Real World Validation of an Artificial Intelligence Characterization Support System for Prediction of Polyp Histology in Colonoscopy: Interim Analysis of a Prospective, Multicentre Study

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Introduction

- Colonoscopy is the gold standard for screening of colorectal cancer
- Diminutive and hyperplastic polyps do not increase a patient's risk for colorectal cancer
- Prediction of hyperplastic polyp histology is crucial for the resect and discard strategy, which saves cost and decreases procedure time in colonoscopy
- However, this is not standard of care due to the low confidence in optical diagnosis of polyp histology in colonoscopy
- This study aims to validate the performance of computer-aided diagnosis (CADx) in distinguishing between hyperplastic and neoplastic polyps during colonoscopy in a real-world setting.

Methods and Materials

- We conducted a prospective multicentre study comparing CADx (Fujifilm Corp., Tokyo) with endocopist optical prediction of polyp histology
- The optical diagnosis according to the NICE classification by the endoscopist
- Following this, the CADx tool was switched on and its prediction recorded
- Imaged polyps were resected for histological analysis, which formed the gold standard
- Primary outcome was diagnostic accuracy (defined by sensitivity for diagnosis of hyperplastic polyps and concordance rate).
- Bowel preparation, polyp size and difficulty in location were recorded for subgroup analysis

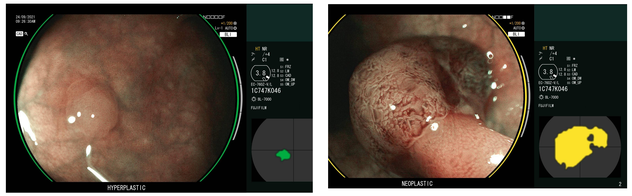

Figure 1. CADx predictions for hyperplastic (left) and neoplastic (right) polyps

- Inclusion criteria
  - Patients 40 years old and above who have an indication for colonoscopy
  - One or more polyps detected during colonoscopy
  - Consent obtained for the study
- Exclusion criteria
  - Patients less than 40 years of age
  - No polyps detected during colonoscopy
  - Incomplete colonoscopy where there is failure to reach the caecum
  - Patients with inflammatory bowel disease
  - Patients with known unresected colorectal cancer
  - Declined participation in study

Results

- 414 patients were assessed for eligibility across 4 large tertiary institutions in Singapore between February 2021 and June 2022
- 625 polyps (303 hyperplastic, 322 neoplastic) were detected in 257 patients
- Concordance rates for CADx and endoscopist predictions were 74.1% [95% confidence interval (CI) 70.5%-77.5%] and 73.1% (95% CI 69.5%-76.6%%), respectively (p=NS)
- Sensitivity for diagnosis of hyperplastic polyps was 84.2% (95% CI 79.6%-88.1%) and 77.6% (95% CI 72.4%-82.1%) for CADx and endoscopists, respectively (p<0.001)
- CADx also showed superior performance in predicting hyperplastic histology in diminutive polyps compared to endoscopist optical prediction using the NICE classification (sensitivity 81.7%; 95% CI 76.2%-86.4%, versus 76.3%; 95% CI 70.4%-81.5%, respectively)
- Diagnostic accuracy was similar when analysed according to bowel preparation and difficulty in polyp location during colonoscopy (defined as polyp location behind fold, around bend, or unable to position at 6 o'clock).

Between February 2021 and June 2022:

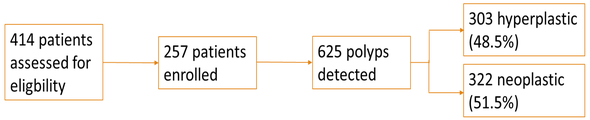

Figure 2. Flow chart of study recruitment and polyps included in analysis

Discussion

- This is the first prospective, multicentre validation study assessed the diagnostic performance of a CADx system for polyp histology during colonoscopy in a real-world clinical setting
- We present the interim analysis of the results
- Accuracy was similar between CADx and endoscopist prediction
- CADx had higher sensitivity compared to endoscopist prediction for hyperplastic polyps
- This may decrease healthcare costs and risks of overtreatment (promote "resect and discard" or "diagnose and leave" strategies)

Conclusions

- CADx showed a higher diagnostic sensitivity for hyperplastic polyps compared to endoscopist prediction during colonoscopy in this interim analysis
- This result was consistent in subgroup analysis for diminutive polyps, moderate bowel preparation and difficult location

Note: The reported results in this poster are the interim analysis. The study has been completed and the final results differ.

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