AI - Assisted Colonoscopy: Where Clinicians and Industry Agree and Diverge

Bijoy Prabhakar | MSc Medical Device Technology | Innopharma Education / Griffith College Dublin
Academic Year 2025–2026 | Supervisor: Brendan McLaughlin | prabhakarbijoy@gmail.com

Introduction / Background

Colonoscopy is the reference test for colorectal neoplasia, yet adenomas are still missed, and missed lesions are the main cause of cancers that appear between screens (Antonelli et al., 2023). Artificial intelligence (AI) tools that flag polyps in real time, known as computer-aided detection (CADe) and characterisation (CADx), were developed to close this gap. A meta-analysis of 28 randomised trials (23,861 participants) found higher adenoma detection rates (ADR) with AI (Makar et al., 2025). The evidence is not uniform, however. A pragmatic trial of 1,627 patients found no ADR gain (Zimmermann-Fraedrich et al., 2026), and an observational study reported that endoscopists' unassisted ADR fell from 28.4% to 22.4% after AI exposure (Budzyń et al., 2025). Few studies set clinicians' and industry professionals' views side by side. This study asked how both groups judge effectiveness, risk, barriers and regulatory readiness.

Methodology

A pragmatist, mixed-methods design used three evidence sources so that no single small sample carries the conclusions. A literature review set the published benchmark. An online survey of 17 gastroenterologists (14 consultants; 12 with over 10 years' endoscopy experience; 14 performing over 20 colonoscopies a month; 13 with prior AI use) measured agreement with statements on benefit, risk and adoption on a five-point scale. Six semi-structured interviews with professionals in AI engineering, quality, regulatory affairs and device development explored regulation and adoption in depth, using 12 open questions. Survey data were analysed descriptively, interviews thematically, and the results were then triangulated. Participation was voluntary, with informed consent and anonymised data.

Why these sample sizes?

Gastroenterologists with hands-on AI experience are a small, hard-to-reach specialist group, so the survey is a purposive expert sample, not a statistical one. Each respondent equals 5.9 percentage points, and confidence intervals are wide (for example, ADR agreement 76%, 95% CI 53–90%). Results are therefore reported as indicative and given most weight where the interviews and published trials agree with them. For the interviews, a small sample of well-chosen experts can be sufficient when the aim is narrow and the dialogue rich, a principle known as "information power" (Malterud *et al.*, 2016). Theme counts are reported as "n of 6".

Key Findings at a Glance

77% agree AI improves adenoma detection (13 of 17; 95% CI 53–90%). Consistent with trial evidence.

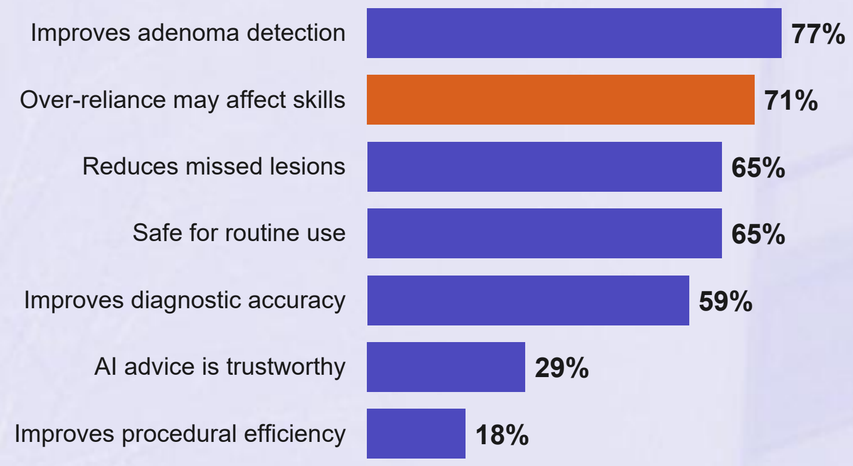
41% say AI could erode long-term skills (7 of 17; 95% CI 22–64%). A further 35% are unsure.

