Pragmatic Resect and Discard Implementation Using Computer-Assisted Optical Polyp Diagnosis

Histopathology assessment is the current standard of care for evaluating diminutive colorectal polyps. The "resect and discard" (RD) strategy, facilitated by optical diagnosis (OD), allows for hyperplastic or low-risk adenomas diagnosed with high confidence to be removed and discarded without pathologic examination.[1] The "diagnose and leave" (DL) strategy permits diminutive hyperplastic polyps in the rectosigmoid to be left in place.[1] Computer-aided diagnosis (CADx) systems have the potential to allow for widespread adoption of OD.[2] Although OD accuracy is high in academic centers, accuracy of CADx-assisted diagnosis, when used by general endoscopists, can be suboptimal.[3] Integrating CADx-based OD into clinical practice could substantially reduce costs, which could be especially important for health care systems with capitation.[4,5] However, pragmatic implementation of OD-based RD and DL strategies remains untested in clinical settings. Previous studies have used theoretical OD testing, calculating its diagnostic performance against pathologic examination without evaluating real-world implementation of CADx-based OD.

To overcome these limitations, we conducted an institutional review board–approved prospective study (CER23.095, ClinicalTrials.gov, Number NCT06059378) in which polyps were truly discarded or diagnosed and left in place based on CADx-assisted OD. We approached patients aged 45–80 years undergoing outpatient colonoscopy at the Montreal University Hospital Center for participation. Patients were provided with written information on the artificial intelligence/CADx system (CAD-EYE, EW10-EC02; Fujifilm), OD, RD, and DL strategies, and a research assistant explained the procedures and answered questions. If patients declined study participation, a voluntary survey was administered to understand reasons for refusal. During colonoscopies, endoscopists used blue-light imaging mode and performed CADx-assisted OD. Endoscopists rated their OD confidence, polyp size, suspected sessile serrated lesions, and advanced histology. Endoscopists were requested to use Workgroup Serrated Polyps and Polyposis criteria to identify potential serrated polyps and JNET criteria (2B or 3) to identify polyps with advanced histology.[6] These polyps were removed and sent for pathology. All study colonoscopies were video recorded in full length. To ensure safety and obtain reference standards and performance metrics, a video-based review of all polyps that underwent RD or DL was conducted with 3 expert endoscopists (D.K.R., H.P., C.H.). Two experts (D.K.R., H.P.) reviewed videos blinded to each other's diagnoses. In case of disagreement, a third reviewer (C.H.) performed arbitration, knowing the previous expert diagnoses. Primary outcome was accuracy of OD; secondary outcome was patient acceptance of replacing pathology evaluation of diminutive polyps with CADx-assisted RD and DL strategies.

Among 102 patients approached, 95% (97 of 102) accepted undergoing CADx-assisted OD and subsequent RD and DL instead of pathology. Among patients who refused participation, 3 stated they did not want to participate in any study and 2 cited lack of trust in OD and/or CADx as reason for refusal. In 97 participating patients (mean [SD] age, 67.2 [8.8] years, 49 were male [50.5%]), 266 polyps were removed, of which 164 polyps (61.7%) were diminutive. CADx-assisted OD was performed on 159 (97%) of these diminutive polyps. A total of 40 of 159 polyps (25.2%) underwent CADx-assisted DL strategy and 98 of 159 (61.6%) underwent RD (4 polyps were discarded by the endoscopist, despite disagreement between endoscopist and CADx OD). Two polyps were suspected to be potentially sessile serrated lesions, both were resected and supposed to undergo histopathology evaluation. However, 1 polyp could not be retrieved and the second was later diagnosed as a hyperplastic polyp in pathology. The remaining 21 of 159 polyps (13.2%) were excluded; 19 because of low-confidence CADx-assisted OD or disagreement between endoscopist's and CADx-based OD and 2 because they were lost after detection, leaving 138 polyps for expert review (Figure 1). Among these 138 diminutive polyps, 86 were in the proximal colon and 52 were located in the rectosigmoid. Based on expert review of all 138 polyps that underwent OD as the reference standard, the accuracy of CADx-assisted RD was 88.8% (95% CI, 80.8%–94.3%) and the negative predictive value (NPV) of DL was 92.3% (95% CI, 87.2%–95.5%). Surveillance interval agreement of CADx compared with expert-based OD was 100% (95% CI, 93.4%–100.0%). The 2 initial experts (D.K.R., H.P.) agreed on 107 of 138 polyps (77.5%), leaving 31 polyps for arbitration. Details are provided in Supplementary Tables 1 and 2.

