



P16/Ki67 Dual Staining Improves the Detection Specificity of High Grade Cervical Lesions

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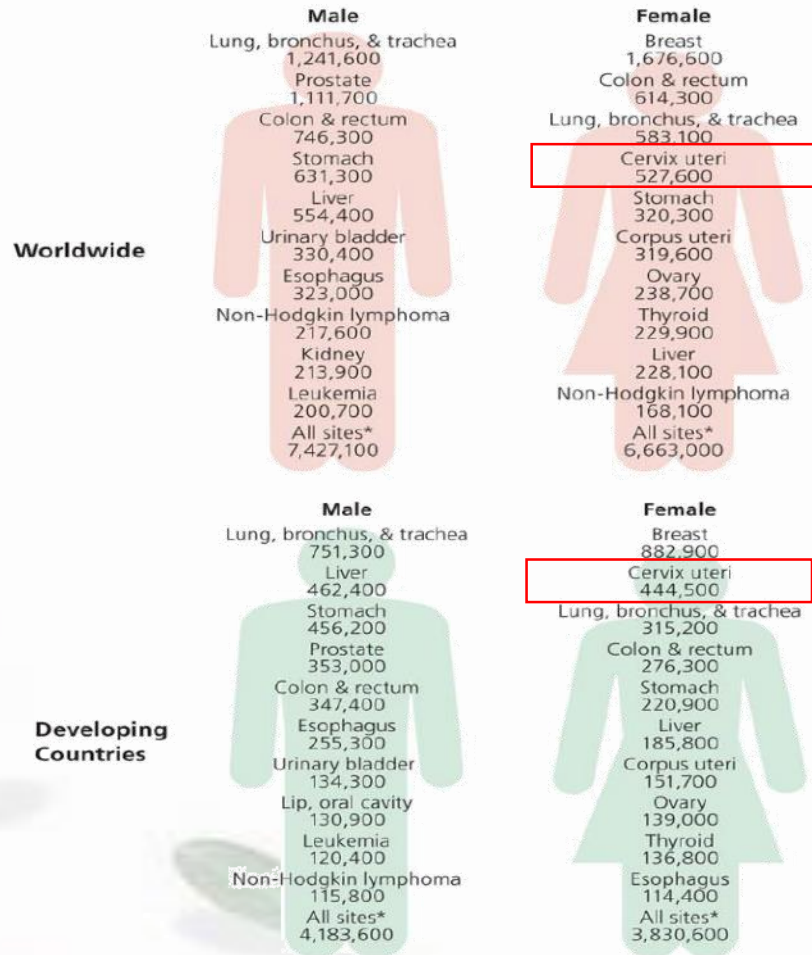
Disclosures

- No financial relationships or conflict of interest to disclose

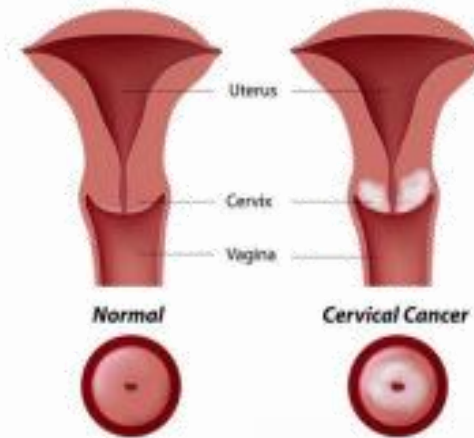
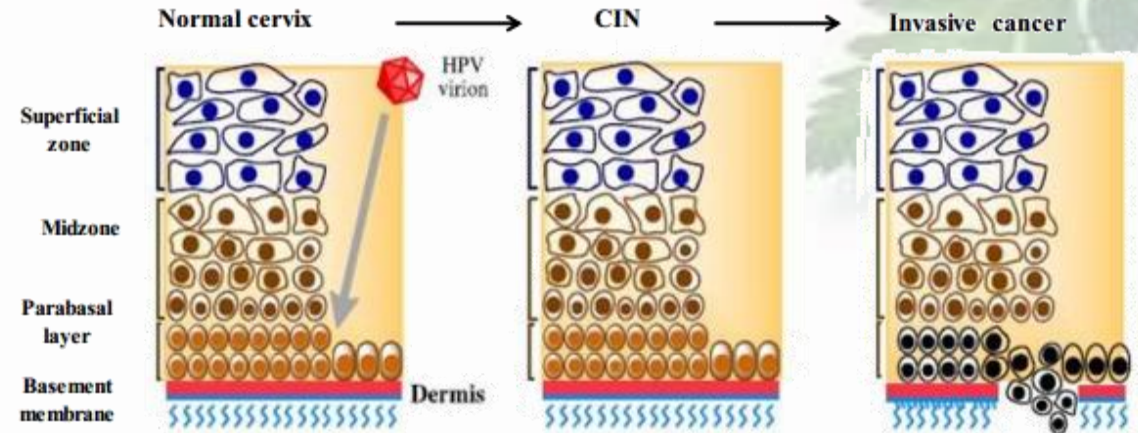


