Development and Validation of an Artificial Intelligence-assisted Strategy Selection System for Colonoscopy Cleaning

Short Title：EndoAngel Study

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Trial number	EA-19-003
Protocol version	1.1
Version date	Dec 12, 2019
Country	China
Device	EndoAngel™
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1. Summary

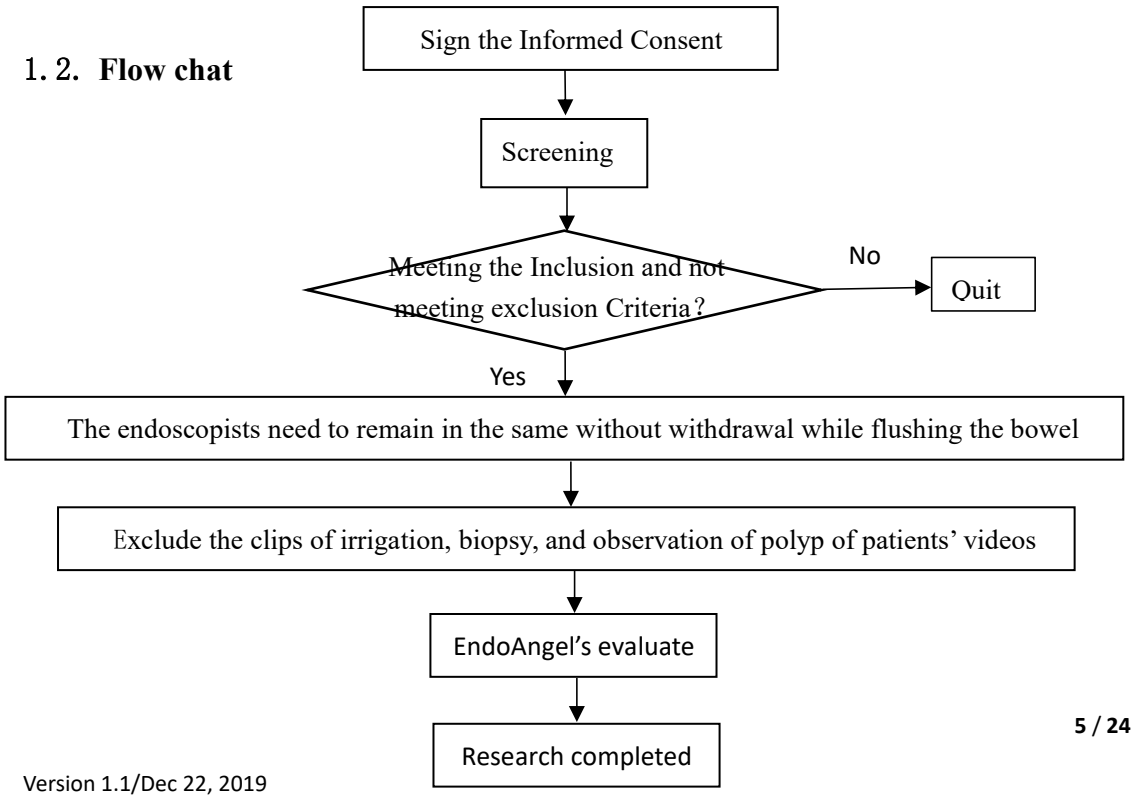
Title：	Development and Validation of an Artificial Intelligence-assisted Strategy Selection System for Colonoscopy Cleaning
Short Title：	*EndoAngel Study*
Trial number：	EA-19-003
Research system	EndoAngel
Expected effect：	ENDOANGEL's intended use is to assist doctors in identifying patients who require a second colonoscopy, thus avoiding missed adenomas and excessive washing time costs due to subjective factors and poor decision-making. It can improve the quality of endoscopy and the detection rate of digestive tract lesions.
Primary Endpoint：	1.Adenoma detection rate (ADR); 2.Boston Bowel Preparation Score of intestinal segment in artificial intelligence system;
Secondary Endpoints:	1.Polyp detection rate (PDR); 2.Mean number of adenomas per procedure (MAP); 3.Mean number of polyps per procedure (MNP); 4.The detection rate of large, small and micro - small adenoma and the average number of detection; 5.The detection rate and average number of polyps in large, small and microsized polyps; 6.Adenoma detection rate (ADR) of different location 7.Mean number of adenomas per procedure (MAP) of different location 8.Scope-forward time; 9.withdrawal time; 10.Cecal intubation rate; 11.Boston Bowel Preparation Score of endoscopists;
Trail design：	prospective, single group, observational, single-cente
Participants：	Male and female subjects aged 18 years or older will require a colonoscopy, and voluntarily provide endoscopic imaging data and sign an informed consent form.
Sample size：	200 samples were collected to explore the sample distribution, and then calculate the sample size according to the sample distribution.
Study Process：	Subjects who met all inclusion criteria and did not meet all exclusion criteria were included in the study before colonoscopy. During the colonoscopy, the endoscopists need to remain in the same without withdrawal while flushing the bowel. The biopsied patients are followed up for one week. the non-biopsied patients are followed up at the end of their colonoscopy , and the results are sent to an independent data analysis team for review. We will collect the patients' video and exclude the clips of irrigation, biopsy, and