This pragmatic CADx-assisted OD implementation study demonstrated high patient acceptance to truly replace histopathology with CADx-assisted OD. Furthermore, we found that when using expert review instead of pathology as the reference standard, Preservation and Incorporation of Valuable Endoscopic Innovations benchmarks for NPV and surveillance interval agreement were achieved. Patient acceptance rate was similar to other studies conducted at Montreal University Hospital Center, which could differ in other countries or health care systems, warranting further

Abbreviations used in this paper: **CADx, computer-aided diagnosis; DL, diagnose and leave; NPV, negative predictive value; OD, optical diagnosis; RD, resect and discard.**

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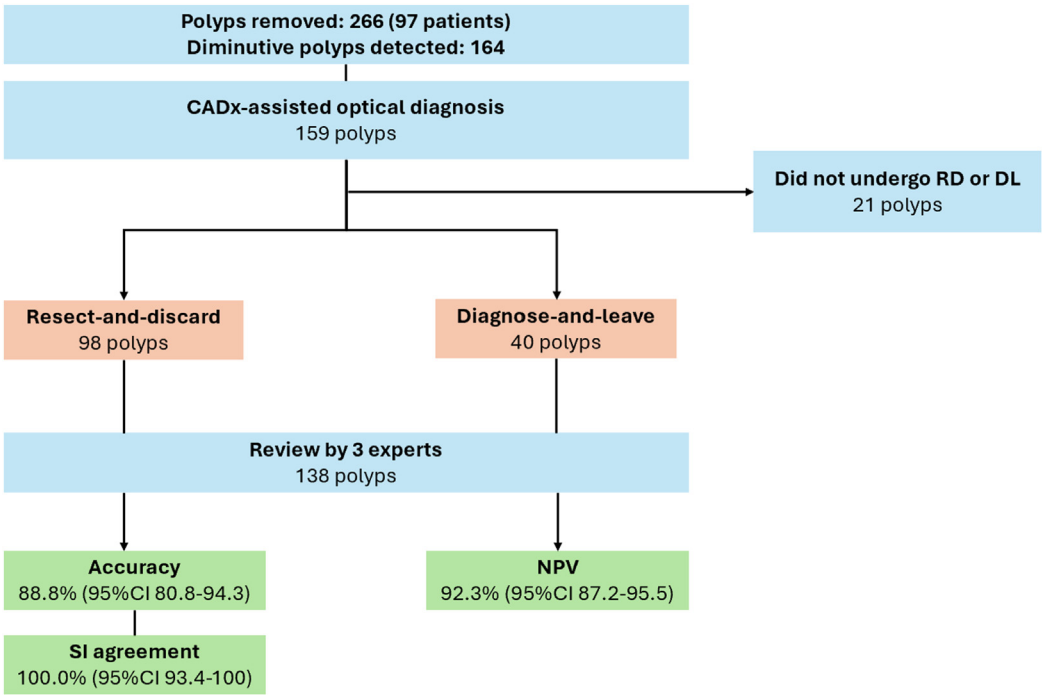

Figure 1. Flow chart and major outcomes of the study. SI, surveillance interval.

evaluation.[7] The study population included a mix of genders, races, and ethnicities, including patients from rural areas. However, sample size was not large enough to perform detailed sub-analyses. Furthermore, the survey for reasons to refuse study participation was only administered to patients who declined participation, providing a limited perspective on overall patient acceptance. This should be evaluated in future studies implementing OD. Accuracy, surveillance interval agreement, and NPV were in line with previous studies evaluating OD at academic centers.[8] In our study, 3 academic endoscopists with training and experience with CADx-assisted and CADx-unassisted OD performed all cases, which might explain the high diagnostic accuracy and NPV. All endoscopists were in favor of implementation of CADx-assisted OD, however, provider attitudes could differ worldwide. The use of AI-based diagnosis might increase endoscopist comfort in performing RD by providing an additional safety net for diagnosis and improving confidence. Conversely, if there is disagreement between endoscopists and CADx, endoscopists might be less willing to perform DL. Using video-based expert review instead of pathology of cases undergoing OD-based RD and DL is a novel approach and requires further evaluation in prospective studies. For polyps up to 3 mm, a combination of expert review and CADx-based diagnosis has been proposed as a potential reference standard for polyp diagnoses.[3,9] In a previous study using the same CADx system and histopathology as a reference standard, 1% of diminutive polyps diagnosed with high confidence had advanced features.[7] The prevalence of advanced histology in diminutive polyps in the literature is 0.5%–1%, however, there is no increased risk at follow-up when advanced features are detected in diminutive polyps, highlighting the safety of OD strategies.[10]

In conclusion, we found that pragmatic implementation of CADx-assisted RD and DL resulted in an 87% reduction of histopathology needed for diminutive polyps. When using expert audit as the reference standard, Preservation and Incorporation of Valuable Endoscopic Innovations benchmarks for NPV and surveillance interval agreement were achieved.

