

Radioactive Iodine Seed placement in the Axilla with Sentinel lymph node biopsy after neoadjuvant chemotherapy in breast cancer:

Results of the prospective multicenter RISAS trial

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On behalf of the RISAS investigators:

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Disclosures

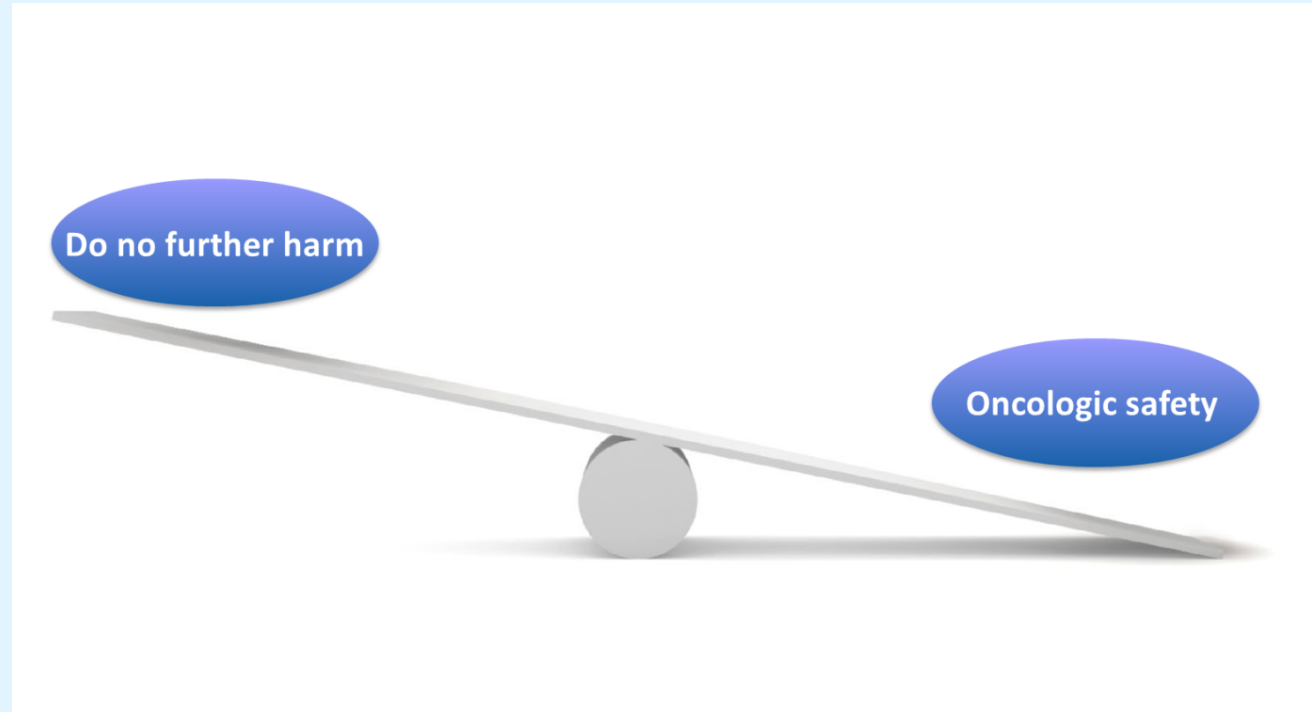
(Potential) Conflict of Interests	None
Relations that could be relevant for the meeting	NA
<ul style="list-style-type: none">• Sponsorship or research funds• Payment or other (financial) remuneration• Shareholder• Other relation, viz	

Background

cN+ treated with NAC → 1/3 axillary pCR

Less invasive alternative to ALND?