	observation of polyp. Then the EndoAngel evaluates the Boston Bowel Preparation Scale of the ascending colon, transverse colon and descending colon, and calculates the proportion of 1 Score.
Security	Safety incidents shall be evaluated and reported according to the quality management measures for clinical trials of medical devices

1.1. Time and Event Tables

Events	Screening period （d -30~-1）	The day of colonoscopy（d 0）	Follow up (d 1-14)
Informed Consent	X		
Basic characteristics	X		
Medical history/surgical history	X		
Inclusion/Exclusion Criteria	X		
Colonoscopy		X	
Concomitant treatment	X	X	
Concomitant medication	X	X	
Adverse Events		X	X
Research completed			X

1. 2. Flow chat



Follow-up Time: The biopsied patients are followed up for one week. the non-biopsied patients are followed up at the end of the study

2.Introduction

Colorectal disease as a common human disease seriously affects the health of human life. With the aging of the population, the change of diet structure and the aggravation of environmental pollution, the incidence of colorectal diseases, such as colon cancer, Colon Polyp and inflammatory bowel disease, has gradually increased[1-2].

Colonoscopy is the simplest and most widely available screening procedure for colorectal cancer(CRC) prevention and early detection[2]. Colonoscopy can clearly observe the small changes in the terminal ileum and the colorectal, such as erosion, ulcers, bleeding, congestion, edema, polyps, early cancer, and so on. Colonoscopy can biopsy the lesion site for pathological examination, to histologically qualitative the characterization of mucosal lesions, such as inflammation, polyp nature, the degree of differentiation of cancer, and so on. It is helpful to understand the severity of the lesion and guide the formulation of the correct treatment plan or judgment of treatment effect. Colonoscopy can also be the minimally invasive endoscopic treatment of colorectal polyps, early cancer, bleeding, foreign bodies and other diseases.

Because the quality of bowel preparation affects the colonoscopy's ability to detect adenomas and polyps, adequate bowel preparation is necessary to ensure optimal use of colonoscopy in CRC prevention[3]. Almost all clinical guidelines recommend adequate bowel preparation before colonoscopy[4-6]. However, up to one third of colonoscopies have been found to show inadequate bowel preparation, which is estimated to increase the cost of colonoscopies by 12% to 22%. And there are 20% of patients' bowel is not adequately prepared. When the patient's bowel preparation is inadequate, the difficulty of flushing may lead to missed detection of adenomas[7-9]. so doctors need to accurately identify such patients and tell them to have a second colonoscopy after a full bowel cleanse[10.] However, the evaluation of intestinal cleanliness is decided by doctors subjectively, and there is no objective and effective scoring standard to guide the patients to accept the second colonoscopy.

Deep learning is an important breakthrough in the field of artificial intelligence in the past decade. It has great potential in extracting tiny features in image analysis and image classification. In 2017, the journal Nature published a paper showing that using artificial intelligence to diagnose skin diseases can reach the level of experts[11]. Subsequently, in the field of digestive endoscopy, more and more studies began to apply artificial intelligence to assist doctors to find polyps and improve the detection rate of polyps and adenomas.Urban, G. team used artificial intelligence to identify polyps with 95% sensitivity[12]. Misawa, M team used artificial intelligence to identify polyps with 90% sensitivity[13]. The purpose of our research group is to develop the EndoAngel with real-time intestinal cleanliness assessment. It can derive a decision curve for bowel cleanliness based on the relationship between the percentage of bowel segments with a Boston score of 1 and the detection rate of missed adenomas. It can help endoscopists to identify patients who need a second colonoscopy, to avoid the detection of missed adenomas and the high cost of cleaning time caused by the wrong decision-making. At the same time, artificial intelligence is in

the preliminary research stage in the field of digestive endoscopy, our research results are expected to provide new ideas in improving the detection rate of colonoscopic adenomas.