53% of top-3 adoption barriers chosen were cost or limited access

Results 1: Online Survey: 17 Gastroenterologists rated agreement on a 5-point scale.

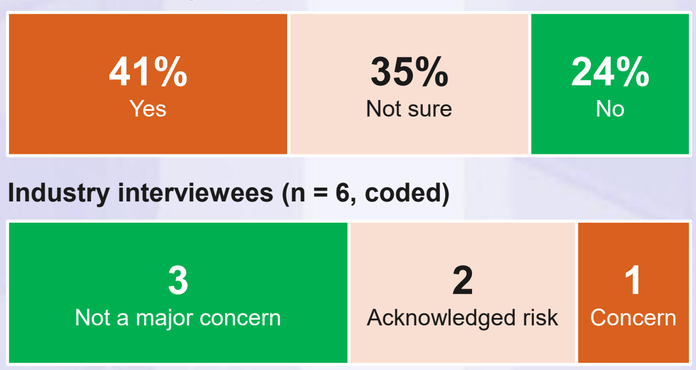
Do clinicians agree that AI delivers benefits, associated risks

%Share agreeing with 7 statements on detection, safety, trust & efficiency (n=17)



Could routine use of AI erode endoscopists' own unassisted skills?

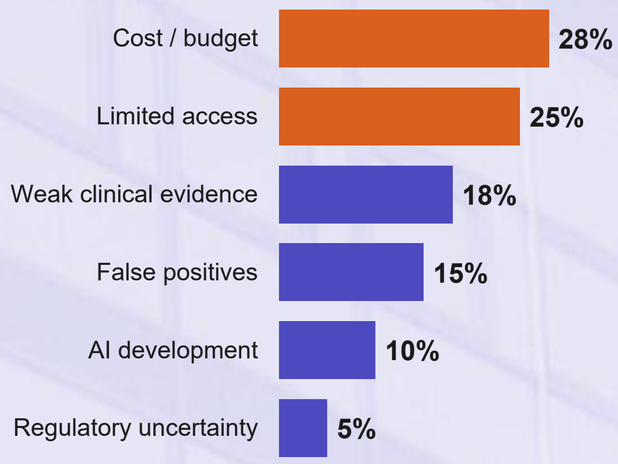
"Deskilling" here means losing the ability to detect and characterise polyps without AI prompts after long-term reliance on AI.



The survey measures attitudes only. Behavioural evidence comes from Budzyń *et al*. (2025), an observational study of 1,443 non-AI colonoscopies in four centres, where ADR fell by 6.0 percentage points (p = 0.0089). That study was retrospective and compared only three months before and after use of AI SaMD.

What stops clinicians' adopting AI?

% Each respondent chose their top 3 barriers (40 selections from 17 clinicians)



Percentages show share of selections, not share of respondents. Interviewees raised the same economic theme..

Results 2: What 6 industry professionals - commercial, quality and regulatory said, count shows how many of 6 raised each theme

Lesion and workflow limitations

Sessile serrated lesion (SSL) detection was flagged as a gap by 5 of 6 interviewees, echoed by a clinicians' survey comment that systems are weaker on SSL. False positives and unnecessary resection of diminutive polyps were seen to erode trust.

Economics and access

Five of six interviewees named hospital investment, reimbursement and ROI as the main brake on adoption. CADe is usually not reimbursed; CADx is viewed more favourably.

Regulatory readiness

Three quality and regulatory leaders said EU rules lag the FDA for adaptive AI. MDR plus AI Act dual compliance is heavy, and the EU has no equivalent of the FDA's change-control plan (PCCP).

Future Direction

EMR integration, automated reporting, computer-aided quality (CAQ) and multi-application platforms.
Priorities: SSL detection, polyp sizing, harmonised rules and independent benchmarking.

