Research Protocol

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Protocol Summary

Tittle	A Study on a New Indicator for Assessing Colonoscopy Insertion Difficulty and Its Associated Factors
Study Design	Cross-sectional Study
Study Objective	To investigate the correlation between the time required for insertion to the cecum and various clinical indicators.
Sample Size	The sample size for this study is based on the recruitment of 10 doctors (5 junior and 5 senior). Each doctor will recruit 220 patients undergoing colonoscopy, leading to a total of 2,200 patients (10 doctors × 220 patients). After excluding patients who are unable to complete the colonoscopy procedure for any reason, each doctor will retain data from 200 patients, resulting in a final sample size of 2,000 patients (10 doctors × 200 patients).
Study Participants:	1. Junior Doctors: 5 junior doctors, each performing colonoscopy on 220 patients. 2. Senior Doctors: 5 senior doctors, each performing colonoscopy on 220 patients. Patients: A total of 2,000 patients (200 per doctor), aged 18 years and older, who voluntarily consent to participate and meet the inclusion criteria for the study.
Study Methodology	This study will recruit five junior doctors and five senior doctors from our department. Each doctor will perform approximately 100 colonoscopies using two different endoscopes (Olympus 290 and Pentax). The time required for insertion to the cecum (Cecal Intubation Time, CIT) and the clinical data characteristics of the patients will be recorded. SPSS statistical software will be used to conduct univariate and multivariate correlation analyses of CIT and patients' clinical data. Next, SPSS will be used to compare whether there is a statistically significant difference in CIT between junior and senior doctors, and to assess whether there is a statistical difference in CIT between the same-level doctors using different equipment (using t-test). The CIT data will be standardized using Z-score, median standardization, and quantile normalization in SPSS. Subsequently, univariate and multivariate correlation

	analyses will be performed to examine the relationship between important clinical features and standardized CIT. SPSS will also be used to perform t-tests on the standardized CIT for junior and senior doctors and to compare whether CIT differs statistically between the same-level doctors using different equipment after standardization. Finally, the study will compare the objectivity of the three standardization methods in measuring colonoscopy insertion difficulty and their ease of computation, in order to identify the most clinically applicable standardized CIT.
Inclusion Criteria	1. Adult patients (aged 18 years and above) who are scheduled to undergo a colonoscopy at the Second Hospital of Jilin University. 2. Patients who voluntarily agree to participate in the study and provide informed consent. 3. Patients who are eligible for painless colonoscopy procedures. 4. Patients who are able to complete the colonoscopy procedure without any contraindications (i.e., without significant complications or failure to complete the procedure).
Exclusion Criteria	1. Patients who are under 18 years of age or do not meet the eligibility criteria for painless colonoscopy. 2. Patients who fail to complete the colonoscopy procedure for any reason (e.g., severe pain, patient discomfort, equipment malfunction). 3. Patients with a history of severe cardiovascular, respiratory, or other systemic diseases that would contraindicate colonoscopy. 4. Patients with known or suspected colorectal malignancies or other conditions that may affect colonoscopy insertion (e.g., significant bowel obstruction, severe inflammatory bowel disease). 5. Pregnant women or breastfeeding mothers who are not suitable for the procedure. 6. Patients who are unable or unwilling to provide informed consent to participate in the study.
Data and Sample	1. Recruitment of Doctors and Patients:

Processing Methods	Five junior doctors and five senior doctors will be recruited from our department. Each doctor will recruit 220 patients undergoing colonoscopy, excluding those who are unable to complete the procedure for various reasons. Each doctor will retain 200 patients for analysis. Each doctor will perform 100 colonoscopies using the Olympus 290 endoscope and 100 using the Pentax endoscope. The time required for insertion to the cecum (Cecal Intubation Time, CIT) will be recorded, along with patient information such as gender, age, height, weight, and surgical history. Other important clinical features, including whether the patient experiences abdominal pain, bloating, or constipation, will also be recorded. 2. Statistical Analysis of CIT and Clinical Features: SPSS statistical software will be used to perform univariate and multivariate correlation analyses of CIT and the related clinical data to determine which factors correlate with the insertion time. 3. Comparison of CIT Between Junior and Senior Doctors: SPSS will be used to compare whether there is a statistically significant difference in CIT between junior and senior doctors. The software will also compare whether there is a statistical difference in CIT for the same level of doctor using different equipment (using t-test). 4. Standardization of CIT Data: SPSS will be used to standardize all CIT data using Z-score standardization, median standardization, and quantile normalization. Afterward, univariate and multivariate correlation analyses will be performed to examine the relationship between important clinical features and the standardized CIT. 5. Comparison of Standardized CIT Between Junior and Senior Doctors: SPSS will perform t-tests on the standardized CIT for junior and senior doctors. The t-test will also compare whether the CIT for the same level of doctor using different equipment remains statistically similar after standardization. 6. Comparison of Standardization Methods: The study will compare the objectivity of the three

	standardization methods in assessing colonoscopy insertion difficulty and evaluate the ease of computation involved in each method. The aim is to identify the standardized CIT that is most suitable for clinical use.
Statistical Analysis Methods	The study investigates the correlation between the CIT standardized using Z-score, median standardization, and quantile normalization with various clinical indicators: To validate the correlation between standardized CIT and key clinical features, and to demonstrate its clinical applicability.
Expected Outcome	CIT and Clinical Features: The study is expected to demonstrate that Cecal Intubation Time (CIT) is correlated with certain important clinical features, such as abdominal pain, bloating, and constipation. However, the correlation may be relatively weak. Impact of Physician Experience and Equipment: CIT is influenced by factors such as the experience of the endoscopist and the type of equipment used. Therefore, as an indicator for measuring insertion difficulty, CIT has certain limitations. Effect of Standardization on CIT: After standardizing CIT using three methods (Z-score, median standardization, and quantile normalization), the correlation with important clinical features strengthens. Standardized CIT is no longer affected by the physician's experience or the equipment used, making it a more objective measure of insertion difficulty. Selection of the Most Suitable Standardization Method: Among the three standardization methods, one will be selected based on its ease of calculation and strong applicability. This standardized CIT can provide an objective reference for diagnosing and treating clinical symptoms such as abdominal pain, bloating, and constipation, and for formulating treatment strategies. Publication Expectation: The study is expected to result in the publication of one SCI article.

	This study aims to establish a more reliable, objective measure for colonoscopy insertion difficulty, which can guide clinical decision-making for related symptoms and conditions.