

Evaluation of artificial intelligence for adenoma detection in water exchange colonoscopy: A two-center randomized controlled trial (WEAID trial)

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Background

- Low adenoma detection rate (ADR) and low adenoma per colonoscopy (APC) are crucial predictors of interval colorectal cancer (CRC).
- Water exchange (WE) and artificial intelligence (AI)-based computer-aided detection (CADE) improve ADR and APC.
- Combining WE and CADe (WE+CADE) increased ADR and APC compared to CADe-assisted standard colonoscopy in a randomized controlled trial (RCT).
- A retrospective pilot study suggested that WE+CADE improved APC compared to WE alone.

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Hypothesis and Study Aim

- Hypothesis:**
 - WE+CADE could significantly increase APC compared to WE alone.
- Study aim:**
 - To confirm whether the combining of WE and CADe achieved a significantly higher APC than WE alone in an RCT (WEAID trial).
- WEAID:** Water Exchange with Artificial Intelligence-assisted Detection.

Methods

- Study design:** A two-arm parallel RCT
- Study group:** WE+CADE group vs. WE alone group
- Study sites (CADE systems):**
 - Evergreen Hospital, Taoyuan, Taiwan (CAD-EYE, Fujifilm, version 1, 05/2020)
 - CTO Hospital, Iglesias, Italy (ENDO-AID, Olympus, version 2, 01/2022)
- Study period:** December 2023 – December 2024
- Sample size:** Planned enrollment of 752 patients (376 patients per group)
- Interim analysis:** After approximately 70% of target enrollment was reached