2. Patient Selection

Male and female subjects aged 18 years or older will require colonoscopy. And they voluntarily provide endoscopic imaging data and sign informed consent form.

Patients not meeting the inclusion criteria or meeting exclusion criteria will not be considered for participation in the study. Patients who met all criteria and singed informed consent may be excluded from the study due to:

• Endoscopists' professional advices/medical reasons (only under very limited conditions to avoid researcher bias).

• Withdraw informed consent.

2.1. Inclusion criteria

All patients meeting the following criteria will be considered for participation in the study:

1) Male or female aged 18 or above;
2) Colonoscopy is needed to further clarify the characteristics of digestive tract diseases;
3) Patients able to give informed consent were eligible to participate.
4) Able and willing to comply with all study process.
5) No intestinal organic disease.

2.2. Exclusion criteria

All patients meeting the following criteria will not be considered for participation in the study:

1) Has participated in other clinical trials, signed informed consent and was in the follow-up period of other clinical trials.
2) Has participated in clinical trials of the drug and is in the elution period of the experimental drug or control drug.
3) Drug or alcohol abuse or psychological disorder in the last 5 years.
4) Patients in pregnancy or lactation.
5) Known polyposis syndromes.
6) Gastrointestinal Bleeding.
7) A history of inflammatory bowel disease, colorectal cancer and colorectal surgery.
8) A history of colorectal surgery.
9) Patients with a contraindication for biopsy.
10) Previous history of allergy to ingredient of bowel cleanser.
11) Patients with intestinal obstruction or perforation, toxic megacolon, Colectomy, heart failure (Grade III or IV) , severe cardiovascular disease, severe liver failure or renal insufficiency, etc. .

12) Patients with poor bowel preparation that are unable to reach their blindness.
13) Researchers believe that the patient is not suitable to participate in the trial.

2.3. Definition of enrollment

After participants signed informed consent, they were regarded as enrolled. The sign time was the enrollment time, and was recorded in CRF.

3. Endpoints

3.1. Primary Endpoint

1) The adenoma detection rate (ADR)：
ADR was calculated by dividing the total number of patients being detected adenomas by the number of colonoscopies.
2) Cleanliness assessment of different intestinal segment in the artificial intelligence system
The artificial intelligence system evaluates the Boston Bowel Preparation score of the ascending colon, transverse colon and descending colon in real-time, and calculates the proportion of 1 Score

3.2. Secondary Endpoints

1) The polyp detection rate (PDR): PDR was calculated by dividing the total number of patients being detected polyps by the number of colonoscopies.
2) The mean number of polyps per patient (MNP). MNP was calculated by dividing the total number of polyps by the number of colonoscopies.
3) The mean number of adenomas per patient (MAP). MAP was calculated by dividing the total number of adenomas by the number of colonoscopies.
4) PDR of different sizes. It was calculated by dividing the number of patients with polyps that large (≥10 mm), small (6-9 mm) and diminutive (≤5 mm) by the number of patients undergoing colonoscopy.
5) MNP of different sizes. It was calculated by dividing the number of polyps that large (≥10 mm), small (6-9 mm) and diminutive≤5 mm) by the number of patients undergoing colonoscopy.
6) ADR of different sizes. It was calculated by dividing the number of patients with adenomas that large (≥10 mm), small (6-9 mm) and diminutive≤5 mm) by the number of patients undergoing colonoscopy.
7) MAP of different sizes. It was calculated by dividing the number of adenomas that large (≥10 mm), small (6-9 mm) and diminutive≤5 mm) by the number of patients undergoing colonoscopy.

8) ADR of different location. It was calculated by dividing the number of patients with adenomas detected in the rectum, sigmoid colon, descending colon, transverse colon, ascending colon, ileocecal region etc. by the Total number of patients undergoing colonoscopy.
9) MAP of different location. It was calculated by dividing the number of adenomas detected in the rectum, sigmoid colon, descending colon, transverse colon, ascending colon, ileocecal region etc. by the Total number of patients undergoing colonoscopy.
10) Scope-forward time. The time is taken to go from the the rectum to the ileocecal region.
11) Withdrawal time. The time is taken to finish the examination from the beginning of the ileocecal region.
12) Cecal intubation rate. It was calculated by dividing the number of colonoscopies that get to the ileocecal region by the total number of colonoscopies.
13) Boston Bowel Preparation Score of endoscopists. Endoscopists evaluate the different intestinal segment according Boston Bowel Preparation Scale(BBPS)

3.3. Safety evaluation endpoints and other secondary endpoints

Adverse events shall be determined according to the definition in the code for the quality management of adverse events of medical devices.The following types of adverse events should be recorded and calculated in the hospital history and CRF. According to the CRF table, the occurrence time, starting and ending time, intervention measures and treatment results should be filled in when recording. The severity should be referred to the previous literature and CTCAE 5.0 standard.

