

# Evaluating The Performance of A Computer-Aided Diagnosis System in Implementing Diagnose-And-Leave And Resect-And-Discard Strategies for Diminutive Colorectal Polyps: A Pragmatic Implementation Performance Improvement Study

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## Background

- Diminutive ( $\leq 5$  mm) polyps constitute  $>80\%$  of detected polyps.
- Diminutive polyps have a negligible risk of invasive neoplasia.
- Artificial intelligence (AI)-based computer-aided diagnosis (CADx) has the potential for in vivo prediction of histology.
- AI-assisted characterization should match PIVI standards to implement diagnose-and-leave and resect-and-discard strategies.

## PIVI Criteria

- The Preservation and Incorporation of Valuable Endoscopic Innovations (PIVI) criteria (Rex et al. GIE 2011;73:419):
- **Diagnose-and-leave strategy:** A negative predictive value of  $>90\%$  for adenoma by CADx for  $\leq 5$  mm rectosigmoid (RS) polyps needed to implement such strategy for  $\leq 5$  mm RS hyperplastic polyps.
- **Resect-and-discard strategy:** A  $>90\%$  agreement in assignment of post-colonoscopy intervals by established guidelines is required to implement such strategy for  $\leq 5$  mm polyps of the entire colon.

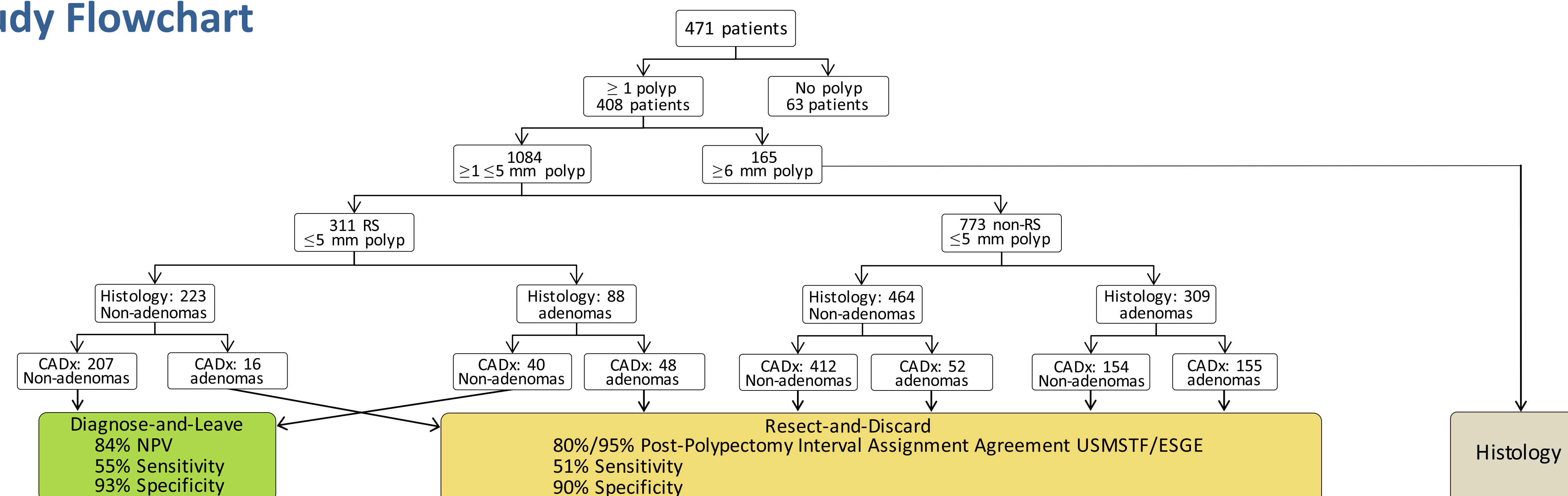
## Hypothesis and Study Aim

- **Hypothesis:** Autonomous AI-based CADx (without human input) of diminutive polyps fulfilled the PIVI performance standards.
- **Study aim:** To assess whether the CADx diagnosis of diminutive polyps met PIVI criteria to be implemented in real-world practice.