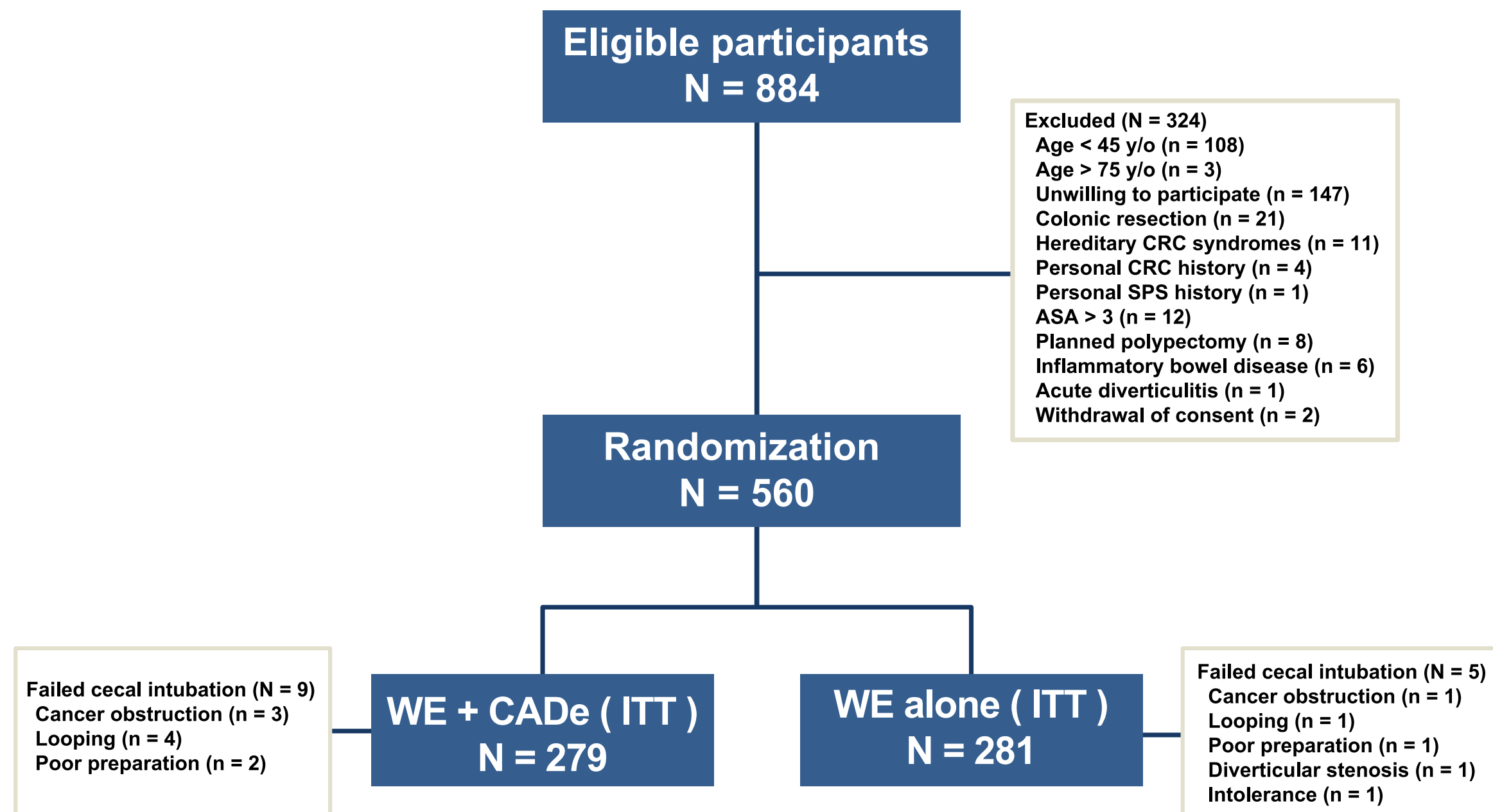
Inclusion and Exclusion

- Eligibility:** Patients aged 45–75 y/o undergoing colonoscopy for screening, surveillance, and positive fecal immunochemical test (FIT+).
- Exclusion:**
 - Previous surgical resection of the colon
 - Inflammatory bowel disease
 - Hereditary CRC syndromes or personal history of CRC
 - Therapeutic or emergent colonoscopy
 - American Society of Anesthesiology classification of physical status >3

Outcome Measurement

- Primary outcome:**
 - APC
- Secondary outcomes:**
 - ADR
 - Sessile serrated lesion (SSL) detection rate
 - Mean number of non-neoplastic lesions per colonoscopy
 - Withdrawal time without biopsies or polypectomies
 - False positives (FPs) per colonoscopy (FPPC)

