Evaluation of a real-time computer aided detection and diagnosis system of Barrett's neoplasia during live endoscopic procedures: A multicenter prospective study

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The aim of this study is to assess the performance of our CADe/CADx system in detecting and diagnosing Barrett neoplasia during live endoscopic procedures.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON56957

Source
ToetsingOnline

Brief title
Real-time CAD

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Esophageal Adenocarcinoma, esophageal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Het onderzoek wordt niet gefinancierd

Intervention

Keyword: Artificial Intelligence, Barrett neoplasia, Endoscopy, Oncology

Outcome measures

Primary outcome

- Per patient combined CADe/CADx sensitivity (i.e. number of patients with a visible abnormality detected by CAD on at least one Barrett level, divided by the total number of neoplasia patients according to the gold standard).

Secondary outcome

- Per patient combined CADe/CADx specificity (i.e. number of patients without a visible abnormality where CAD does not identify a lesion on any level, divided by the total number of NDBE patients according to the gold standard).
- Per level combined CADe/CADx sensitivity and specificity (i.e. number of levels with a visible abnormality identified by CADe/CADx, and number of levels without a visible abnormality where CADe/CADx does not identify a lesion; both divided by the total number of neoplasia/NDBE levels according to the gold standard).
- Per patient and per level CADe sensitivity and specificity

Study description

Background summary

Barrett's esophagus (BE) is a known precursor for esophageal adenocarcinoma

(EAC). When detected in an early stage, EAC is often still treatable endoscopically. Therefore, BE patients undergo regular endoscopic surveillance by the gastroenterologist. Early Barrett neoplasia however is difficult to recognize by the general endoscopist due to its subtle appearance.
Our research group has developed a computer aided detection (CADe) system that can detect and localize early Barrett*s neoplasia using artificial intelligence (AI). This CADe system assists the endoscopist during the procedure and provides alerts when an abnormality is detected. We have furthermore integrated a previously developed computer aided diagnosis (CADx) system that can characterize detailed imagery and thereby confirm of dismiss any CADe detections. Both systems have been evaluated extensively in an ex-vivo setting, showing superior performance when compared to endoscopists. Furthermore, an earlier clinical pilot study of 30 patients has already shown the feasibility of real-time utilization of the CADe system in the endoscopy room. The next step is to evaluate the systems, that are now further developed, clinically during live endoscopic procedures in a more extensive, prospective, multicenter cohort.

Study objective

The aim of this study is to assess the performance of our CADe/CADx system in detecting and diagnosing Barrett neoplasia during live endoscopic procedures.

Study design

Multicenter prospective cohort study

Study burden and risks

During the endoscopic procedure, the computer system essentially monitors the endoscopic imagery through its own monitor. The imagery is immediately analyzed by the system for possible abnormalities. The computer system does not introduce additional risks to the patient and never operates independently. This means that each part of the Barrett's segment is first evaluated by the endoscopist for abnormalities. At most, in the case that CAD detects a visible abnormality and the endoscopist assesses the Barrett's segment as normal, a target biopsy may be taken, but always in addition to the random biopsies taken as part of standard care. The target biopsy counts as one of the 4 random biopsies taken per 2 cm of Barrett's segment (standard protocol). This way, no extra biopsies are taken compared to regular Barrett's care. Even a false-positive CAD finding therefore does not pose additional risks to the patient. The endoscopic examination may take 5-10 minutes longer due to following the CAD workflow.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- BE patients without prior treatment that are undergoing regular endoscopic surveillance, or an endoscopic treatment in the Barrett segment.
- Age >= 18 years
- Signed informed consent

Exclusion criteria

- Prior endoscopic or surgical treatment of the esophagus for neoplasia
- Reflux esophagitis > grade B (LA classification)
- Inability to undergo EMR/ESD and/or obtain biopsies (e.g. due to anticoagulation, coagulation disorders, varices)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-11-2024
Enrollment:	200
Type:	Actual

Medical products/devices used

Generic name:	Comuter aided detection and diagnosis system (CADe and CADx)
Registration:	No

Ethics review

Approved WMO

Date:	06-08-2024
Application type:	First submission
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL86341.018.24