BACKGROUND

Estimated New Cases

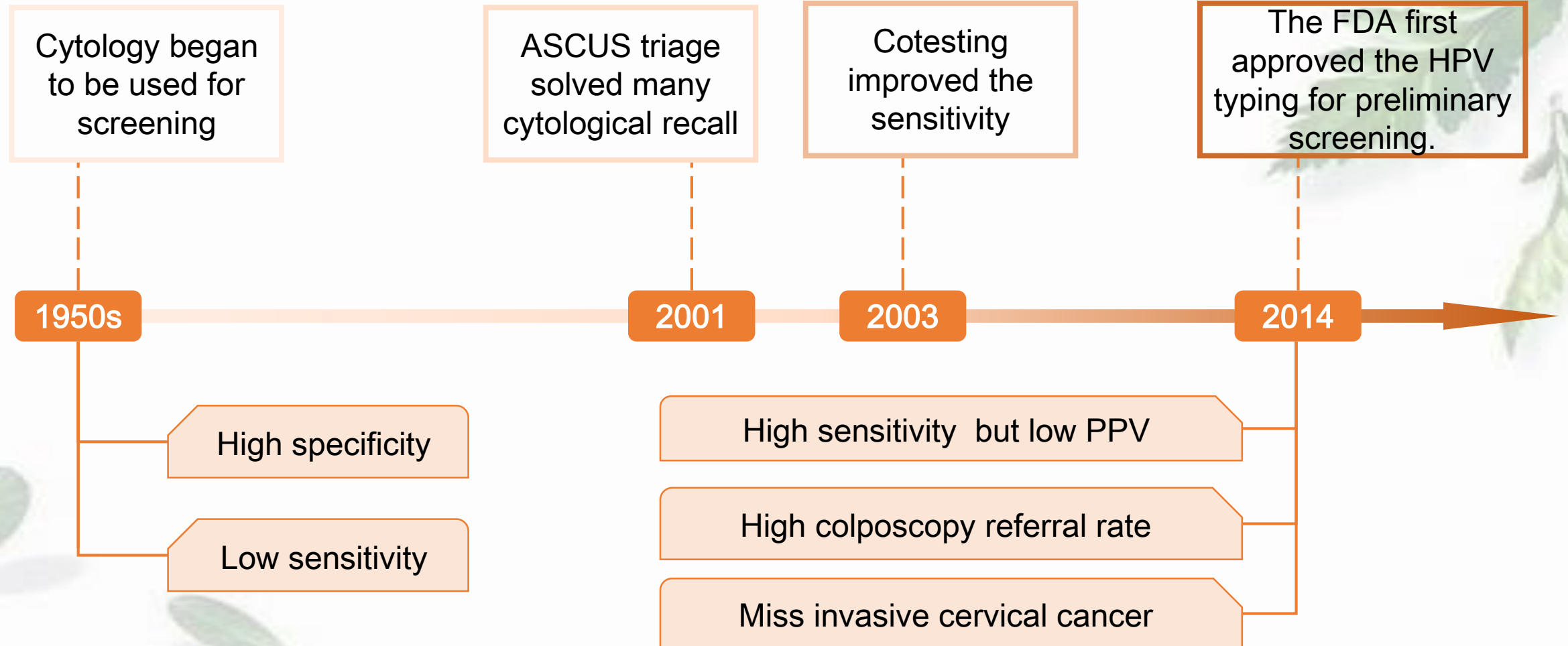


Progress of Cervical Cancer



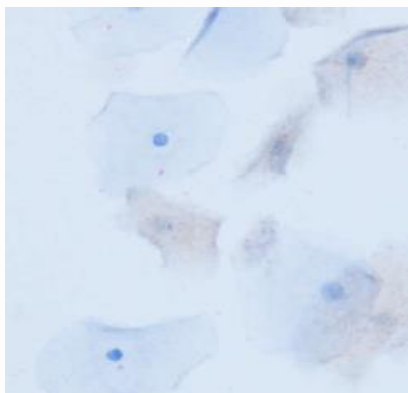


BACKGROUND

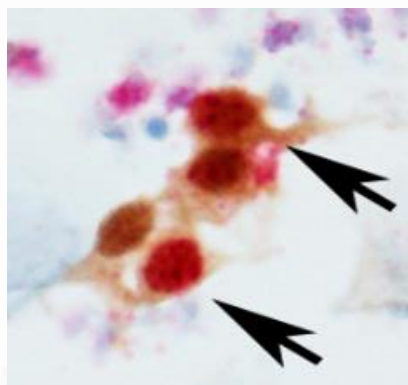




BACKGROUND



Negative



Positive

P16 & Ki67 Co-express

- p16/Ki-67 dual staining in the same cell indicates **cell cycle deregulation**
- Identification of double-immunoreactive cells in cervical cytology preparations can be an **indicator** for the presence of **high-grade cervical dysplastic lesions**



METHODS

- A total of 223 patients with an average age of 39 years old were enrolled
- All samples were analyzed by
 - P16/Ki67 dual stain
 - Liquid-based cytology
 - High-risk HPV test
- Diagnosis of each patient was verified by histopathological test.