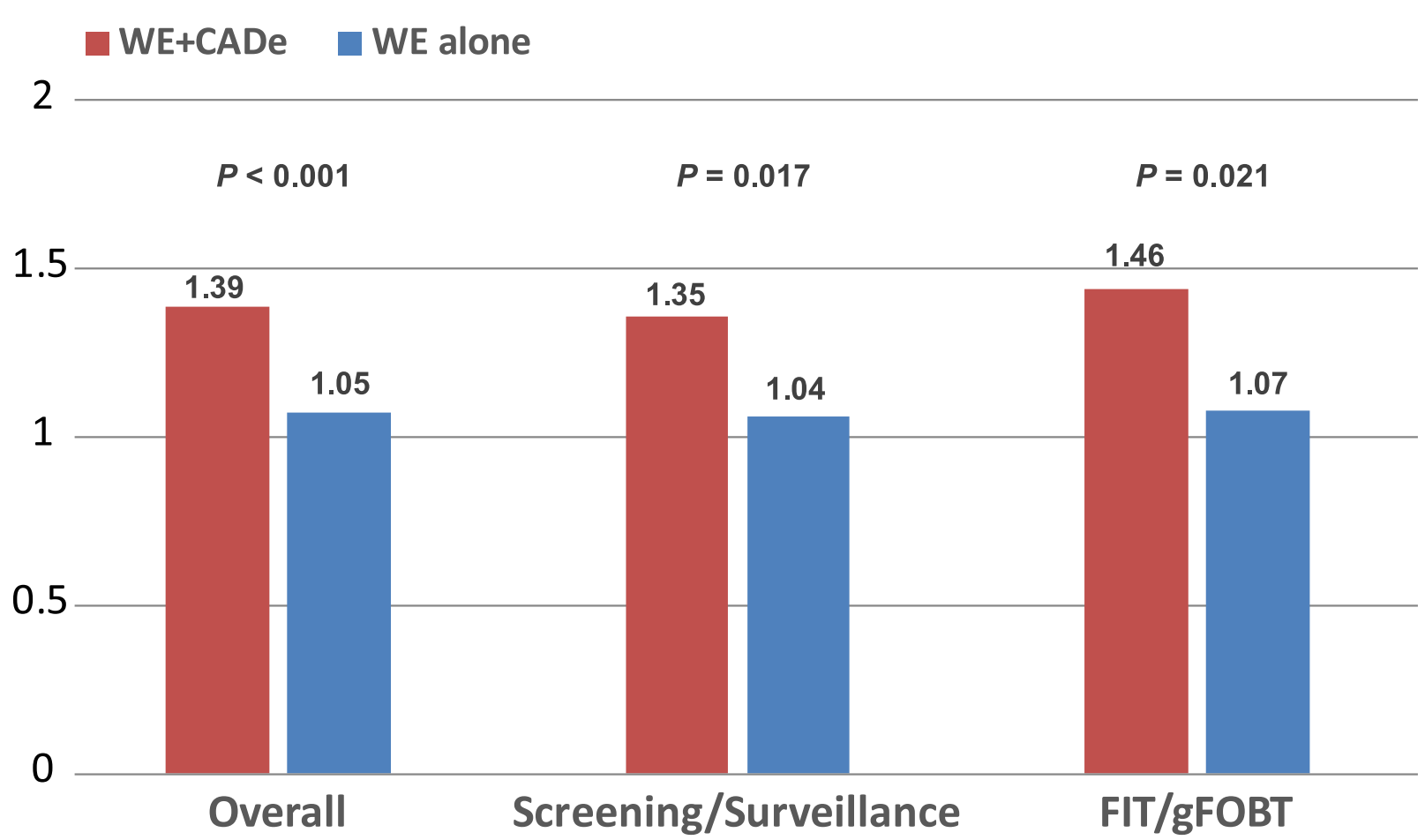
Study Flowchart of Interim Analysis



Results: Demographics

Enrolled patients (N=560)	WE+CADE (N=279)	WE alone (N=281)	P value
Male sex, n (%)	145 (52.0)	154 (54.8)	0.502
Age, mean (SD), years	59.3 (7.6)	59.5 (7.8)	0.822
Body mass index, mean (SD), kg/m ²	25.5 (3.7)	25.6 (3.8)	0.686
Indications of colonoscopy			0.823
Screening, n (%)	103 (36.9)	99 (35.2)	
Surveillance, n (%)	75 (26.9)	82 (29.2)	
Positive FIT, n (%)	101 (36.2)	100 (35.6)	