4. Purpose and overall design

4.1. Purpose

The purpose of this study is to develope the Endoangel with real-time intestinal cleanliness assessment. It can derive a decision curve for bowel cleanliness based on the relationship between the percentage of bowel segments with a Boston score of 1 and the detection rate of missed adenomas. To assist endoscopist in identifying patients who require a second colonoscopy, thus avoiding missed adenomas and excessive washing time costs due to subjective factors and poor decision-making. It can improve the quality of endoscopy and the detection rate of digestive tract lesions.

4.2. Overall design

This is a prospective, single group, observational, single-centel study.

5. Study process

5.1. Summary of Study Process

• If the patient meets the inclusion criteria, the patient is invited to participate in the study and then the informed consent procedure for the clinical trial is applied.
• Assess patients' eligibility based on the inclusion/exclusion criteria.
• If the patient meets the inclusion/exclusion criteria, information prior to endoscopy will be collected.
• A colonoscopy is performed after informed consent. Any intraoperative adverse events are recorded on the CRF for submission and subsequent analysis.
• Follow-up will be performed from the postoperative to the study completion, as detailed in the time and event table.

5.2. Enrollment

Only after patients signed the informed consent, can the research-related procedures be conducted.

5.2.1. Informed Consent

According to the Helsinki Declaration, patients are not allowed to participate in the study without adequate informed consent. The principal investigator is responsible for ensuring that no patient was enrolled in the study without adequate informed consent. Failure to obtain informed consent and failure to document this process is considered a violation of the Helsinki Declaration and the study protocol.

All informed consent documents (ICDs) must be approved by ethics. Patient's informed consent requires documentary record on the informed consent by himself in his primary language.

The investigator or trained designated person performs a preliminary screening to determine if the patient generally meets the eligibility criteria for the study. If yes, the investigator or trained designee should recommend the patient to participate in the study. If the patient agrees to participate, they will need to sign an informed consent document.

The investigator or trained designated person should confirm that the subject understands the following points in the study:
• the purpose of research,
• potential risks or adverse events,
• Potential risks or adverse events directly related to participating the research,
• The likelihood of failure,
• Research requirements include follow-up visits,

• All rights of the subject as a participant in the clinical study.

After explaining the purpose of the study, the investigator or trained designee should answer any questions from the subject. If the subject agrees to participate, his or her wishes must be recorded by signing and dated on the EC-approved ICF, and the document should be signed and dated by the patient receiving the informed consent.

After successful completion of the informed consent process, the investigator or trained designated person will assess the eligibility of patients based on the protocol.

5.2.2. Patient Selection

All patients who underwent colonoscopy, agreed to use EndoAngel and generally meet the study requirements were screened based on the inclusion/exclusion criteria. Patients who passed the screening were enrolled and recorded in the subject screening and enrollment tables. There is no bias in the choice of the enrolled subjects. The date of screening, the results (enrolled or not), and the primary reason for not selecting subjects (such as not meeting inclusion criteria, or not interested in participating in the study) will be recorded.

After the patients are enrolled, the research center should complete the preoperative study data collection.

It is desirable to be able to collect complete data for all enrolled patients, without those withdrawal from the study.

5.2.3. Subject identification number

Patients were numbered after signing informed consent.

The subject number begins with EA as a fixed number and is numbered starting from 0001 at the time of signing the informed consent. For example, the first patient who signed the informed consent was EA0001, and the second one was EA0002.

Once the subject identification number is assigned, the number is not reusable.

5.3. Treatment Description

This section applies to individuals who have signed an approved informed consent and have been identified as eligible to participate in this study on the basis of the inclusion and exclusion criteria. This section introduces the preoperative, surgical and postoperative management of subjects in detail.

5.3.1. Patient Screening Assessments

1） History
2） Physical examination
3） Hematuria pregnancy test (if required)

5.3.2. Pre-Procedure Managements

1） Fasting for 14 hours and water deprivation for 2 hours before examination
2） Routine bowel preparation.
3） Psychological counseling.
4） Performing routine anesthesia for painless enteroscopy patients.