## Methods

- **Study design:** A retrospective study of  $\geq 40$  y/o patients undergoing elective colonoscopy of all indications in Evergreen General Hospital, Taoyuan, Taiwan.
- **CADx system:** CAD-EYE (Fujifilm, Japan) differentiated adenomas from non-adenomas using blue-light non-magnified imaging.
- **Investigators:** 3 endoscopists examined 1,084 polyps in 471 patients.
- **Accuracy of CADx:** Histology as the gold standard.
- **Study Period:** March – August 2023

## Study Flowchart



## Study Primary Outcomes

- CADx performance in the **diagnose-and-leave strategy** and **resect-and-discard strategy** for all  $\leq 5$  mm polyps.
- The post-colonoscopy follow-up interval was determined by combining CADx diagnosis for  $\leq 5$  mm polyps and histological diagnosis for  $\geq 6$  mm polyps.

## Results: Patients, Procedures, Overall Polyp Data

Total patient number	N = 471	Total polyp number	N = 1,249
Male, n (%)	222 (47)	<b>Polyp size</b>	
Age, mean (SD), years	55.2 (9.7)	1-5 mm, n (%)	1,084 (87)
<b>Indications of colonoscopy</b>		6-9 mm, n (%)	128 (10)
Screening, n (%)	231 (49)	$\geq 10$ mm, n (%)	37 (3)
Surveillance, n (%)	165 (39)	<b>Polyp morphology</b>	
Diagnostic, n (%)	44 (7)	Type 0-Ip (pedunculated), n (%)	15 (1.2)
Positive FIT, n (%)	22 (5)	Type 0-Is (sessile), n (%)	705 (56.5)
<b>Withdrawal time, mean (SD), min</b>	22.0 (7.8)	Type 0-IIa (flat-raised), n (%)	516 (41.3)

## Polyp Location and Histology

Total polyp number	N = 1,249	Polyp Histology	N = 1,249
<b>Anatomical location, n (%)</b>		<b>Adenomas, n (%)</b>	464 (37)
Cecum to Hepatic flexure	554 (44.4)	Non-advanced, n/N (%)	367/464 (79)
T-colon and Splenic flexure	254 (20.3)	Advanced, n/N (%)	97/464 (21)
Descending colon	91 (7.3)	<b>Non-adenomas, n (%)</b>	785 (63)
Sigmoid colon	261 (20.9)	Hyperplastic polyp, n/N (%)	729/785 (93)
Rectum	89 (7.1)	Sessile serrated lesion, n/N (%)	28/785 (3.6)
		Traditional serrated adenoma, n/N (%)	8/785 (1.0)

## Evaluation of Diagnose-and-Leave Performance

Entire-colon $\leq 5$ mm polyp No. (n=1,084)	Histological diagnosis		CADx diagnosis
CADx diagnosis	Adenoma (n=397)	Non-adenoma (n=687)	
<b>Adenoma (n=271)</b>	203	68	<b>NPV (95% CI)</b> 76.1% (73.1%–78.9%)
<b>Non-adenoma (n=813)</b>	194	619	<b>Sensitivity (95% CI)</b> 51.1% (46.2%–56.0%)
			<b>Specificity (95% CI)</b> 90.1% (87.6%–92.1%)
			<b>PPV (95% CI)</b> 74.9% (69.4%–79.7%)
			<b>Accuracy (95% CI)</b> 75.8% (73.2%–78.3%)

