Observer variability of visible light spectroscopy during upper endoscopy

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Primary objectives: - to determine the inter-observer variability of VLS- to determine the intra-observer variability of VLSSecondary objectives:- to determine the inter-observer variability of VLS per specific measurement location: antrum of the...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal vascular conditions
Study type	Observational invasive

Summary

ID

NL-OMON45584

Source
ToetsingOnline

Brief title
VLS-observer study

Condition

- Gastrointestinal vascular conditions
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
bowel ischemia, chronic mesenteric ischemia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: chronic mesenteric ischemia, mucosal oxygen saturation, observer variability, visible light spectroscopy

Outcome measures

Primary outcome

Primary endpoints:

- to determine the inter-observer variability

- to determine the intra-observer variability

Secondary outcome

Secondary objectives:

- to determine the inter-observer variability of VLS per specific measurement

location: antrum of the stomach, duodenal bulb and descending duodenum

- to determine the intra-observer variability of VLS per specific measurement

location: antrum of the stomach, duodenal bulb and descending duodenum

Study description

Background summary

The abdominal aorta delivers three branches to the gastrointestinal tract: the celiac arty (CA), the superior mesenteric artery (SMA) and the inferior mesenteric artery (IMA). Between these vessels exists an extensive collateral circulation. When one or more of these mesenteric arteries becomes significant stenotic and the collateral circulation is insufficient, the oxygenated blood supply to the gastrointestinal tract can decrease resulting in chronic mesenteric ischemia (CMI)(1, 5-7). CMI is mostly caused due to atherosclerotic stenosis of the supplying arteries, but other underlying mechanisms are arterial stenosis based on vasculitis, median arcuate ligament syndrome (MALS) or non-occlusive mesenteric ischemia due to a decreased cardiac output(8).

Patients with CMI suffer often from postprandial pain and unexplained weight loss due to fear of eating. During physical examination a bruit in the abdomen

can be heard(4). The diagnosis of CMI is a clinical challenge because CMI is difficult to distinguish by the frequent incidence of chronic abdominal pain and the high prevalence of stenosis of one or more mesenteric arteries in the general population(9-12). The current diagnostic work-up to diagnose CMI comprises clinical symptoms, radiological imaging and a functional test to detect mucosal ischemia (tonometry or visible light spectroscopy (VLS))(1, 5, 13, 14). Subsequently, all patients will be discussed in a multidisciplinary team consisting a gastroenterologist, a vascular surgeon and an interventional radiologist, all specialized in CMI leading to an expert-based consensus diagnosis(1).

Tonometry combined with radiological imaging has shown to be accurate in the detection of CMI(5, 6, 13, 15). Previously, 24-hours tonometry was used in the diagnostic work-up of CMI in our centre. However, tonometry has an invasive character. Therefore, we currently use endoscopic VLS as mucosal ischemia test in our centre. VLS is a minimally invasive test, performed during upper endoscopy with no requirement of hospital admission.

VLS measures the mucosal capillary haemoglobin oxygen saturation(16). VLS measurement is performed using a fiberoptic probe that uses white light to detect differences in the absorption spectra of the oxygenated and deoxygenated haemoglobin molecules(16). This saturation reflects the adequacy of the mucosal blood flow. In patients diagnosed with CMI the mucosal saturation was significant lower compared to healthy individuals(1, 3). VLS measurements are performed at three different locations during upper endoscopy: the antrum of the stomach, duodenal bulb and the descending duodenum. Based on cut-off values determined by van Noord et al. in CMI suspected patients, the outcomes are positive for ischemia if the measured saturation value is lower than 63% in the antrum, 62% in the duodenal bulb and 58% in the descending duodenum in fasting state.

The diagnostic accuracy of VLS measurements appears to be similar with prior used tonometry. The sensitivity and specificity rates are 90% and 60%, respectively(1). Whether VLS measurements are also reproducible is not clear yet. The rationale of this study is to determine the inter-observer and intra-observer variability of the VLS measurements in order to establish the reliability and reproducibility of this method.

