RESEARCH TOPIC CLI34

Development and validation of artificial intelligence algorithms for screening and surveillance of oncological pathologies of digestive tract

Clinical Unit name
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Abstract

BACKGROUND: gastrointestinal cancer is the second diagnosed cancer worldwide. It is usually diagnosed through endoscopic exams, that allow the proper visualization of the internal mucosa of the organs, as well as the identification of abnormalities in the tissues. During endoscopic procedures, surgeons can also perform biopsies and removal of small lesions. The outcome of the described endoscopic procedures highly depends on the operator experience. Moreover, the presence of folds in the mucosa, a non-optimal preparation in the patient, and the limited endoscopic manoeuvrability can lead to blind spots, i.e. areas of the mucosa non properly seen during the inspection phase. Artificial intelligence (AI) in gastroenterology, particularly in endoscopy, has proven effective as a tool to support medical diagnosis, especially in the automatic identification of cancerous and precancerous lesions and their histological classification. Both in digestive endoscopy and in other clinical areas, AI algorithms have shown a huge potential in navigation and 3D reconstruction of the model of the examined organ. The aim of the study is therefore the development and validation of AI algorithms to support medical diagnosis. The envisioned applications aim to increase the accuracy of lesion identification and classification algorithms, as well as expand the portion of mucosa properly visualized during the procedure, thereby reducing the number of lesions not correctly visualized during exploration phase.

STUDY OBJECTIVES:

- *Primary study objective*

The primary objective of lesion identification and characterization algorithms is to improve diagnostic accuracy, defined as an improvement in the number of correctly identified and classified lesions. The primary objective of navigation algorithms is to enhance the quality of

the examination, particularly by increasing the percentage of mucosa correctly visualized during the diagnostic procedure and reducing areas not seen during exploration.

- *Secondary study objectives*

The secondary objective of lesion identification and characterization algorithms is to improve the diagnostic capabilities of the examination, with a reduction in false positives and false negatives. The secondary objective of navigation and reconstruction algorithm is to improve cecal intubation rate.

STUDY ENDPOINTS/OUTCOMES

- Primary study endpoints/outcomes

The primary endpoint of lesion identification and navigation is the accuracy of the algorithms.

The primary endpoint for navigation and reconstruction is the percentage of mucosa correctly visualized.

- Each Secondary study endpoints/outcomes

The secondary endpoints are sensitivity and specificity for lesion detection and classification, cecal intubation rate and monitoring of the duration of the endoscopic examination for navigation and reconstruction.

STUDY DESIGN: endoscopic procedures will be recorded, and endoscopic videos will be created. During the endoscopic examination, the operator will capture the necessary images. The captured images and videos will be uploaded and saved in the Endox software. The recorded data will be automatically transferred from Endox to other specific systems. Patient reports and images will be acquired from the W-Hospital clinical software and uploaded to the cloud. Finally, the data will be standardized, anonymized, and identified with keywords. These data will be used within the described preclinical study for the development and testing of artificial intelligence algorithms for screening and surveillance of digestive pathologies. The described study is a multicenter phase 2 preclinical study funded by two PNRR projects, MUSA and ANTHEM. The goal is to collect videos from 500 patients. Assuming a 5% dropout rate, the collected sample will consist of 525 patients.

The study will last 3 years and will be subdivided in 5 phases:

1. Data Collection
2. Data analysis and annotation
3. Development and evaluation of algorithm

4. Manuscripts writing
5. Study closure.

ELIGIBILITY CRITERIA:

Inclusion criteria:

1. Adults (male and female) able to give informed consent
2. Age >= 18 years old

Exclusion criteria:

1. Patients who underwent surgery for digestive tracts removal
2. Pregnant women

NUMBER OF PATIENTS: the objective is to collect videos from 500 patients. Assuming a 5% dropout rate, the collected sample will consist of 525 patients. The aim is to achieve a 90% (±5%) accuracy in the algorithms for automatic detection and classification of lesions, as well as a 50% (±5%) reduction in the percentage of mucosa not correctly visualized during exploration. Videos of esophagogastroduodenoscopies and colonoscopies will be collected from the study patients. The collected videos will be anonymized in full compliance with privacy rights and used for the development and validation of artificial intelligence algorithms that can assist in the diagnostic phase of digestive tract pathologies.

SAMPLE SIZE AND STATISTICAL CONSIDERATION: videos of esophagogastroduodenoscopies and colonoscopies will be collected and annotated from 500 patients. Assuming an expected dropout rate of 5%, a total of 525 patients will be enrolled in the study. During the implementation phase of the artificial intelligence algorithms, the goal will be to achieve a 90% (±5%) accuracy for the detection and automatic classification algorithms of lesions.
Navigation and reconstruction methods will be tested to achieve a 50% (±5%) reduction in the percentage of mucosa not correctly visualized during exploration.

STUDY TIMETABLE: provide the following study milestones:

- Planned date of the First Patient In (FPI - date of the Informed Consent signature of the first study patient): September 2023
- Planned date of the Last Patient In (LPI - date of the Informed Consent signature of the last study patient): September 2024

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- Planned date of the Last Patient Out (LPO – date of the last visit of the last study patient): September 2024
- Planned study duration (from FPI to LPO):

  September 2023 – September 2024

The described study is a Prospective Study

GCP STATEMENT: this study will be conducted in compliance with the protocol, the current version of the Declaration of Helsinki and applicable guidelines as well as all national legal and regulatory requirements.

To protect patient privacy, the videos obtained with patient consent will be anonymized.

Type of contract

PhD scholarship of € 22.400 gross per year awarded by Humanitas University. This sum is exempt from IRPEF income tax according to the provisions of art. 4 of Law no. 476 of 13th August 1984, and is subject to social security contributions according to the provisions of art. 2, section 26 and subsequent sections, of Law no. 335 of 8th August 1995 and subsequent modifications.

Borsa di dottorato pari a € 22.400 annui lordi erogata da Humanitas University. Importo non soggetto a tassazione IRPEF a norma dell'art. 4 della L. 13 agosto 1984 n. 476 e soggetto, in materia previdenziale, alle norme di cui all'art. 2, commi 26 e segg., della L. 8 agosto 1995, n. 335 e successive modificazioni.