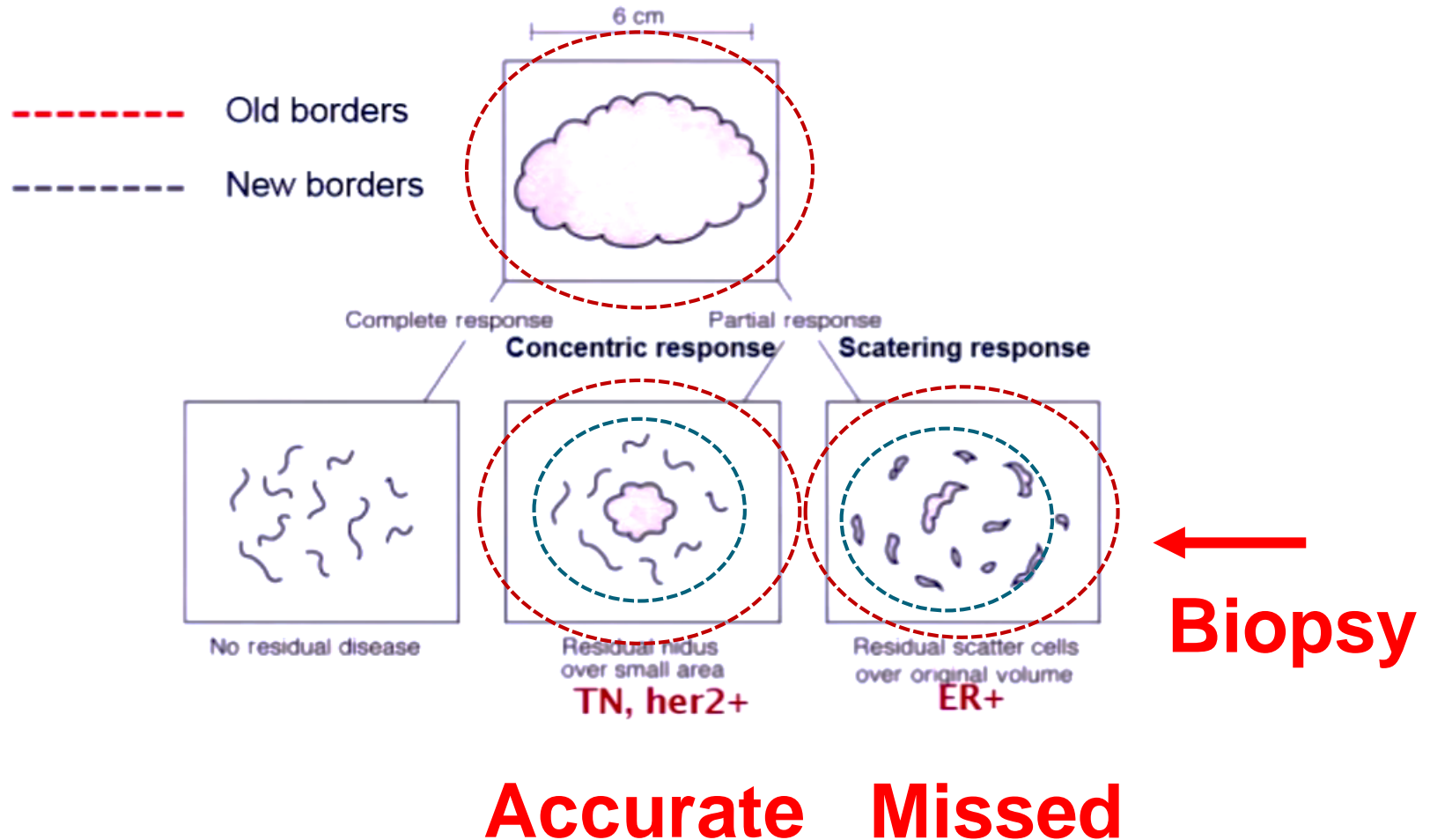
164 pts	Surgical specimen		
	Negative	Positive	Total
MIB			
Negative Number $n =$ % in MIB % in surgical specimen	87 71.3% (NPV) 93.5% (spec.)	35 28.7% 49.3% (FNR)	122 100.0% 74.4%
Positive Number $n =$ % in MIB % in surgical specimen	6 14.3% 6.5%	36 85.7% (PPV) 50.7% (sens.)	42 100.0% 25.6%

TOO HIGH !!!

