International Platform of Registered Systematic Review and Meta-analysis Protocols

INPLASY

Machine Learning Models for the Assessment of the Mayo Endoscopic Score in Ulcerative Colitis Trial Endpoints: A Systematic Review

INPLASY202530077

doi: 10.37766/inplasy2025.3.0077

Received: 17 March 2025

Published: 17 March 2025

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ADMINISTRATIVE INFORMATION

Support - Iterative Health.

Review Stage at time of this submission - Completed but not published.

Conflicts of interest - DTR has received grant support from Takeda; and has served as a consultant for Abbvie, Altrubio, Apex, Avalo Therapeutics, Bristol-Myers Squibb, Buhlmann Diagnostics Corp, Celgene, Connect BioPharma, Intouch Group, Iterative Health, Janssen Pharmaceuticals, Lilly, Pfizer, Samsung Neurologica, and Takeda. He serves on the Board of Trustees for the Crohn's & Colitis Foundation and is on the Board of Directors for Cornerstones Health. WR has served as a speaker for AbbVie, Celltrion, Falk Pharma GmbH, Ferring, Janssen, Galapagos Medice, MSD, Roche, Pfizer, Pharmacosmos, Shire, Takeda, Therakos; as a consultant for AbbVie, Amgen, AOP Orphan, Arena Pharmaceuticals, Astellas, Astra Zeneca, Bioclinica, Boehringer Ingelheim, Bristol Myers Squibb, Calyx, Celgene, Celltrion, Eli Lilly, Falk Pharma GmbH, Ferring, Galapagos, Gatehouse Bio, Genentech, Gilead, Grünenthal, ICON, Index Pharma, Inova, Janssen, Landos Biopharma, Medahead, MedImmune, Microbiotica, Mitsubishi Tanabe Pharma Corporation, MSD, Novartis, OMass, Otsuka, Parexel, Periconsulting, Pharmacosmos, Pfizer, Protagonist, Provention, Quell Therapeutics, Sandoz, Seres Therapeutics, Setpointmedical, Sigmoid, Sublimity, Takeda, Teva Pharma, Therakos, Theravance, Zealand; as an advisory board member for AbbVie, Amgen, Astra Zeneca, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Celltrion, Galapagos, Janssen, Mitsubishi Tanabe Pharma Corporation, MSD, Pharmacosmos, Pfizer, Sandoz, Takeda; and has received research funding from AbbVie, Janssen, MSD, Sandoz, Sanofi, Takeda.

INPLASY registration number: INPLASY202530077

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 March 2025 and was last updated on 17 March 2025.

INTRODUCTION

Review question / Objective What is the totality of publications on the development/validation of AI algorithms for the automated endoscopic score Endoscopic Mayo Score (eMS) in UC?

Condition being studied We aimed to provide a systematic review of original research studies on training and/or testing of machine learning models for the assessment of the eMS on endoscopic video recordings in UC patients to inform guidance on the general reporting and evidence needed to advance the application of this technology in clinical trials.

METHODS

Search strategy Three databases including PubMed/MEDLINE, EMBASE, and Web of Science will be systematically searched. Google search will be supplemented to capture journals not indexed in these datasets. Since the field of artificial intelligence moves fast, we will also look into top conferences (MICCAI, MIDL, and IPMI) to see if any conference abstracts were missing.
Search term will include “inflammatory bowel disease”, “ulcerative colitis”, “automated”, “machine learning”, “artificial intelligence”, “deep learning”, “neural networks”, “supervised learning”, “unsupervised learning”, “algorithm”, “model”, “endoscopic activity index”, “endoscopic disease activity”, “Mayo Sore”, “Endoscopic Mayo Score”, “Mayo Endoscopic Score”, “MES”, “eMS”, “development”, “validation”.

Participant or population Patients with ulcerative colitis.

Intervention These patients had automated eMS scores using artificial intelligence models reading endoscopy images/videos.

Comparator Human reader (Gastroenterologist, endoscopist, etc).

Study designs to be included We included full manuscripts published in English from human studies with a clear definition of outcomes (automated ML eMES grade on endoscopic videos in UC).

Eligibility criteria Inclusion criteria:
- Clear outcome of an automated ML score for MES assessments in UC on endoscopy videos
- Human studies
- Full-length manuscripts
- English article
- A video dataset not incorporated in model training was used for model testing

Exclusion criteria
- Literature reviews, commentaries, editorials, letters, case reports
- Not English
- Non-human animal studies
- No full text.

Information sources Three databases were systematically searched, including PubMed/MEDLINE, EMBASE, and Web of Science. References were checked in the manuscript screening stage and Google search was supplemented to identify potential studies that were not found in three databases.

Main outcome(s) Automated endoscopic score Endoscopic Mayo Score produced by artificial intelligence algorithms using ulcerative colitis videos.

Quality assessment / Risk of bias analysis QUADAS-2 tool would be used.

Strategy of data synthesis This systematic review does not include a meta-analysis; therefore, no data synthesis will be performed. Instead, the results from each study will be presented in tables and figures within the manuscript.This is a systematic review only, no meta-analysis part, so there would not be any data synthesis in the manuscript, but rather, results from each study will be presented in the tables and figures of the manuscript.

Subgroup analysis Studies reported algorithm performance based on their use of a test dataset that was independent of the model development dataset.

Sensitivity analysis Since this systematic review does not include a meta-analysis, there is no statistical synthesis of previous results, and a traditional sensitivity analysis was not conducted. However, we assessed publication bias to evaluate its potential impact on the findings.

Language restriction We included studies in English only.

Country(ies) involved All authors and affiliations are based in the USA.

Keywords ulcerative colitis; endoscopy; artificial intelligence; clinical trials; mayo endoscopic score.

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