Primary Outcome: APC

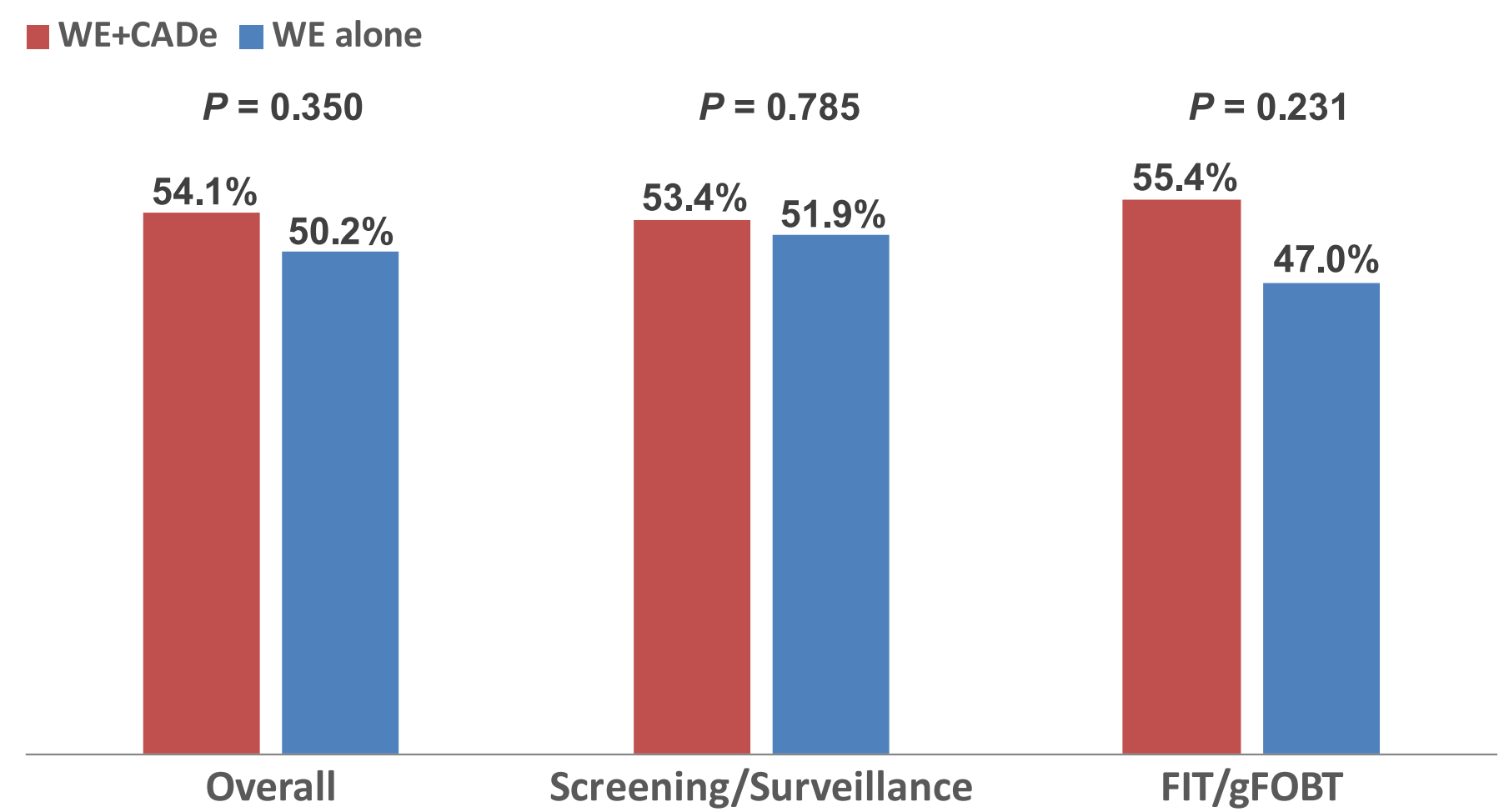


Analysis of APC by Location and Size

APC, mean (SD)	WE+CADE (N = 279)	WE alone (N = 281)	Adjusted IRR (95% CI)	P value
Right-sided colon	0.63 (1.92)	0.49 (0.94)	1.28 (1.02–1.59)	0.032
Proximal colon	0.93 (2.39)	0.70 (1.29)	1.32 (1.09–1.59)	0.003
Distal colon	0.46 (0.89)	0.35 (0.65)	1.33 (1.02–1.73)	0.035
1–5 mm adenoma	1.11 (2.64)	0.75 (1.27)	1.47 (1.23–1.75)	<0.001
6–9 mm adenoma	0.14 (0.43)	0.19 (0.54)	0.74 (0.49–1.12)	0.156
≥10 mm adenoma	0.14 (0.44)	0.11 (0.34)	1.31 (0.81–2.11)	0.267

Poisson regression analysis was used to calculate incidence rate ratios (IRRs) comparing APC between the two groups.