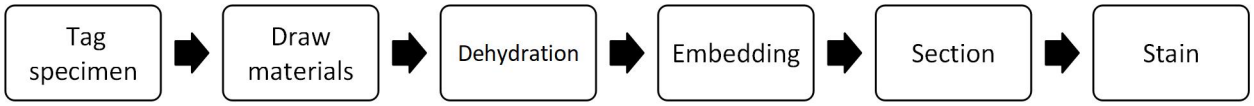
5.3.3. Intraoperative Managements

1） Patient position: lateral position with appropriate restraint.
2） Insertion route: according to the actual situation of the subject, usually through the anus
3） Routine observation

5.3.4. Post-operative Managements

1） Postoperative routine nursing
2） Subjects were observed to wake up
3） Patients without polyps and other lesions were followed up until the patient woke up and left the endoscopic room.
4） Patients with polyps and other lesions detected but no biopsy was taken during the operation should be followed up until the patient received polypectomy and other treatments, and the follow-up period should be within 7 days after the colonoscopy.
5） Record complications (if any).

5.3.5. Specimen handling procedure



5.4. Suspension and withdrawal

Patients who were screened and confirmed to be eligible for the study, signed the informed

consent and completed the randomization were considered as enrolled. If serious program deviation, withdrawal, or death occurs, the subject study is considered to be suspended. If the subject discontinues the study after obtaining informed consent, the data before the discontinuation will still be included in the study-related analysis.

5.4.1. Pre-Procedure

In any time during the study period, even before colonoscopy, participants could withdraw their informed consent whenever necessary. Researchers can withdraw participants before surgery according to safety considerations in the inclusion and exclusion criteria.

5.4.2. Intraprocedure

For safety reasons, the investigator may have the subject quit during the procedure. For example, the patient is not suitable for receiving the instrument for the study or the endoscopists do not use the specified instrument for any reason. If the following serious cases occur, please withdraw during the operation:

1） Perforation
2） Bleeding
3） Allergy to narcotic drugs
4） Poor intestinal cleanliness
5） Unable to complete colonoscopy due to obstruction or other reasons

5.4.3. Replacement

Subject will be deemed to have commenced the study upon completion of the informed consent process, and any subject who has been discontinued prior to or during the endoscopic examination will not subsequently be replaced by other subjects.

5.5. Concomitant therapy and medication

The concomitant treatment and concomitant medication were recorded from the time the subject signed the informed consent to the time the study was completed. Concomitant treatment and concomitant medication should be recorded in the CRF, or a clear copy of the form available from the research center should be kept in the CRF as research data to identify other factors affecting the end of the study. When recording the concomitant treatment and concomitant medication, the indications and the starting and ending time of use should be clearly defined, and the corresponding types of adverse events should be indicated for the treatment measures to cope with adverse events. When using a copy of the study center form, the investigator should sign the copy and indicate the date of review to confirm that the document is a study document.

6. Basis of study protocol and risk/benefit analysis

EndoAngel is used to provide assistant to monitor the operation of endoscopists, which will not provide diagnosis. Doctors make their own diagnosis on the basis of EndoAngel's results. The security of the software and the improvement of endoscopic physician's diagnosis and treatment level have also been confirmed in the previous feasibility study. And the patients in this study carry out the diagnosis and treatment according to the conventional treatment measures, which are formulated in accordance with the standard medical treatment procedures and do not increase the risk of the subjects.

6.1. Selection of endpoints

The primary outcome of the study are the adenoma detection rate (ADR) and Cleanliness assessment of different intestinal segment in artificial intelligence system.

The secondary outcomes of this study were: 1.Polyp detection rate (PDR);2.Mean number of adenomas per procedure (MAP); 3.Mean number of polyps per procedure (MNP);4.The detection rate of large, small and micro - small adenoma and the average number of detection;5.The detection rate and average number of polyps in large, small and microsized polyps;6.Adenoma detection rate (ADR) of different location;7.Mean number of adenomas per procedure (MAP) of different location;8.Scope-forward time;9.withdrawal time;10.Cecal intubation rate;11.Boston Bowel Preparation Score of endoscopists;

Adverse events in safety indicators shall be judged in accordance with relevant regulations, and serious adverse events shall be recorded and reported in accordance with regulations.

Other evaluations are detailed in the Case Report Form (CRF).