**Omitting ALND
in case of pCR**



**Accurately identifying
residual disease**

Background

	ALND +	ALND -
New procedure +	True Positive (TP)	False Positive (FP)
New procedure -	False Negative (FN)	True Negative (TN)

False negative rate (FNR) = $FN / (FN + TP)$

Negative predictive value (NPV) = $TN / (TN + FN)$

Background: less invasive alternatives

	Identification rate	FNR	NPV
SLNB¹	89%	17%	57-86%
MARI²	97%	7%	83.3%
TAD^{3,4}	100%	2-4%	92-97%

1:6 ypN0
actually ypN+

¹Simons et al., Ann Surg, 2019

²Donker et al., Ann Sug, 2015

³Caudle et al., JCO, 2016

⁴Siso et al., Ann Surg Onc, 2018



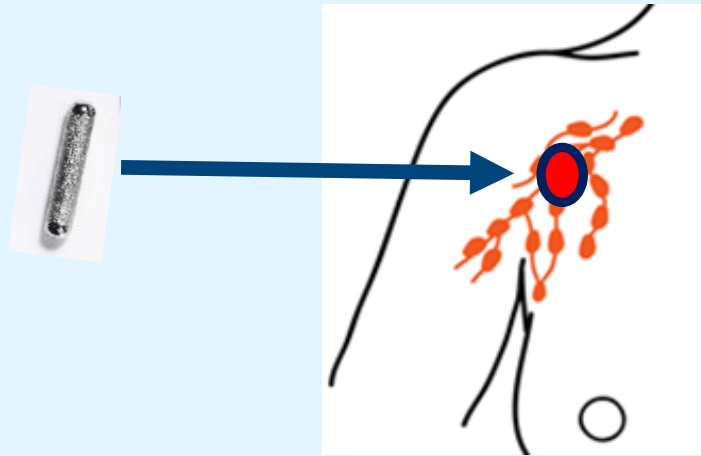
Prospective, multicenter, validation trial

cN+ treated with NAC

RISAS procedure + ALND



Methods



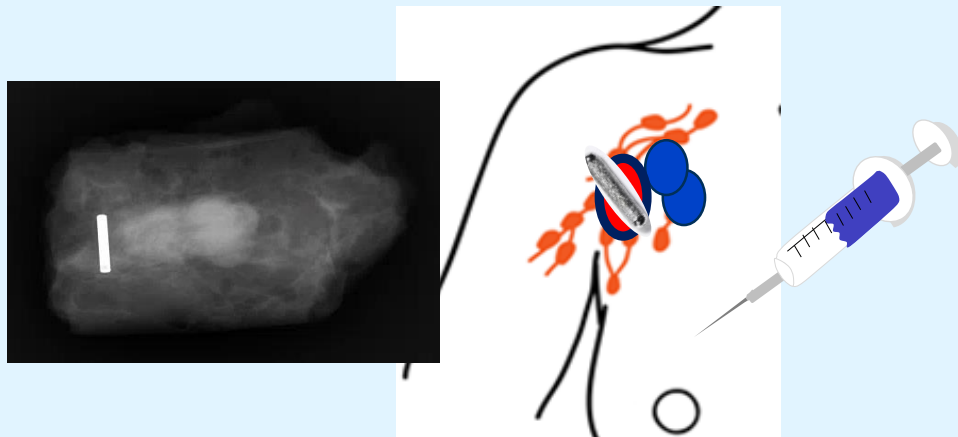
Iodine seed/ I^{125} (max 0.2mCi / 7.4Mbq)
in positive node