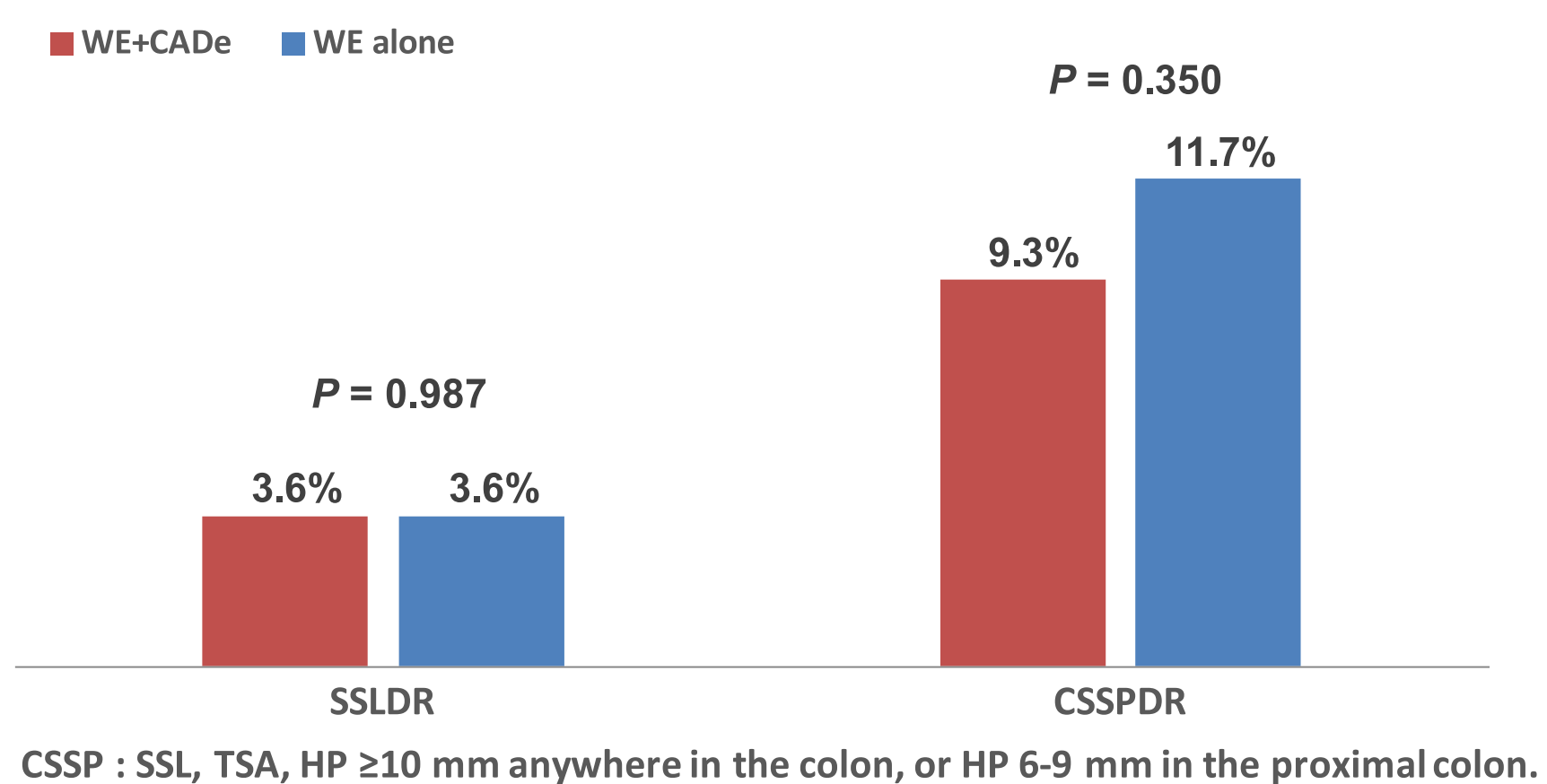
Adenoma Detection Rate



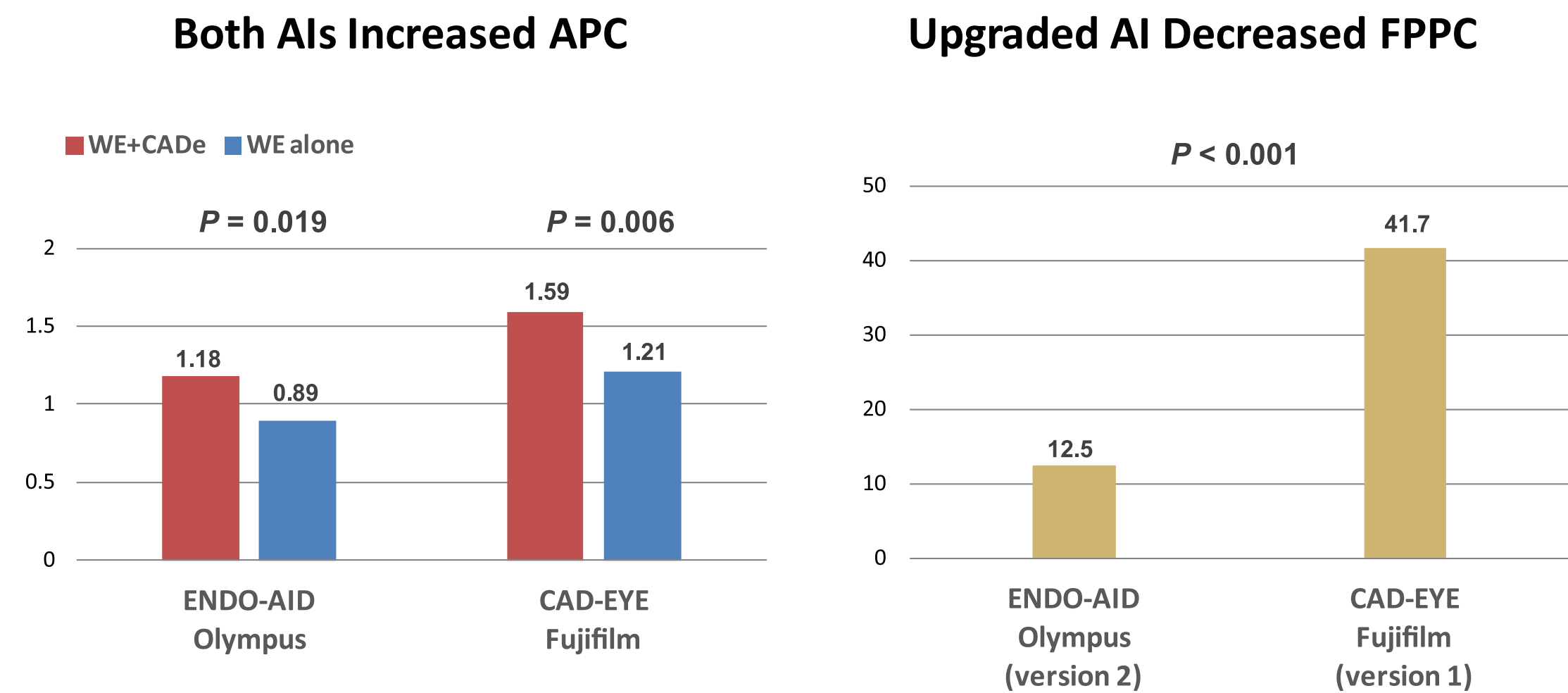
Analysis of ADR by Adenoma Characteristics

ADR, n (%)	WE + CADe (N = 279)	WE alone (N = 281)	Total	Relative Risk (95% CI)	P value
Nonadvanced	142 (50.9)	130 (46.2)	272 (48.6)	1.10 (0.97–1.23)	0.273
Advanced	43 (15.4)	41 (14.6)	84 (15.0)	1.06 (0.80–1.38)	0.785
Nonpolypoid	100 (35.8)	78 (27.8)	178 (31.8)	1.29 (1.10–1.50)	0.040
Polypoid	95 (34.1)	90 (32.0)	185 (33.0)	1.06 (0.90–1.24)	0.611
Proximal colon	106 (38.0)	103 (36.7)	209 (37.3)	1.04 (0.89–1.20)	0.743
Distal colon	87 (31.2)	75 (26.7)	162 (28.9)	1.17 (0.98–1.38)	0.241

Detection Rates of SSL and CSSP



Performance of Individual AI Systems



Colonoscopy Procedural Data

Variables	WE + CADe (N = 279)	WE alone (N = 281)	P value
Cecal intubation rate, n (%)	270 (96.8)	276 (98.2)	0.273
Insertion time, mean (SD)	11.9 (5.7)	12.4 (6.5)	0.289
Infused water during insertion, mean (SD), mL	773 (454)	785 (459)	0.760
Aspirated water during insertion, mean (SD), mL	744 (432)	765 (450)	0.561
Boston Bowel Preparation Scale score, mean (SD)	7.9 (1.2)	7.9 (1.3)	0.620
Withdrawal time in negative cases, mean (SD), min	10.4 (3.3)	10.3 (3.3)	0.799
Total procedure time, mean (SD), min	29.9 (11.0)	30.7 (12.2)	0.427

Discussion

- Inclusion of CADe in WE colonoscopy significantly increased APC across indications and anatomical locations compared to WE alone.
- APC enhancement by CADe mainly occurred in diminutive adenomas.
- Use of CADe did not prolong withdrawal time or increase detection of nonneoplastic lesions.
- Use of upgraded AI system significantly reduced false positive rates.
- The significant difference documented in interim analysis led to early termination of the study.