CINtec PLUS cytology kit

Thinprep LBC & Pap stain

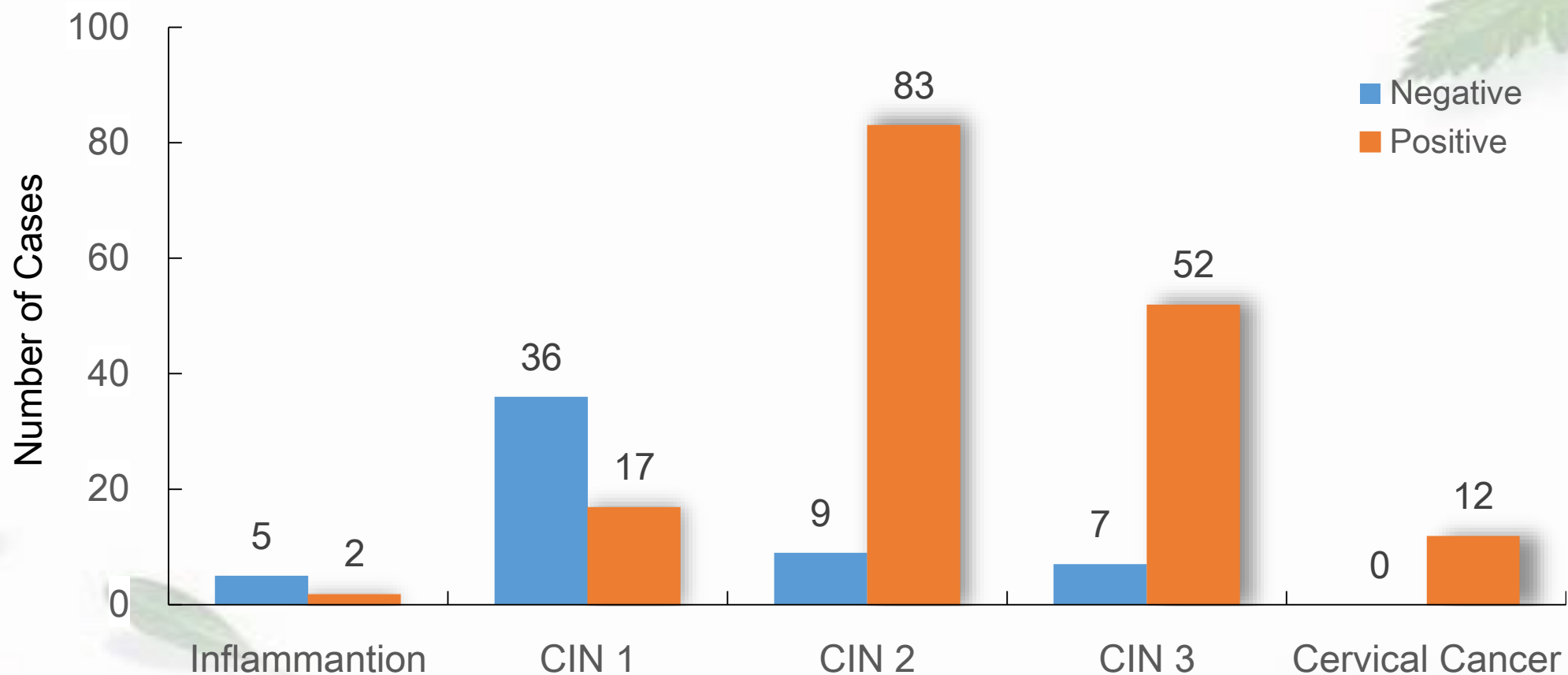
Cobas 4800 detection system



RESULTS

p16^{INK4a}/Ki67 dual staining had high specificity to detect CIN2 or greater lesions

- The result of P16/Ki67 dual stain in 223 patients.