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Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of *Gastroenterology* at www.gastrojournal.org, and at https://doi.org/10.1053/j.gastro.2024.08.037.

References

1. ASGE Technology Committee, Abu Dayyeh BK, Thosani N, et al. Gastrointest Endosc 2015;81:502.e1–502.e16.
2. Mori Y, East JE, Hassan C, et al. Dig Endosc 2023;35:422–429.
3. Rex DK, Bhavsar-Burke I, Buckles D, et al. Ann Intern Med 2024;177:911–918.
4. Hassan C, Pickhardt PJ, Rex DK. Clin Gastroenterol Hepatol 2010;8:865–869; 869.e1–e3.
5. Mori Y, Kudo SE, East JE, et al. Gastrointest Endosc 2020;92:905–911.e1.
6. Rex DK, Kahi C, O'Brien M, et al. Gastrointest Endosc 2011;73:419–422.
7. Djinbachian R, Haumesser C, Taghiakbari M, et al. Gastroenterology 2024;167:392–399.e2.
8. Bang CS, Lee JJ, Baik GH. J Med Internet Res 2021;23:e29682.
9. Djinbachian R, El Mehdi El Yamani M, Rex DK, et al. Clin Gastroenterol Hepatol 2024;22:2344–2346.e1.
10. Vleugels JLA, Hassan C, Senore C, et al. Gastroenterology 2019;156:623–634.e3.

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Data Availability
Data, analytic methods, and study materials will be made available to other researchers upon reasonable request.

Supplementary Methods

Optical Diagnosis Safety Measures

Magnification colonoscopes were available for the conduction of this study for the majority of colonoscopies. When endoscopists had doubts about advanced histology within a diminutive lesion, high magnification could be activated to better ascertain JNET classification of lesions. Magnification was not routinely used during colonoscopy to capture routine endoscopic practice for OD in North America. When a lesion was diagnosed and left in the rectosigmoid and subsequent expert evaluation established that the lesion was an adenoma or sessile serrated lesion, patients were contacted to undergo flexible sigmoidoscopy to resect those polyps.

Patient Survey

A survey was administered to patients refusing study participation. The survey asked about the reason for refusing study participation; response options were: 1) unwillingness to participate in any research study; 2) concerns about replacing pathology with OD; 3) concerns about using artificial intelligence to replace pathology; and 4) other.

Supplementary Table 1. Diagnostic Performance of Computer-Aided Diagnosis–Assisted Optical Diagnosis Compared With Expert Optical Diagnosis

Diagnostic performance	Sensitivity, % (95% CI)	Specificity, % (95% CI)	PPV, % (95% CI)	NPV, % (95% CI)	Accuracy, % (95% CI)
Overall (n = 138 polyps)	89.9 (81.0–95.5)	89.8 (79.2–96.2)	92.2 (84.7–96.2)	86.9 (77.4–92.8)	89.9 (83.6–94.3)
RD (n = 98 polyps)	93.3 (85.1–97.8)	73.9 (51.6–89.8)	92.1 (85.4–95.9)	77.3 (58.5–89.1)	88.8 (80.8–94.3)
DL (n = 40 polyps)	25.0 (0.63–80.6)	100.0 (90.3–100.0)	100.0 (2.5–100.0)	92.3 (87.2–95.5)	92.5 (79.6–98.4)

PPV, positive predictive value.

Supplementary Table 2. Agreement Between Experts (Disagreements Solved With Arbitration Diagnosis by Third Expert)

	Expert 2				
Expert 1	Adenoma	Hyperplastic	Indeterminate	SSL	Total
Adenoma	62	12[a]	5[b]	0	79
Hyperplastic	3[c]	36	1[d]	0	40
Indeterminate	2[e]	3[f]	2[g]	0	7
SSL	0	5[h]	0	7	12
Total	67	56	8	7	138

SSL, sessile serrated lesion.
[a]Final diagnosis: adenoma (n = 8), hyperplastic (n = 4).
[b]Final diagnosis: adenoma (n = 4), hyperplastic (n = 1).
[c]Final diagnosis: adenoma (n = 2), hyperplastic (n = 1).
[d]Final diagnosis: hyperplastic (n = 1).
[e]Final diagnosis: adenoma (n = 2).
[f]Final diagnosis: hyperplastic (n = 3).
[g]Final diagnosis: adenoma (n = 1), SSL (n = 1).
[h]Final diagnosis: hyperplastic (n = 3), SSL (n = 2).