6.2. Definition of participants

Patients were included according to the indications and contraindications described in the use plan. Because of practical reasons (such as younger patients, participation in a number of clinical studies, alcohol/drug dependence patients, and other factors that may affect the completion and/or reliability of gastroscopy) and ethical reasons (whether informed consent can be completed, etc.), the entry and discharge criteria have been reduced.

6.3. Adverse events

The relevant definitions of adverse events are as follows:

Adverse Events (AE): Any adverse medical event, unexpected disease or injury, or adverse clinical manifestations (including abnormal laboratory findings) that occur in a subject, user or other person, whether or not associated with medical devices.

Serious Adverse Events (SAE): Adverse Events with the following information:
- causing death.
- leading to severe deterioration of the health of the subjects, including
- leading to life-threatening diseases or injuries,
- Causing impairment of body structure or function.
- Need hospitalization or extended hospitalization
- lead to hospitalization and preventive medical or surgical intervention
- Permanent damage to body structure or function
- Fetal distress, fetal death or congenital abnormalities or congenital defects.

Note: Hospitalization for existing conditions, or surgery required in the program, without serious deterioration of health status, is not considered a serious adverse event. Purposeful hospitalization, such as economic or reimbursement reasons, is not considered a serious adverse event.

Unexpected adverse device response (UADE): refers to adverse events related to medical devices that were not previously identified in the current version of the risk analysis report in terms of nature, severity or incidence. The definition includes any event caused by insufficient or inadequate description of the use or deployment of the device. This definition includes any event caused by a user's error.

6.4. Expected and trial-related adverse events

Previous studies have shown that the expected adverse events are basically the same as the complications of conventional endoscopic diagnosis and treatment.

The instrument used in this experiment is a medical software which is not in contact with human body. There is no difference between the experimental operation and the routine operation. The intervention measures (such as randomized process) in the experiment may slightly increase the incidents of diagnosis and treatment.

6.5. Risk minimization

In this study, when there are bugs in the software, doctors can still operate under their own judgment without affecting conventional diagnostic and treatment measures, greatly reducing the risk of the test.

6.6. Related benifits

Subjects will be randomly assigned to an experimental group or a control group. And experimental subjects may increase the detection of polyps and other lesions.

6.7. Overall feasibility analysis

EndoAngel is an independent system including both software and computer hardware, which can monitor image data 24 hours a day. The system is not invasive. The overall operability is strong.

7. Statistical Analysis

7.1. Statistical Analysis Plan

Data management and statistical analysis were implemented by Renmin Hospital Wuhan University.

7.2. Methods

Continuous variables should be described by number of subjects, mean, standard deviation, median, minimum and maximum.The classification variables are summarized by frequency and percentage.

7.3. Hypothetical test

The main assumptions are:There is a correlation curve between intestinal cleanliness score and the detection rate of adenoma.The use of EndoAngel can assess the intestinal cleanliness score in real time,and give a decision whether the patients need second colonoscopy

7.4. Sample Size Calculation

The primary endpoint was the detection rate of Adenomas and the percentage of 1 score to get a correlation curve. In order to calculate the sample size more accurately, we prepare to collect 200 colonoscopies to explore the sample distribution, and then calculate the sample size according to the sample distribution.

7.5. Statistical analysis set

All patients who met the inclusion and exclusion criteria were considered eligible for recruitment.

The two analysis sets in this study are defined as follows:

• The full analysis set (FAS) population analysis set will contain all eligible cases and shedding cases, but does not include culling cases.

• The Compliance (PP) population analysis set will include all subjects in the FAS analysis set with no significant deviation from the program.

Intention-to-treat and conformity analysis sets should be used to analyze the primary efficacy endpoints. The main analysis will be based on the PP analysis set. FAS analysis was regarded as supportive analysis.

8. Device Description

EndoAngel
Version: EA 2301

9. Abbreviations

Abbreviations	Full Name	Chinese
AE	Adverse Event	不良事件
CFDA	China Food and Drug Administration	国家食品药品监督管理总局
CNDA	China National Drug Administration	国家食品药品监督管理总局
CRF	Clinical Record File	病例报告表
CTCAE	Common Terminology Criteria for Adverse Events	不良事件常规评价标准
EC	Ethical Committee	伦理委员会
ICD	Informed Consent Document	知情同意文件
ICF	Informed Consent Form	知情同意书
ITT	Intention to Treat	意向治疗分析集
PP	Per Protocol	符合方案集
SAE	Serious Adverse Event	严重不良事件
CRC	Colorectal cancer	结肠癌
MNP	the Mean Number of Polyps per Procedure	平均每例肠镜发现的息肉个数
MAP	the Mean Number of Adenomas per Procedure	平均每例肠镜发现的腺瘤个数
PDR	Polyp Detection Rate	息肉发现率
ADR	Adenoma Detection Rate	腺瘤检出率
BBPS	Boston Bowel Preparation Scale	波士顿肠道评分量表