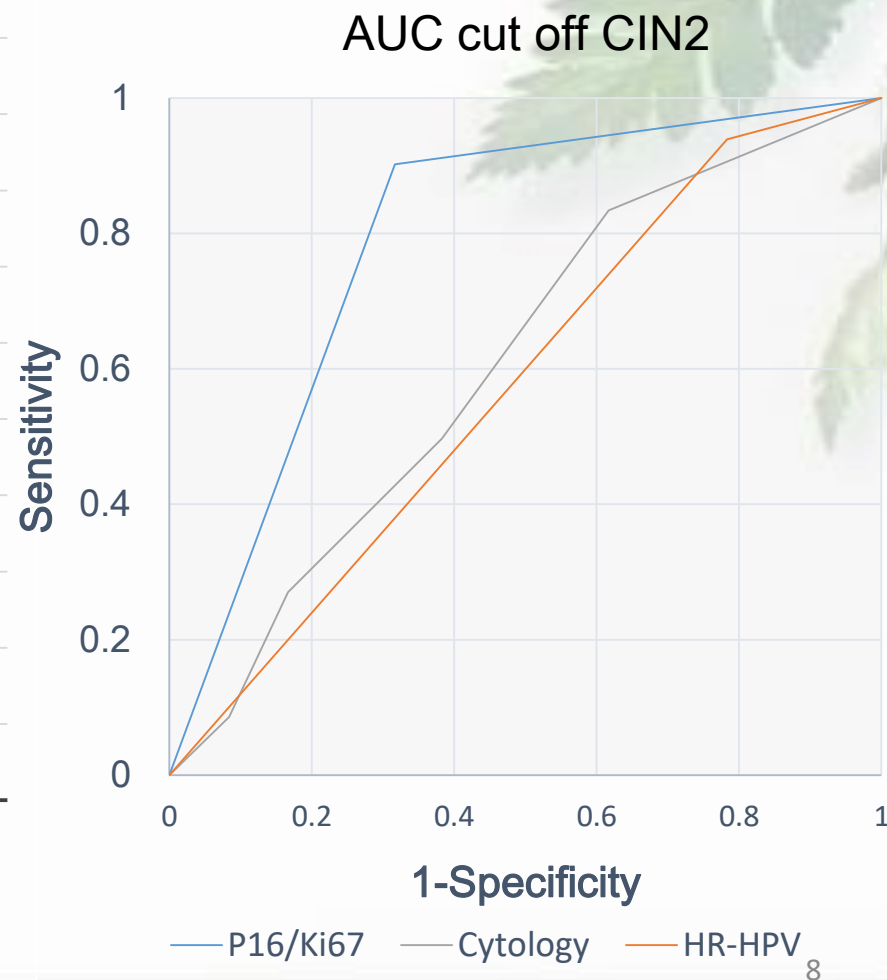