Neoadjuvant chemotherapy



During surgery removal of
 I^{125} -marked node and all SLNs



Methods

Non-inferior if 95% upper-bound of FNR is $< 6.25\%$

- i.e. maximum 4 false negative results in 144 ypN+ patients

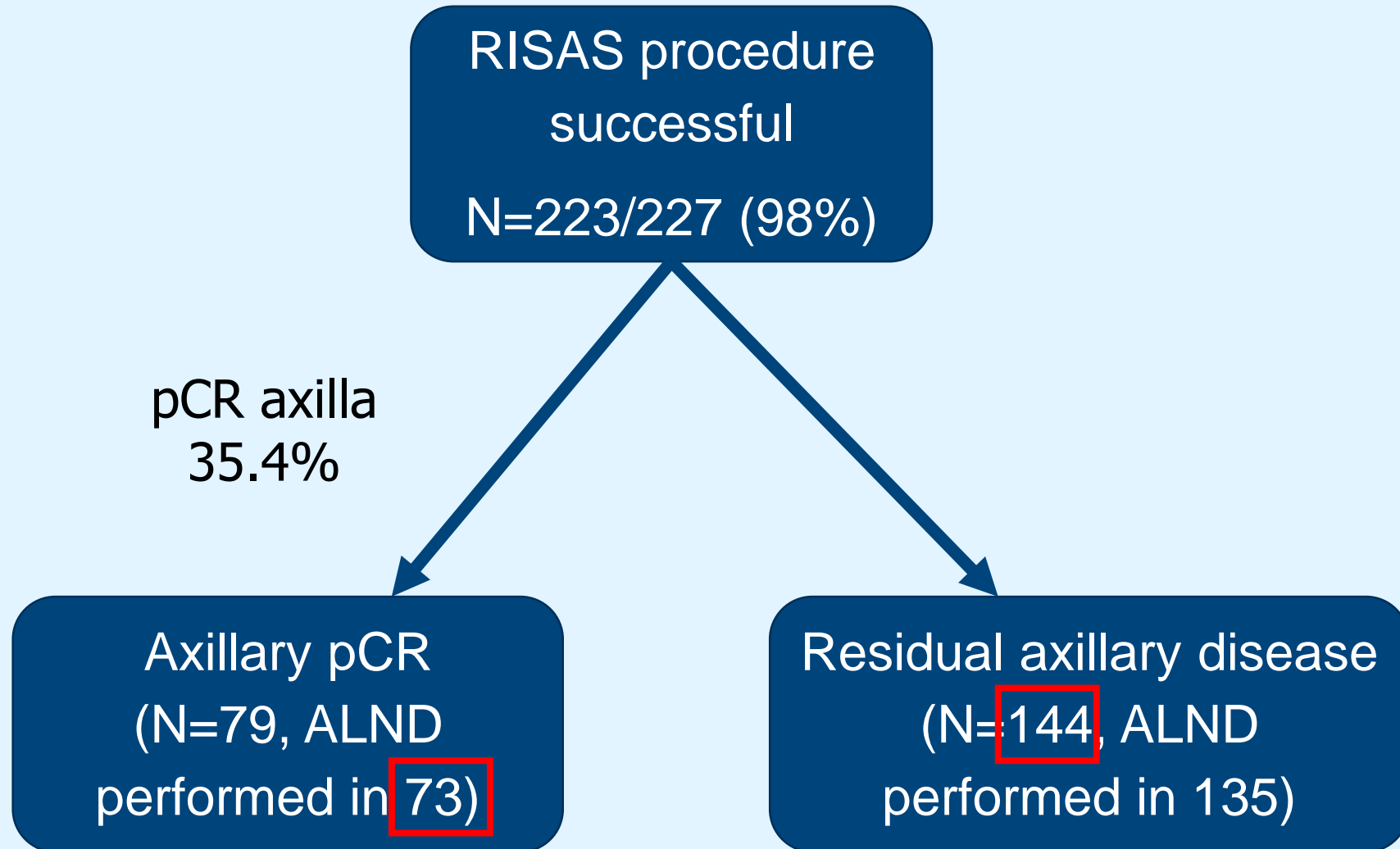
248 patients needed (based on 36% pCR and 10% drop-out)