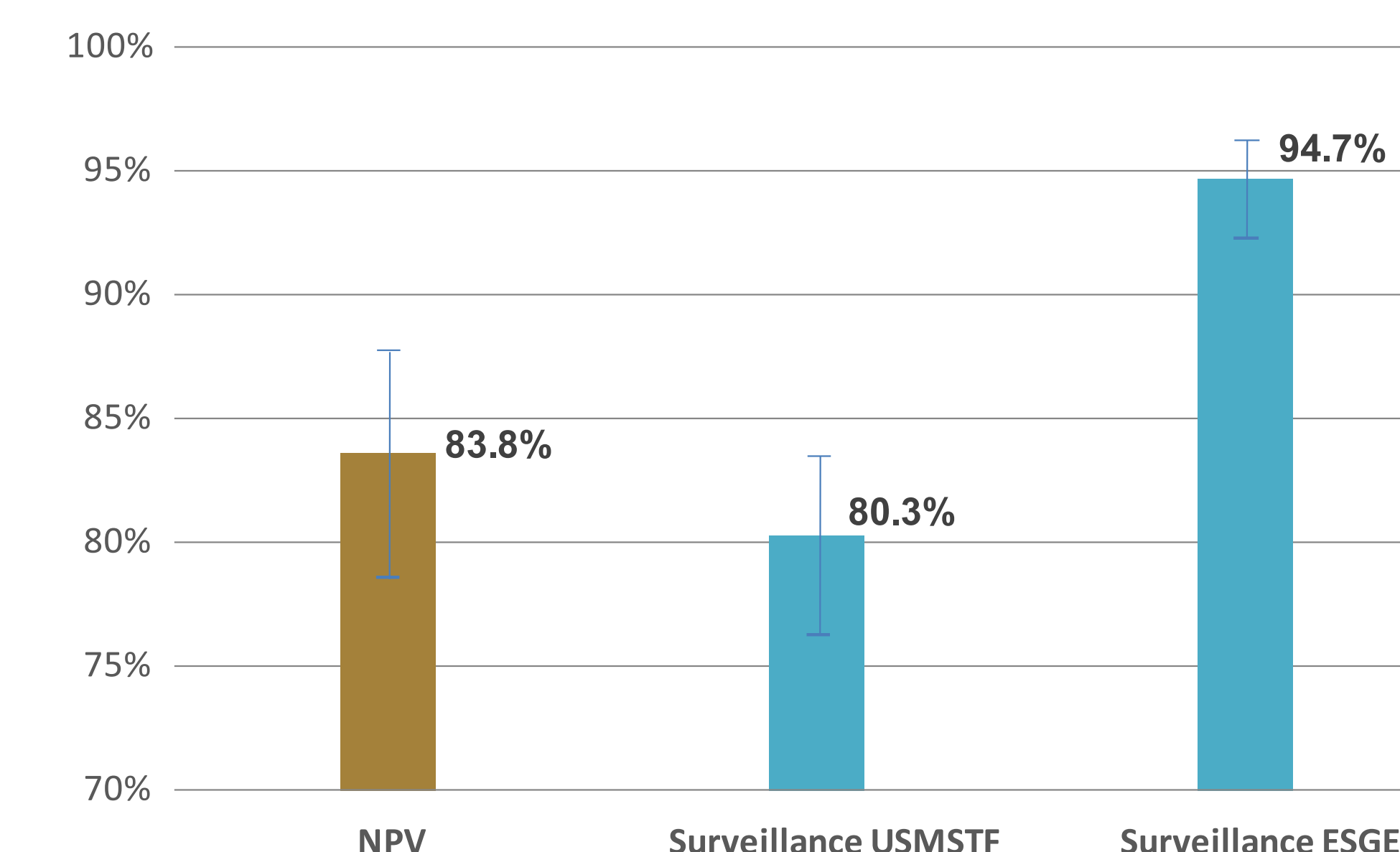
CADx for $\leq 5$ mm polyps	RS-colon	Proximal to S-colon	P value
<b>Accuracy (95% CI)</b>	82.0% (77.3%–85.9%)	73.4% (70.1%–76.3%)	0.003

## Evaluation of Resect-And-Discard Performance

Patient No. (n = 471)	Histology-based surveillance interval (USMSTF)		
	$\leq 3$ years	5 years	10 years
<b>CADx (<math>\leq 5</math> mm) + Histology (<math>\geq 6</math> mm)</b>			
$\leq 3$ years	15	1	0
5 years	14	8	1
10 years	55	22	355

Patient No. (n = 471)	Histology-based surveillance interval (ESGE)	
	$\leq 3$ years	10 years
<b>CADx (<math>\leq 5</math> mm) + Histology (<math>\geq 6</math> mm)</b>		
$\leq 3$ years	13	3
10 years	22	433

## Summary of CADx Performance Using PIVI Criteria



## Discussion

- CADx fell short of expectation in the diagnostic accuracy and sensitivity of diminutive neoplastic polyps in a validation study.
- CADx had a high specificity for diminutive neoplastic polyps.
- CADx systems are trained with still images which do not represent the real-world setting of dynamic colonic segment.
- Endoscopist-machine interaction is critical to properly implement the accurate optical diagnosis of CADx.

Li et al. AJG 2023;118:1353.

## Conclusions

**CURRENT CADx OPTICAL DIAGNOSIS SYSTEM DID NOT MATCH THE PIVI STANDARDS FOR IMPLEMENTATION IN THE DIAGNOSE-AND-LEAVE AND RESECT-AND-DISCARD STRATEGIES FOR DIMINUTIVE POLYPS ACCORDING TO US MULTI-SOCIETY TASK FORCE GUIDELINES. UPGRADE OF CADx PROGRAMS AND MORE RESEARCHES ARE NEEDED TO IMPROVE PERFORMANCE.**