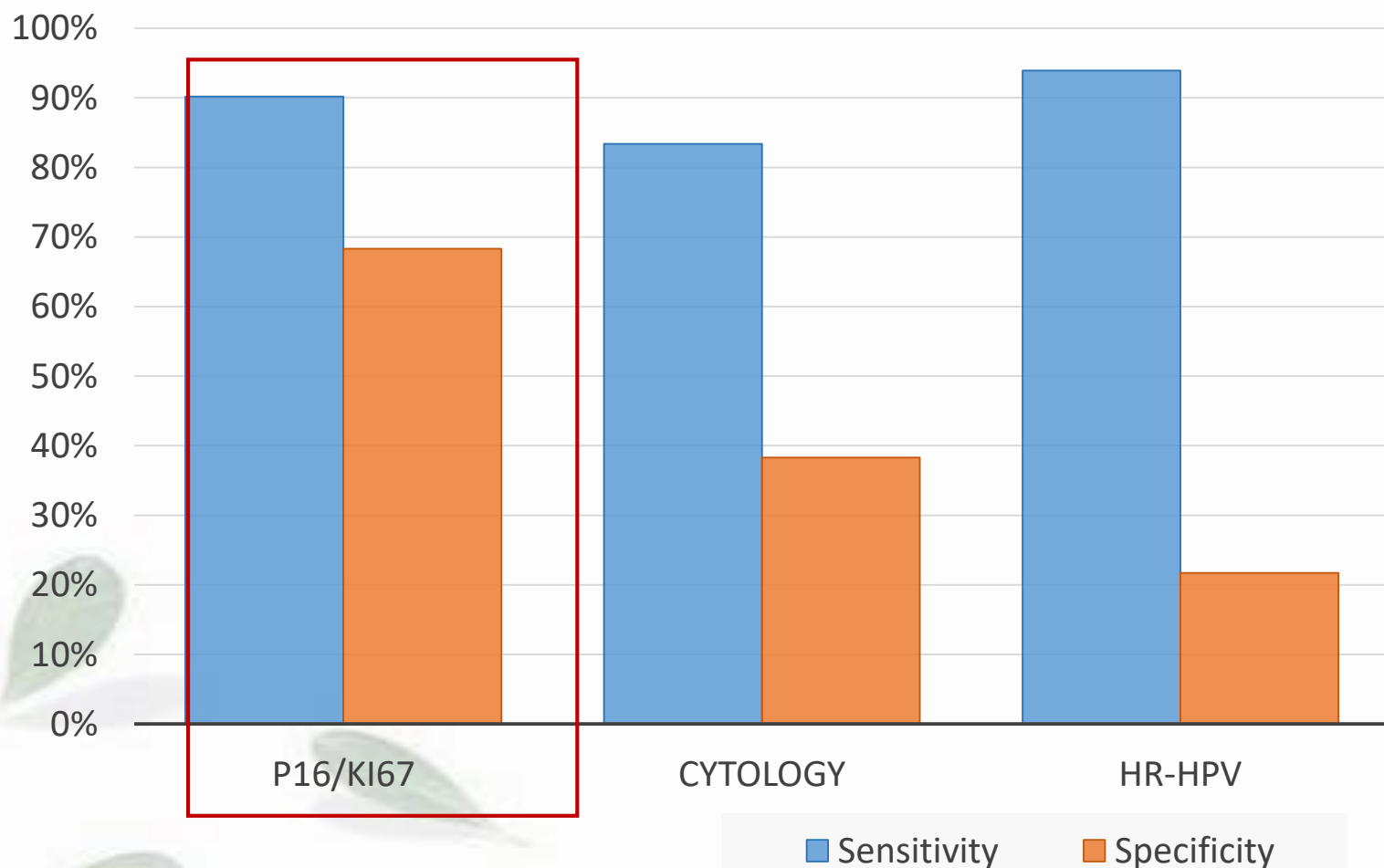