1. How to assess pCR w/o surg?



▶ Tumor response modes



1. How to assess pCR w/o surg?



- ▶ Minimally invasive biopsy methods

ORIGINAL STUDY

A Clinical Feasibility Trial for Identification of Exceptional Responders in Whom Breast Cancer Surgery Can Be Eliminated Following Neoadjuvant Systemic Therapy

- ▶ To determine the accuracy of fine-needle aspiration (FNA) and vacuum-assisted core biopsy (VACB) in assessing the residual cancer after NST
 - ▶ 40 pts, T1-3N0-3, **TNBC or HER2+ve**
 - ▶ pCR: no evidence of residual invasive or in situ carcinoma in the breast surgical and biopsy specimen

1. How to assess pCR w/o surg?



- ▶ VACB more accurate than FNA (P=0.011)

Measure	FNA	VACB
Accuracy, %	73 (56–85)	95 (83–99)
Sensitivity, %	48 (26–70)	90 (70–99)
Specificity, %	100 (82–100)	100 (82–100)
False-negative rate, %	52 (30–74)	10 (1–30)

2. Who will likely obtain pCR?



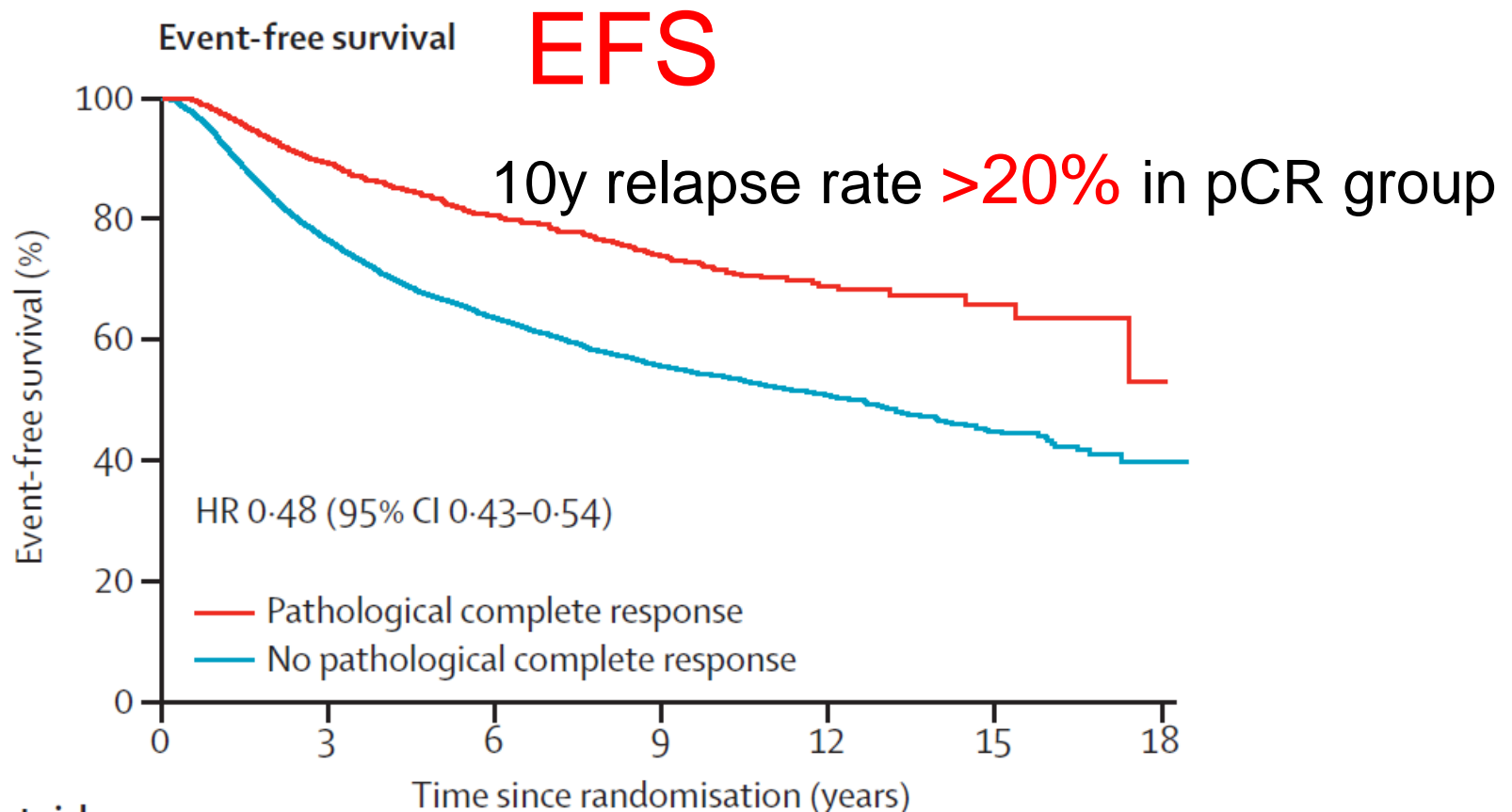
▶ pCR rates by subgroups

Subgroups	N	pCR rate(%)
ER/PR+, HER2-, G I/II	1986	7.5
ER/PR+, HER2-, G III	630	16.2
ER/PR+, HER2+, with trastuzumab	385	30.9
ER/PR+, HER2+, without trastuzumab	701	18.3
ER/PR-, HER2+, with trastuzumab	364	50.3
ER/PR-, HER2+, without trastuzumab	471	30.2
TNBC	1157	33.6