10. References

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Informed Consent Form

“Development and Validation of an Artificial Intelligence-assisted Strategy Selection System for Colonoscopy Cleaning”

Informed Consent Form for clinical study subjects

Informed Consent Form:Information page

Release date: 1.1,12 December 2019

Principal investigator: Yu Honggang

Dear sir / Madam,

We will invite you to participate in a clinical study “Development and Validation of an Artificial Intelligence-assisted Strategy Selection System for Colonoscopy Cleaning”. During this study, we will collect your colonoscopy video for analysis by a new colonoscopy-assisted system to derive your score of bowel preparation, Doesn’t interfere the physician's original observations and procedures.

Before you decide whether to participate in the study, please read the following as carefully as possible to help you understand the study and why it was conducted, the procedure and duration of the study, the potential benefits or risks of participating in the study. If you wish, you can discuss it with your family or friends, or ask your doctor for an explanation to help you make a decision

1.Background and Purpose

Colorectal disease as a common human disease seriously affects the health of human life. With the aging of the population, the change of diet structure and the aggravation of environmental pollution, the incidence of colorectal diseases, such as colon cancer, Colon Polyp and inflammatory bowel disease, has gradually increased.

Colonoscopy is the simplest and most widely available screening procedure for colorectal cancer(CRC) prevention and early detection. Colonoscopy can clearly observe the small changes in the terminal ileum and the colorectal, such as erosion, ulcers, bleeding, congestion, edema, polyps, early cancer, and so on. Colonoscopy can biopsy the lesion site for pathological examination, to histologically qualitative the characterization of mucosal lesions, such as inflammation, polyp nature, the degree of differentiation of cancer, and so on. It is helpful to understand the severity of the lesion and guide the formulation of the correct treatment plan or

judgment of treatment effect. Colonoscopy can also be the minimally invasive endoscopic treatment of colorectal polyps, early cancer, bleeding, foreign bodies and other diseases.

Because the quality of bowel preparation affects the colonoscopy's ability to detect adenomas and polyps, adequate bowel preparation is necessary to ensure optimal use of colonoscopy in CRC prevention. Almost all clinical guidelines recommend adequate bowel preparation before colonoscopy. However, up to one third of colonoscopies have been found to show inadequate bowel preparation, which is estimated to increase the cost of colonoscopies by 12% to 22%. And there are 20% of patients' bowel is not adequately prepared. When the patient's bowel preparation is inadequate, the difficulty of flushing may lead to missed detection of adenomas. so doctors need to accurately identify such patients and tell them to have a second colonoscopy after a full bowel cleanse. However, the evaluation of intestinal cleanliness is decided by doctors subjectively, and there is no objective and effective scoring standard to guide the patients to accept the second colonoscopy.

Deep learning is an important breakthrough in the field of artificial intelligence in the past decade. It has great potential in extracting tiny features in image analysis and image classification. In 2017, the journal Nature published a paper showing that using artificial intelligence to diagnose skin diseases can reach the level of experts. Subsequently, in the field of digestive endoscopy, more and more studies began to apply artificial intelligence to assist doctors to find polyps and improve the detection rate of polyps and adenomas.Urban, G. team used artificial intelligence to identify polyps with 95% sensitivity. Misawa, M team used artificial intelligence to identify polyps with 90% sensitivity. The purpose of our research group is to develop the EndoAngel with real-time intestinal cleanliness assessment. It can derive a decision curve for bowel cleanliness based on the relationship between the percentage of bowel segments with a Boston score of 1 and the detection rate of missed adenomas. It can help endoscopists to identify patients who need a second colonoscopy, to avoid the detection of missed adenomas and the high cost of cleaning time caused by the wrong decision-making. At the same time, artificial intelligence is in the preliminary research stage in the field of digestive endoscopy, our research results are expected to provide new ideas in improving the detection rate of colonoscopic adenomas.

2.Who can participate in the study

1)Male or female aged 18 or above;
2)Colonoscopy is needed to further clarify the characteristics of digestive tract diseases;
3)Patients able to give informed consent were eligible to participate.
4)Able and willing to comply with all study process.
5)No intestinal organic disease.