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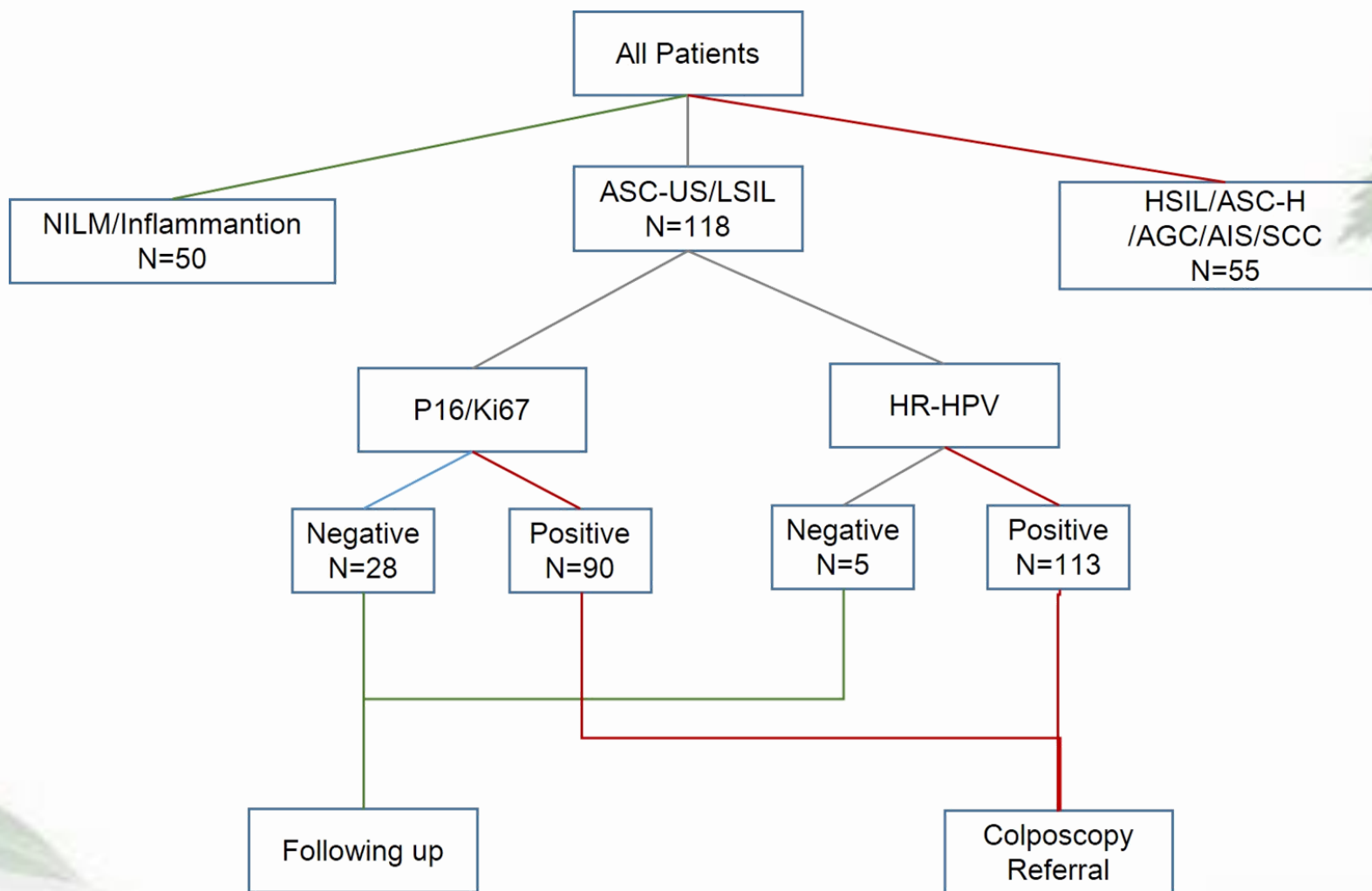
- Detection for CIN2+ in P16/Ki67 compared with cytology and high risk HPV test.