Non-inferiority margin of FNR corresponds to NPV of 90%

Results

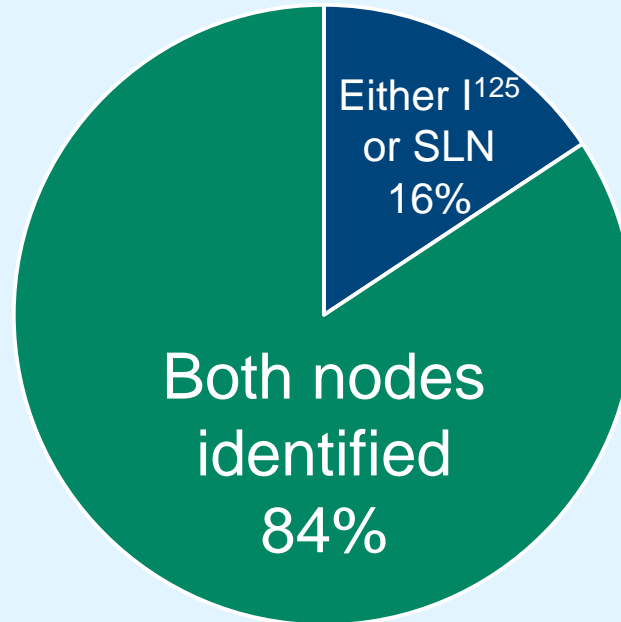
Informed consent in 252 patients (March 2017 – December 2019)

227 patients underwent RISAS procedure

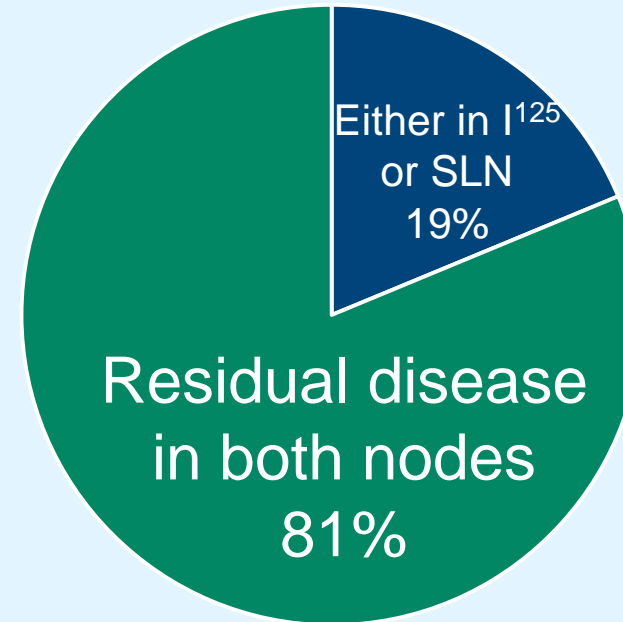


Results

Identification



Residual disease



I¹²⁵-marked node was retrieved as SLN in 71.3%

Results

5 false negative results in 5 different institutions

4/5 within first 10 included patients of involved institutions

Residual disease in ALND:

- micrometastasis: 1 pt (2 nodes)
- macrometastasis: 3 pts (1 node), 1 pt (2 nodes)

