Polyp size measurement during real-time colonoscopy using the virtual scale function SCALE EYE: variability and systematic differences

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1. To assess the variability (spread) and systematic differences in polyp size measurement between SCALE EYE and several other measurement techniques (without reference [i.e. 'carpenters eye'], opened snare (of known size) as reference,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal neoplasms benign
Study type	Observational invasive

Summary

ID

NL-OMON51622

Source
ToetsingOnline

Brief title
SCALE EYE

Condition

- Gastrointestinal neoplasms benign

Synonym
bowel polyps, colorectal polyps

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Fujifilm Europe GmbH

Intervention

Keyword: Colorectal polyps, Polyp measurement, Polyp size, SCALE EYE

Outcome measures

Primary outcome

The difference in residual variance (variability) between (1) polyp size measurement with SCALE EYE and (2) polyp size measurement using an opened snare (of known size) as reference.

Secondary outcome

- The difference in residual variance (variability) between polyp size measurement with (1) the SCALE EYE functionality, (2) polyp size measurement without reference and (3) polyp size measurement during histopathological analysis.

- The systematic difference in polyp size measurements between (1) the SCALE EYE functionality and the other measurement techniques: (2) polyp size measurement without reference, (3) polyp size measurement with an opened snare as a visual reference and (4) polyp size measurement during histopathological analysis.

- Aformentioned parameters / outcomes (and primary study paramater) based on assessment by fellow endoscopists (for other analyses assessment by experts will be used)

- Inter-observer variability within techniques (residual variance)

- The accuracy of the SCALE EYE functionality for predicting the size of polyps. Accuracy is defined as the percentage of correctly predicted polyp sizes with the SCALE EYE functionality when polyp size measurement with an opened snare is considered as reference standard. Polyp size will be assigned as correctly predicted if the polyp size measurement with SCALE EYE lies within a 25% margin of error. The mean of the polyp size measurements by all experts endoscopists will be used for the comparison.

- The accuracy of the SCALE EYE functionality for predicting polyp size for different polyp size categories (1-5 mm vs. 6-9 mm vs. >10 mm). Accuracy is defined as the percentage of correctly predicted polyp sizes with the SCALE EYE functionality when polyp size measurement with an opened snare is considered as reference standard. Polyp size will be assigned as correctly predicted if the polyp size measurement with SCALE EYE lies within a 25% margin of error. The mean of the polyp size measurements by all expert endoscopists will be used to assign the polyp size category.

- The proportion of successful polyp size measurements by SCALE EYE during live endoscopy

- Average time to manoeuver SCALE EYE during live endoscopy (i.e. time to perform measurement of one polyp)

- Satisfaction score for usage of SCALE EYE (scale from 1-10)

Study description

Background summary

Polyp size plays an important role in early detection and prevention of colorectal cancer (CRC). First of all, since the size of polyps at index colonoscopy contribute to the estimated risk of future CRC, endoscopic measurement of polyp size is important for deciding on appropriate surveillance intervals. For example, most international guidelines advise a 3-year surveillance interval for individuals diagnosed with lesions >= 10mm and 5 or 10-year intervals for smaller polyps. Besides this 10 mm cut-off, polyp size is also correlated with the chance that a lesion harbors invasive growth (higher chances of invasive growth with increasing polyp size). As such, size also affects the choice of treatment modality for polypectomy. Last but not least, polyp size is essential for safe implementation of an optical diagnosis strategy, in which 1- to 5-mm polyps are characterized during endoscopy and resected and discarded without histopathological analysis (no guidelines are available for larger polyps yet).

Although assessment of polyp size is important for clinical decision making, no reference standard is available. In daily practice, polyp size is assessed visually by endoscopists (*carpenters eye*) or with instruments of known size adjacent to the lesion as a visual reference. Hence, polyp size measurment is a mostly intuitive and subjective proces, prone to inter-observer variability. In addition, although measurement of polyps using uncalibrated devices of known size might improve realiabilty, measurement is usually performed without additional disposable devices, because it leads to prolonged examination times and increased costs.

Recently, Fujifilm has developed a new real-time virtual scale functionality to their endoscopy system, known as *SCALE EYE*. SCALE EYE is developed to assist endoscopists in measuring polyp size during colonoscopy. This function makes use of a built-in laser and an image processing technology. As such, no additional disposable devices are required. When a polyp is detected, the endoscopist can switch on a red laser and the virtual scale (displayed on the monitor screen) of the SCALE EYE functionality by pressing a button on the handle of the endoscope. When the image sensor of the endoscope detects the laser dot and the laser dot is correctly positioned on the left border of the polyp, the polyp size within the image can be measured in real-time using the virtual scale. We hypothesize that SCALE EYE can aid to make polyp size measurment more objective, and hence reduce inter-observer variability.

Study objective

1. To assess the variability (spread) and systematic differences in polyp size measurement between SCALE EYE and several other measurement techniques (without reference [i.e. 'carpenters eye'], opened snare (of known size) as reference, pathologist assessment).
2. To assess the time-efficacy and user satisfaction of the SCALE EYE polyp size measurement during colonoscopy.

Study design

The study is designed as a single center prospective observational study. We will compare polyp size measurements using SCALE EYE with several other polyp size measurement techniques: size measurements by endoscopist without a reference (*carpenters eye*) , size measurements by endoscopist with an opened snare (of known size) as a reference and size measurements by the pathologist during histopathological analysis.

During screening colonoscopies, detected polyps (maximum of four per colonoscopy) will be measured using all three different colonoscopy measurement techniques. This will be done by experienced endoscopists (i.e. endoscopist accredited for colonoscopies within the national CRC screening program). The colonoscopy will be videotaped and subsequently digitally stored. Video recording extracts of the polyp size measurements will later be presented to eight expert endoscopists and four to eight fellows (depending on availability). They will estimate polyp size by all three different endoscopic measurement techniques (i.e. based on the video recording extracts). Histopathological analysis and size measurements of the resected polyps will be performed by pathologists with expertise in gastrointestinal pathology. Variability and systematic differences in polyp size measurement between these four measurements will be assessed.

Study burden and risks

Possible risks accompanied with the procedure are similar to that of regular colonoscopy procedures. These risks comprehend, among others, a small risk for colorectal bleeding (~1.5%) or perforation (~0.1%). Usage of the SCALE EYE functionality and performance of additional measurements does not cause additional risks. However, the additional measurements might cause short lengthening of the procedure (to an esimation an average of 5 additional minutes).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients:
- Age >18 years
- Screening colonoscopy after positive fecal immunochemical test (FIT) within the Dutch colorectal cancer screening program
- Signed informed consent

Exclusion criteria

Patients:
- Patients with diagnosis of inflammatory bowel disease, Lynch syndrome or (serrated) polyposis syndrome

- Patients who are unwilling or unable to give informed consent

Colorectale poliepen:
- Polyps greater than 20 mm (based on initial visual size measurement by the executing endoscopist without endoscopic tool as visual reference)
- Polyps removed in a way other than cold snare resection

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-10-2022
Enrollment:	66
Type:	Actual

Medical products/devices used

Generic name:	SCALE EYE
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	21-07-2022
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	23-09-2022

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	05-12-2022
Application type:	Amendment
Review commission:	MEC Academisch Medisch Centrum (Amsterdam) Kamer G4-214 Postbus 22660 1100 DD Amsterdam 020 566 7389 mecamc@amsterdamumc.nl

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	NL81269.018.22