RESULTS

p16^{INK4a}/Ki67 dual staining had high specificity of CIN2 or greater lesions for patients with ASC-US and LSIL in cytology test





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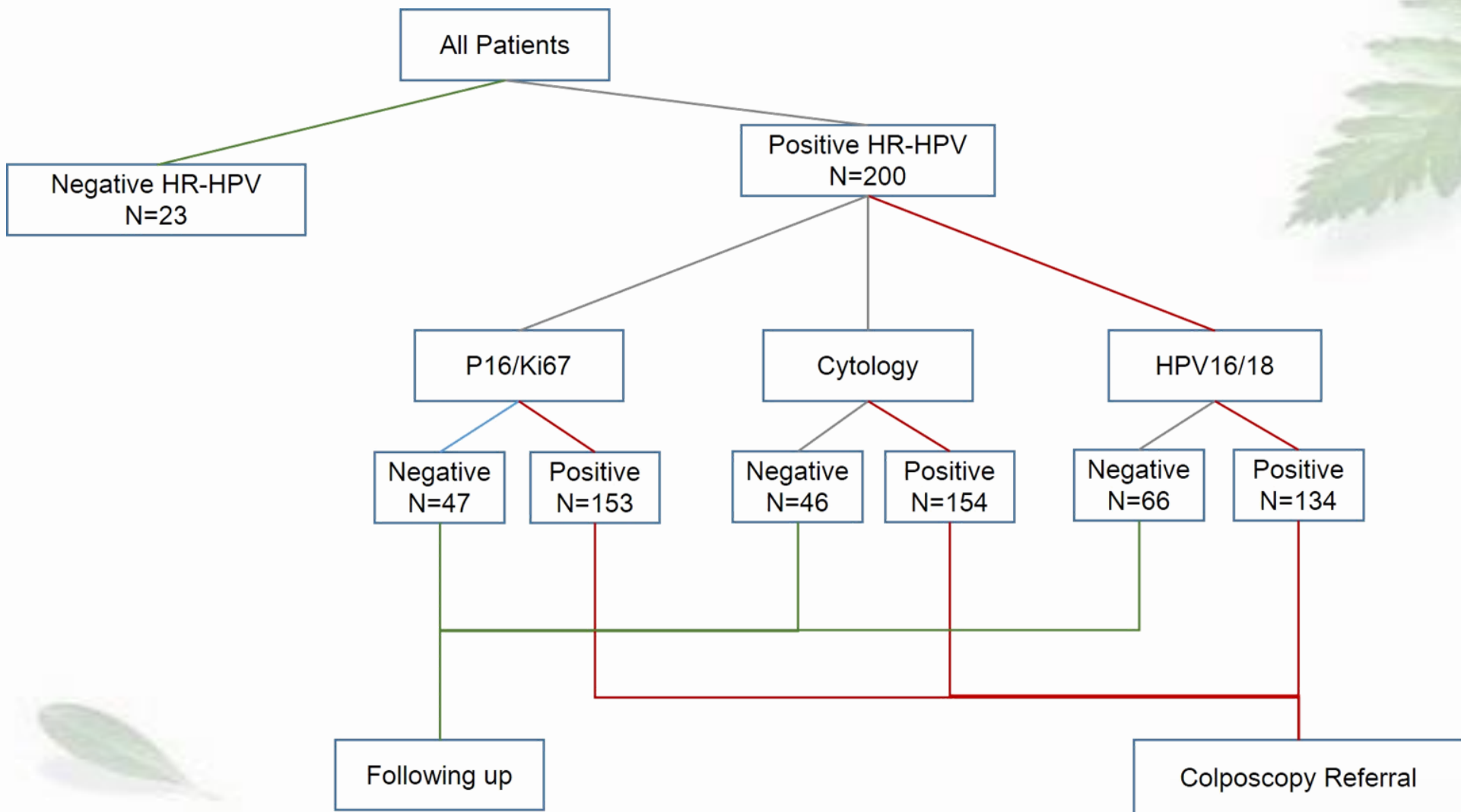
- Detection of CIN2+ in ASC-US and LSIL cytology by p16/Ki67 and HR-HPV test.