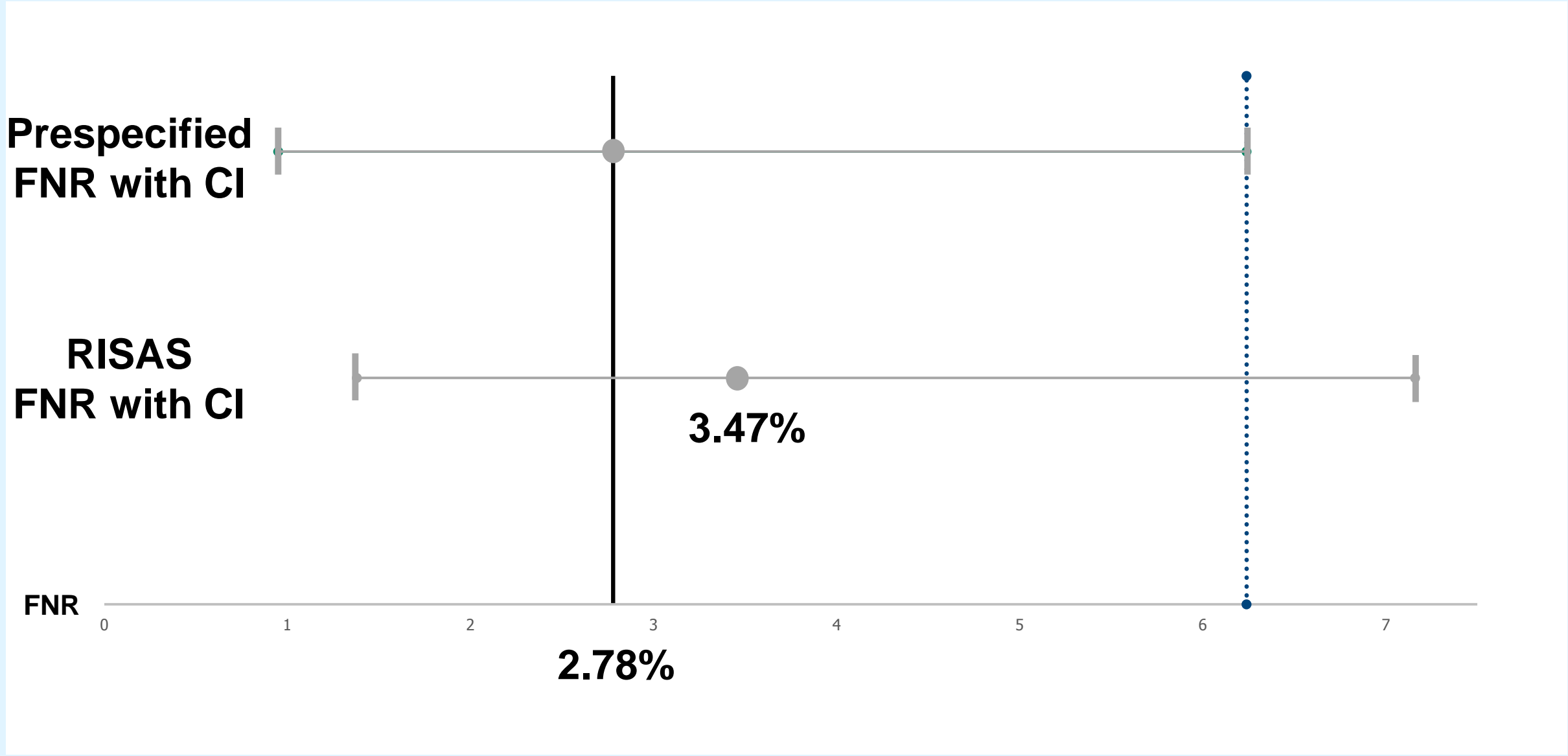
Results

$$\text{FNR} = 5/144 = 3.47\% \text{ (CI 1.38 – 7.16)}$$

$$\text{NPV} = 73/78 = 93.59\% \text{ (CI 87.0 – 97.4)}$$

	ALND +	ALND -
RISAS +	139	NA
RISAS -	5	73

Non-inferiority inconclusive → upper bound CI > 6.24%



	Identification rate	FNR	NPV
SLNB¹	89%	17%	57-86%
MARI²	97%	7%	83.3%
TAD^{3,4}	100%	2-4%	92-97%
RISAS	98%	3.5%	93.6%

1:6 ypN0
actually ypN+

1:16 ypN0
actually ypN+

¹Simons et al., Ann Surg, 2019

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Take-Home Message

RISAS FNR 3.5% and NPV 93.6% in large, multicenter trial

RISAS/TAD most accurate staging procedure after NAC in cN+ BC

Optimal response-based axillary management still in progress...

Thank you for your attention!

Acknowledgments:

All patients for participating in this trial

All local study teams of the involved institutions

All RISAS investigators

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