3. Survival data after pCR w/o Surg?



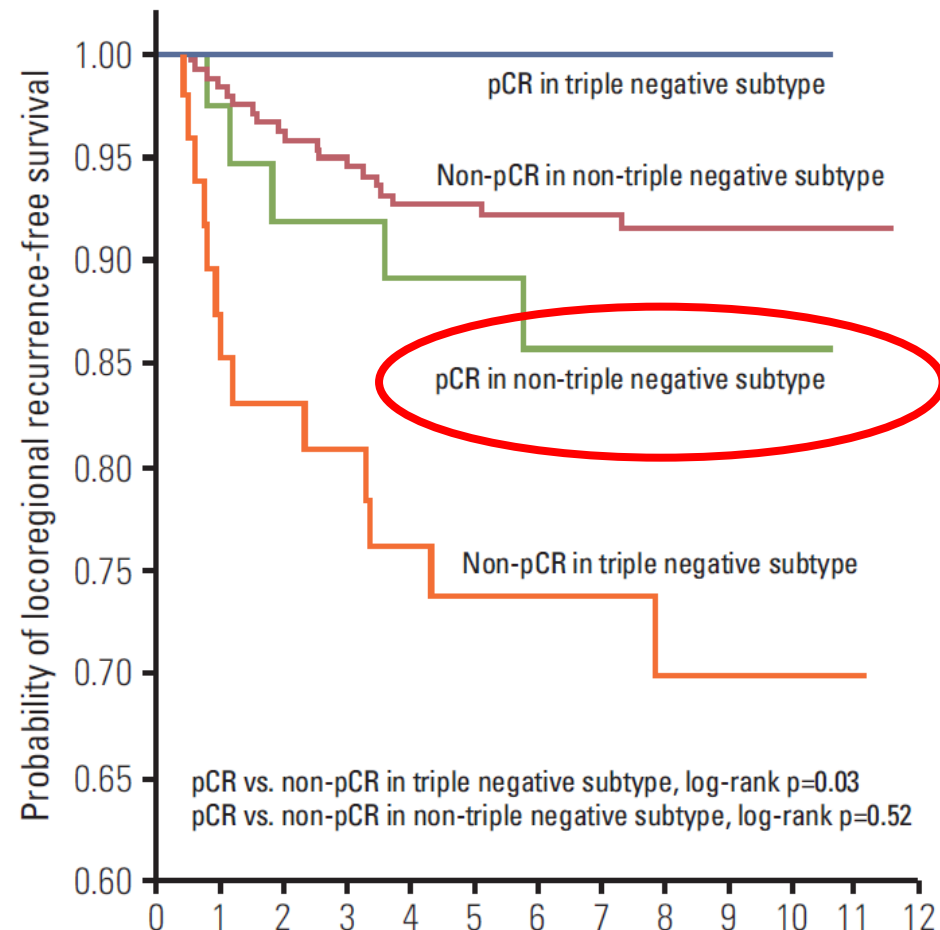
- ▶ pCR (proven by surg) is a surrogate for “good” but not “perfect” survival



3. Survival data after pCR w/o Surg?



- ▶ pCR (proven by surg) is a surrogate for “good” but not “perfect” survival
 - ▶ **LRR**: 335 pts, II-III
 - ▶ NCT+Surg, 2002-2009