	p16/Ki67	HR-HPV test	P value
Sensitivity (95%CI)	0.89(0.81-0.95)	0.95(0.89-0.98)	0.180
Specificity (95%CI)	0.67(0.46-0.83)	0.04(0.01-0.19)	< 0.001
PPV (95%CI)	0.90(0.82-0.95)	0.77(0.68-0.84)	0.015
NPV (95%CI)	0.64(0.44-0.81)	0.20(0.11-0.71)	0.065
AUC (95%CI)	0.78(0.69-0.85)	0.50(0.41-0.60)	< 0.001
Referral Rates* (95%CI)	0.76(0.69-0.84)	0.95(0.92-0.99)	< 0.001



RESULTS

p16^{INK4a}/Ki67 dual staining had high specificity to detect CIN2+ lesions in patients with positive high-risk HPV test





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- Detection of CIN2+ in HR-HPV positive patients by p16/Ki67 ,Cytology and HPV16/18 type.

	p16/Ki67	Cytology	HPV16/18	P value*	P'value#
Sensitivity (95%CI)	0.91(0.85-0.94)	0.83(0.76-0.88)	0.71(0.63-0.77)	0.065	< 0.001
Specificity (95%CI)	0.70(0.55-0.82)	0.43(0.28-0.57)	0.45(0.32-0.59)	0.007	0.006
PPV (95%CI)	0.91(0.85-0.94)	0.82(0.76-0.88)	0.80(0.73-0.86)	0.031	0.004
NPV (95%CI)	0.70(0.55-0.82)	0.44(0.29-0.58)	0.31(0.21-0.44)	0.009	< 0.001
AUC (95%CI)	0.81(0.74-0.85)	0.68(0.61-0.74)	0.57(0.51-0.64)	0.013	< 0.001
Referral Rates (95%CI)	0.77(0.70-0.82)	0.77(0.71-0.83)	67.0(60.5-73.5)	0.906	0.035



CONCLUSIONS

- Our result shows p16/Ki67 dual staining could improve the specificity of high grade cervical lesions detection and have similar sensitivity to HPV test for CIN2+ detection.
- When triaging women with ASC-US or LSIL liquid-based cytology, compared positive HR-HPV, the specificity of CIN2+ lesion detection was increased by p16/Ki67 dual staining.
- p16/Ki67 dual staining could reduce colposcopy referrals and avoid excessive diagnosis and treatment.

The End



Thank You