References:
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Study objective

Primary objectives:
- to determine the inter-observer variability of VLS
- to determine the intra-observer variability of VLS
Secondary objectives:

- to determine the inter-observer variability of VLS per specific measurement location: antrum of the stomach, duodenal bulb and descending duodenum
- to determine the intra-observer variability of VLS per specific measurement location: antrum of the stomach, duodenal bulb and descending duodenum

Study design

Inclusion
Patients planned for upper endoscopy at the department of Gastroenterology and Hepatology, are asked to participate in our study. The patients will receive a Patient Information Folder (PIF) about this study. Furthermore, the patient will be asked permission to be called by one of the investigators minimally 24 hours later. Questions of the patient can be answered during the call and participating in the study by the patient can be confirmed.
If the patient gives informed consent for this study, the upper endoscopy will take place with the additional VLS measurements. If the patient declines informed consent, the upper endoscopy will take place without the additional VLS measurements.

Upper endoscopy
Upper endoscopy can be performed with or without sedation of the patient, depending on the preferences of the patient and the endoscopist. Sedation will be administered as midazolam 2.5-5 mg intravenously and combined with fentanyl 0.05 mg prior to the upper endoscopy. To prevent luminal spasms butylscopalamin 20mg is admitted intravenously before the start of VLS measurements. As to minimize the effect of confounding by cardiopulmonary diseases we aim to keep peripheral oxygen saturation above 94% by administering oxygen intra-nasally. The systemic oxygen saturation is continuously monitored by pulse oximetry.

VLS measurements will be performed during upper endoscopy using a fiberoptic catheter-based oximeter (T-Stat 303 Microvascular Oximeter, Spectros, Portola Valley, California, USA), that can be passed through the accessory channel of the endoscope. Measurements of the oxygen saturation will be performed at three locations in the stomach and duodenum: antrum of the stomach, duodenal bulb and descending duodenum. After irrigation of the target area and positioning the probe approximately 1-5 mm above the mucosa, three repeated readings will be taken of different areas of each location once a stable reading is obtained with less than 5% variation in panel read-out. The average of the three readings per location will be regarded as the actual measurement of that specific location.

For the patients included for the intra-observer variability analysis, the endoscopist will repeat the three measurements as described previously. The endoscopist is blinded for the VLS outcomes. For the intra-observer variability the same endoscopist will perform the measurements in all patients.
For the patients included for the inter-observer variability analysis, a second endoscopist will continue the upper endoscopy and repeat the VLS measurements

as described previously. Both endoscopists are blinded for the VLS outcomes. For the inter-observer variability the same two endoscopists will perform the measurements in all patients.
All VLS measurements will be written down by one of the investigators of this study. This investigator will also export the digital output of the device to confirm the noted values.

After the upper endoscopy, the patient will be brought to the endoscopy recovery room if the patient received sedation. The time to sleep off the sedative is the usual amount of time after an upper endoscopy procedure. When no sedation is used, the patient is allowed to go immediately after the upper endoscopy.

Participation in our study includes once repeated mucosal saturation measurements with VLS during one planned upper endoscopy. To participate in this study no additional hospital visits are needed. The research investigator can be contacted any time prior to procedure, should the patient have any further questions or decide to withdraw from the study which is possible at any time for any reason if a patient wish to do so. After withdrawal of the patient new patients will be included until the required number of patients is reached for the study.

Follow-up
Participants will not be followed-up after the upper endoscopy for this study.

Study burden and risks

Participation in this study will bring no additional benefit for the individual patient.
The whole procedure will take 5 to 10 minutes longer compared to patients that do not participate in this study.

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

- *18 years
- Informed consent
- Planned for an upper endoscopy

Exclusion criteria

- <18 years
- Unable to give informed consent
- Pregnancy
- Surgery of upper gastro-intestinal tract including small bowel
- A contraindication for the use of butylscopalamin
- Other criteria the physician considers are not compatible with the study

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2017
Enrollment:	28
Type:	Actual

Ethics review

Approved WMO

Date:	10-02-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL59989.078.17