Discussion

Clinicians accept evidence for detection (77%) but are less convinced on workflow gains & trust. This agreement mirrors the meta-analytic evidence, and aligns with stakeholder responses in the research. The low efficiency rating (18%) contradicts with trail data showing that false positives occupy under 1% of withdrawal time (Antonelli *et al.* 2023).Deskilling split the groups, clinicians' views are aligned with findings of Budzyn *et al,*2025.Clear actions listed for adoption barriers, regulatory governance& training.

Strengths & Limitations: Triangulating 3 sources strengthens findings, addressing inherent bias. The samples are small & purposive. Findings are indicative and hypothesis generating, though not generalizable.

Conclusion

Within the limits of a small mixed-methods sample, clinicians and industry professionals agreed that AI improves detection, so perceived clinical benefit is not the main obstacle to adoption

.The barriers are practical and structural: hospital investment and reimbursement, regulation not yet suited to adaptive AI, and unresolved questions about whether routine use erodes unassisted skills.

The most robust findings (detection benefit, SSL limitations, cost and access) were supported by at least two data sources. Deskilling concern and workflow doubts are signals that need larger behavioural studies. The study shows where evidence and perception diverge, and offers manufacturers, hospitals, trainers and regulators an evidence-based priority list.

Recommendations

1. Protect unassisted skills (training programmes and hospitals). Build in regular AI-off colonoscopy and audit ADR with and without AI. Teach endoscopists to interpret and challenge AI prompts. This responds to the 41% of clinicians concerned about deskilling and to the unassisted ADR fall in Budzyń *et al.* (2025).

2. Build the economic case (hospitals, manufacturers, payers). Cost and access were the top clinician barriers (21 of 40 selections) and the main theme in interviews. Interviewees said CADe is usually not reimbursed while CADx is viewed more favourably. Real-world cost-effectiveness data and reimbursement pathways would turn a proven detection benefit into access.

3. Provide lifecycle oversight for adaptive AI (regulators). Three regulatory interviewees noted that the EU has no equivalent of the FDA's Predetermined Change Control Plan. Clearer guidance on change control, post-market surveillance and joint MDR/AI Act documentation (MDCG, 2025) would cut delay, especially for smaller companies. Independent performance benchmarking was also proposed.

4. Close the evidence gaps (researchers, manufacturers). Prioritise prospective studies of unassisted performance and long-term outcomes, better SSL detection (flagged by 5 of 6 interviewees and in the literature), and measurement of real workflow effects, including alarm fatigue.

References:

Antonelli, G., et al. (2023). Current and future implications of artificial intelligence in colonoscopy. *Annals of Gastroenterology, 36*(2), 114–122. https://doi.org/10.20524/aog.2023.0781

Budzyń, K., et al. (2025). Endoscopist deskilling risk after exposure to artificial intelligence in colonoscopy. *Lancet Gastroenterology & Hepatology, 10*(10), 896–903. https://doi.org/10.1016/S2468-1253(25)00133-5

Makar, J., et al. (2025). Use of artificial intelligence improves colonoscopy performance in adenoma detection. *Gastrointestinal Endoscopy, 101*(1), 68–81. https://doi.org/10.1016/j.gie.2024.08.033

MDCG. (2025). *MDCG 2025-6: Interplay between the MDR/IVDR and the Artificial Intelligence Act.* European Commission.

Malterud, K., Siersma, V. D., & Guassora, A. D. (2016). Sample size in qualitative interview studies: Guided by information power. *Qualitative Health Research, 26*(13), 1753–1760.

Zimmermann-Fraedrich, K., et al. (2026). No effect of computer-aided diagnosis on colonoscopic adenoma detection in a large pragmatic multicenter randomized study. *American Journal of Gastroenterology, 121*(4), 881–889. https://doi.org/10.14309/ajg.0000000000003500

Acknowledgements

I acknowledge the guidance from Brendan McLaughlin to complete this research.

I thank all gastroenterologists and industry professionals who shared their views in this research.

I appreciate the support from faculty & staff of Innopharma Education / Griffith College Dublin.

Conflict of interest: The authors declare no conflicts of interest.