Artificial Intelligence validation trial for polyp detection: Pilot study

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AI validation study for polyp detection

DO NOT USE A ZOOM CAP DURING THE COLONOSCOPY

Any brand of endoscope can be used since we aim to develop a general system, independent of the brand or type.

A GPU computer is connected to the Panasonic AG-MDR25P recorder. This recorder is directly connected via SDI to one of the SDI output ports of the processor. The computer will then in real-time analyse the video that is provided by the processor and show the polyp detections by overlaying a green bounding box on a separate screen.

The endoscopist will perform his colonoscopy as always and he will only see the unaltered video feed from the endoscope processor. In the same room, a second human observer (who is experienced with the appearance of endoscopic video and polyps) will observe the second AI-enhanced screen connected to the computer. The procedure will then go as follows:

1. Start recording with the Panasonic recorder from insertion of the endoscope.

2. Take a still image when starting pullback from the caecum (to mark this point for easier analysis later). The second observer notes down the time indicated on the screen.

3. After the caecum has been reached, the second observer will take note of the following events during the rest of the procedure (by marking it in the attached document):
    i. **OBVIOUS FALSE POSITIVES**
    The AI system gives a positive prediction but it is an obvious false positive (e.g. stool, biopsy forceps, coagulation tip, diverticulum, air bubble, …). These are nuisances caused by the system, but would never cause the endoscopist to take action. These detections are **NOT communicated** to the endoscopist.
    ii. **OTHER FALSE POSITIVES**
    The AI system gives a positive prediction but the endoscopist does not indicate the presence of a polyp. In this case, a polyp could potentially be missed. If this location disappears from the field-of-view of the endoscopist (i.e. out of the image), the second observer should notify the endoscopist and ask him/her to go back and inspect the location in question. Three outcomes are possible here:
        1. The location did not contain a polyp, so it was really a false positive.
        2. The location did contain a polyp, so it was an additional detection polyp by the system.
        3. The location could not be re-identified
    iii. **FALSE NEGATIVES**
    A polyp was found by the endoscopist, but the AI system never identified this location to contain a polyp.
    iv. **TRUE POSITIVES**
    The AI system and the endoscopist found the same polyp (irrespective of who

was first).

4. At the same time, the endoscopist performs the procedure as he would typically proceed until he gets interrupted by the second observer. He then tries to find the location as instructed by the second observer and proceeds after the location has been confirmed to contain a polyp or not.

5. Stop recording when the whole procedure is over.

Additional information needed:
Please provide each video with the following information:

- Number of polyps present in the video
- For each polyp (in the order of appearance or by time indication of when they appeared)
    - Histological report conclusion
    - Size
    - Polypectomy type
    - Location
    - Morphology
- Brand and type of endoscope that were used

Statistical analysis plan:

Pilot trial to determine:

a) Performance of novel Artificial intelligence tool
b) Power and sample size calculation for ideal set-up of large multicentre validation trial