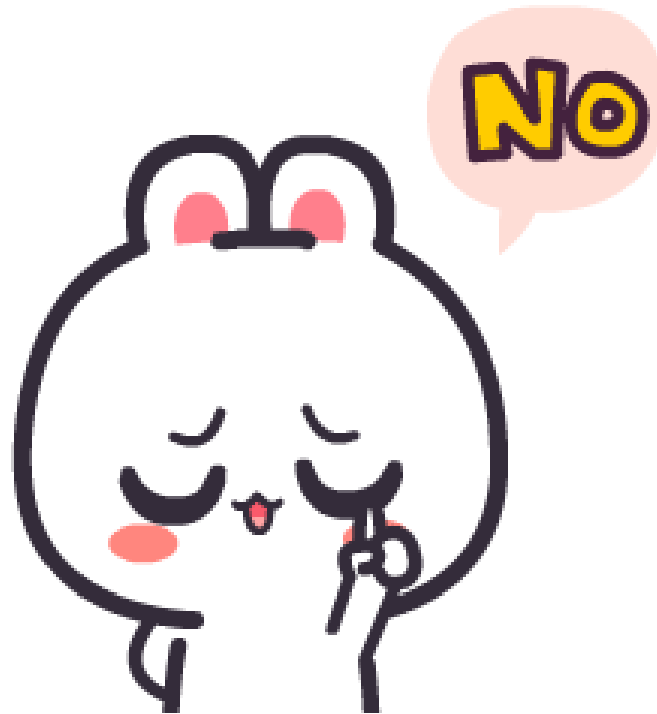


Research Institute and Hospital,
National Cancer Center, Goyang,
Korea.
Cancer Res Treat. 2016;48:1363-72

3. Survival data after pCR w/o Surg?



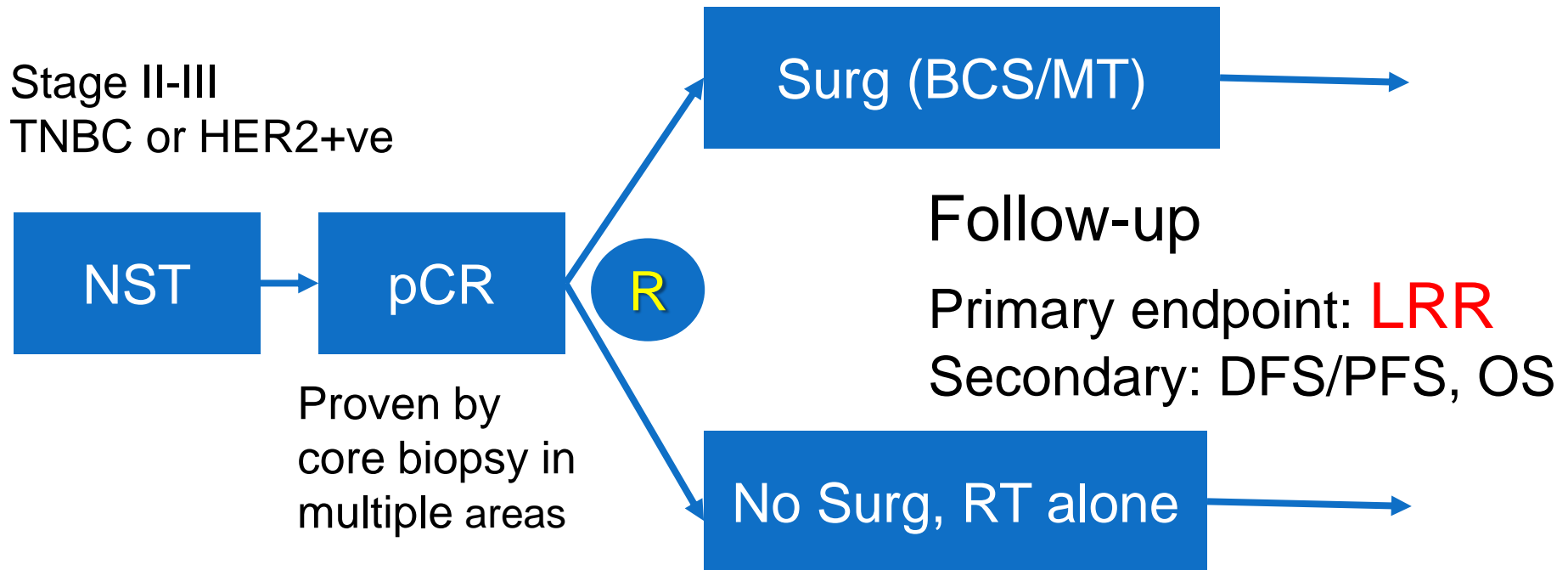
- ▶ Neither prospective nor retrospective data



3. Survival data after pCR w/o Surg?



- ▶ Future clinical trial design



Omit Surgery in Breast after NST?

Insufficient evidence...



cCR is **NOT** an indicator for “no surg”

- Assessed by imaging and/or physical examination: **cCR is not reliable**

pCR is a **POTENTIAL** indicator for “no surg”

- How to assess pCR w/o surg? **Imaging-guided VACB, FNR~10% in TN and HER2+ve**
- Who will likely obtain pCR? **TN, HER2+ve >30%**
- Relapse and survival data? **No, waiting**

Thanks! Welcome to Shanghai



复旦大学附属肿瘤医院

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