3.Who can not participate in the study

1)Has participated in other clinical trials, signed informed consent and was in the follow-up period of other clinical trials.
2)Has participated in clinical trials of the drug and is in the elution period of the experimental drug or control drug.
3)Drug or alcohol abuse or psychological disorder in the last 5 years.
4)Patients in pregnancy or lactation.
5)Known polyposis syndromes.
6)Gastrointestinal Bleeding.
7)A history of inflammatory bowel disease, colorectal cancer and colorectal surgery.

8)A history of colorectal surgery.
9)Patients with a contraindication for biopsy.
10)Previous history of allergy to ingredient of bowel cleanser.
11)Patients with intestinal obstruction or perforation, toxic megacolon, Colectomy, heart failure (Grade III or IV) , severe cardiovascular disease, severe liver failure or renal insufficiency, etc. .
12)Patients with poor bowel preparation that are unable to reach their blindness.
13)Researchers believe that the patient is not suitable to participate in the trial.

4.What would you need to do

Patients need to prepare for colonoscopy routinely, fasting for at least 14 hours and water deprivation for at least 2 hours before the procedure. Patients undergoing painless operation receive general anesthesia, while patients undergoing general operation do not need it.The doctor will be assisted by EndoAngel, which will be able to evaluate intestinal cleanliness according BBPS.

5.Benefits

Patients who have access to the colonoscopy with EndoAngel will likely have a better view of the lesion, more accurate recommendations for interval colonoscopy, and more comprehensive disease information.

6.Adverse events

The adverse events are basically the same as the complications of conventional endoscopic diagnosis and treatment.Participation in this study does not increase other additional risks.

7.Related fees

Routine colonoscopy for your clinical examination items, the cost of your own. Participation in this study does not involve additional testing and does not increase the cost of your care.

8.Personal Information

During the colonoscopy process, your endoscopic electronic images and case information will be collected and preserved in the hospital. Your doctor, the researcher, will be given access to this electronic information for scientific research. Your personal identity will not be disclosed in any public report of the results of the relevant research and development. We will do everything within the law to protect the privacy of your personal medical data.

9.For more information

You can ask any question about this study at any time.

Your doctor will give you his or her phone number so that he or she can answer your questions

Your doctor will keep you informed if there is any important new information during the course of the study that may affect your willingness to continue participating in the study.

10.Participation and withdrawal are voluntary

Participation in the study is entirely up to you. You may refuse to participate in the study or withdraw from the study at any time during the course of the study. You will not be discriminated against or retaliated against for refusing to participate in the study. Your medical treatment and entitlements will not be affected.

Your doctor or researcher may suspend your participation at any time in the best interest of you.

If you withdraw from the study for any reason, you may also be required to undergo a laboratory and physical examination if your doctor deems it necessary.

If you choose to participate in this study, we hope that you can adhere to the completion of the entire research process.

11.Others

Participation in this study is up to you. You can discuss it with your family or friends before making a decision.

Before you decide to participate in the study, ask your doctor as many questions as you can about the study until you have a complete understanding of it.

Thank you for reading this. If you decide to participate in the study, please tell your doctor, he or she will arrange for you to participate in all matters related to the study. Please keep this information.

Informed Consent Form:Information page

Name of Clinical Research Project： Development and Validation of an Artificial Intelligence-assisted Strategy Selection System for Colonoscopy Cleaning

Research physician commitment:

As a research physician, I confirmed that I had clearly explained to the subject the details of this trial, including their rights and possible benefits and risks, and gave them a signed copy of my informed consent.

Name：_____ Date;_____

Contact：_____

Subject commitment:

I have read and understood the introduction to this study on the informed consent page, and have had the opportunity to ask questions. I understand the research physician's explanation.

I am aware of the risks and benefits of participating in this study. I am aware that participation in the study is voluntary, and I am sure that there has sufficient time to consider and volunteer for the trial. I can always ask my doctor for more information, and I can always withdraw from the study without discrimination or retaliation, and without prejudice to medical benefits and entitlements.

I also knew that if I dropped out of the study, I would tell my doctor and complete the physical and chemical tests. If I need to take any other medication for my illness, I will consult with my doctor in advance or tell him the truth afterwards.

I agree□ or refuse□ Use my medical records for any other study.

I agree to participate in the study and promised to follow the doctor's advice to the best of my ability. I will receive a signed and dated copy of the Informed Consent Form.

Name：_____ Date;_____

Contact：_____

-End-