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The articulated laparoscopic total mesorectal excision for rectal cancer (ATOME trial): a single-arm, prospective trial with pre-specified comparison to robotic surgery

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Abstract

Background Laparoscopic total mesorectal excision (TME) has become the standard surgical treatment for rectal cancers, despite being a technically challenging procedure due to the straight and rigid nature of the laparoscopic instrument within a narrow bony pelvis. A robotic system with multi-joint instruments, three-dimensional vision, and improved ergonomics was introduced, however it is not yet cost-effective. Recently, several articulating laparoscopic instruments have been developed and introduced as substitutes for multi-joint robotic system instruments. The prospective study aims to demonstrate that the positive rate of circumferential resection margin following laparoscopic surgery with articulated laparoscopic instruments is non-inferior to that of robotic surgery in the treatment of rectal cancer.

Methods/design Patients with primary rectal cancer who are treated with low anterior resection using articulated laparoscopic instruments will be included in the study. Participating colorectal surgeons must use articulated laparoscopic instruments at least during TME. We hypothesize that the positive rate of circumferential resection margin after robotic surgery will be 6%, 3 based on the previous studies. A trial with 157 patients contributing to the primary outcome analysis would have 80% power to declare non-inferiority with a 5.2% non-inferiority margin, assuming a 10% dropout rate. To compare laparoscopic TME group and robotic TME group, we adjust for variables such as gender, T stage, N stage, sphincter saving status, and preoperative chemoradiation using propensity score matching. The primary end-point of this study is cicumferential resection margin after surgery.

Discussion Based on this study, we hope to demonstrate the efficacy and viability of articulated laparoscopic instruments in the treatment of rectal cancer at a lower cost than robotic surgery.

Trial registration Clinical Research Information Service KCT0008896. Registered on 15 August 2023.

Keywords Rectal neoplasms, Laparoscopy, Colorectal surgery, Treatment outcome, Surgical instruments

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Introduction

Many randomized controlled trials have demonstrated that laparoscopic surgery is a more favorable option compared to open surgery due to reduced blood loss, expedited recovery of bowel motility, and shorter hospitalization duration, while maintaining comparable oncologic outcomes. Consequently, laparoscopic surgery has emerged as the established approach for the management of colon cancer [1–3]. Nevertheless, the laparoscopic surgery has several inherent technical limitations. In rectal surgery, the confined pelvic cavity limits the range of motion for long straight instruments. Moreover, the use of two-dimensional vision and reduced tactile sensitivity and dexterity compound the difficulties of this surgical intervention.

Robotic surgery is introduced and developed to overcome the limitations of laparoscopic surgery with providing wristed surgical instruments, three-dimensional (3D) and high-definition (HD) vision, a stable camera command, tremor filtration for surgeons and motion scaling [4, 5]. However, some randomized controlled trials failed to confirm the superiority of robotic surgery compared to laparoscopic surgery in rectal cancer [6, 7]. Furthermore, given the current level of evidence, the high costs to maintenance and running a surgical robotic system are still consistent hurdles limiting the widespread use of robotic surgery.

The ArtiSential[®], developed by LIVSMED Inc. in the Republic of Korea, is a laparoscopic instrument with a pistol-handle design and a 5 mm or 8 mm diameter. It possesses a fully articulating function, resembling the human wrist, with intuitive controllability. Registered with the United States Food and Drug Administration (FDA) as a Class I medical device in 2019, it allows surgeons to utilize two articulating devices simultaneously with force feedback, notably reducing expenses. We have introduced a surgical technique for multiport laparoscopic low anterior resection for rectal cancer [8].

The circumferential resection margin (CRM) is one of the strongest oncologic surrogate marker in rectal cancer surgery [9, 10]. Strong quality measures are those for which compliance translates into improved patient outcomes. Studies have already reported that a decrease in CRM positivity rate is associated with lower rates of cancer recurrence and death [11–14]. Therefore, we designed this randomized controlled trial to demonstrate that positive rate of circumferential resection margin following laparoscopic surgery with articulated laparoscopic instruments is non-inferior to that of robotic surgery.

Methods/design

Study design

This study is a multi-center, prospective single-arm trial that investigates the safety and feasibility of articulated instruments for rectal cancer surgery, with a prespecified comparison to retrospectively collected data of robotic rectal cancer surgery in our institution. This protocol has been developed following the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) checklist [15].

Objectives and hypotheses of the study

The primary objective of this research is to examine the oncologic safety of articulated laparoscopic total mesorectal excision (TME) in the presence of CRM in comparison to robotic surgery. The secondary objectives of this study are to evaluate the clinical feasibility and cost-effectiveness of this surgical technique. Our hypothesis posits that in conjunction with robotic surgery, the CRM of articulated laparoscopic TME could potentially contribute significantly to the treatment of rectal cancer if it is clinically feasible and cost-effective, and is not inferior to the CRM of robotic TME.

Study participants

We will enroll the patients with primary rectal cancer who are scheduled to undergo for laparoscopic low anterior resection with total mesorectal excision. We will recruit eligible patients from an outpatient clinic prior to surgery. The investigator will explain to give adequate study information to eligible patients about the study objective, interventions, potential benefits and risks, and their rights with sufficient time. Patients will read and voluntarily sign an informed consent form. We will also request consent for the review of participants' medical records and for the collection of blood samples to assess recurrence. Even if patients decline to participate in the study, their treatment will not be affected. Patients have the right to withdraw the participation in the study at any time if they want.

Inclusion criteria are primary rectal cancer (from 0 to 15 cm from the anal verge), patients aged 18–82 years, stage I–III (American Joint Committee on Cancer 8th edition), and those who provide a written consent to participate in the study (Fig. 1). The study will include both preoperatively irradiated and non-irradiated patients. Exclusion criteria will consist of patients who need emergent surgery due to preoperatively colon obstruction or perforation and patients with stage IV rectal cancer, familial adenomatosis polyposis and hereditary non-polyposis colon cancer.

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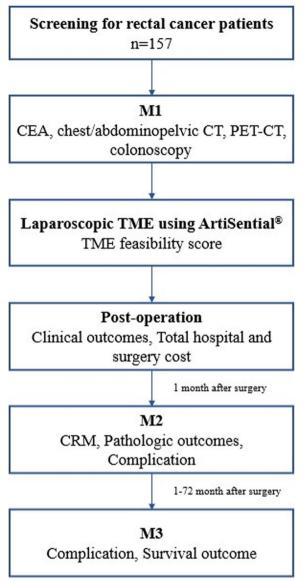


Fig. 1 Flow chart

Adherence to intervention protocols

To ensure adherence to the intervention protocols, several strategies will be employed in this study. First, all participating surgeons must have prior experience with laparoscopic cancer surgeries using articulated instruments, ensuring familiarity with the intervention. Additionally, the surgeons participating in this study will perform the surgery according to the currently standardized colorectal cancer surgical techniques. Regular monitoring will be conducted through surgical video reviews, case discussions, and compliance assessments. To further enhance adherence, periodic audits and feedback sessions will be implemented to identify deviations and

reinforce adherence to protocol guidelines. The study will also include a data collection and monitoring system to track protocol compliance, with investigators reviewing intraoperative and postoperative data for quality assurance. Any deviations from the protocol will be documented and analyzed to implement corrective actions where necessary.

Surgical intervention

All patients will receive a second-generation cephalosporin as a prophylactic antibiotics and anti-thrombotic prophylaxis with pneumatic compression stockings. All participating surgeons performed at least 10 laparoscopic rectal cancer surgeries using articulated instruments. All patients who participated in this study will undergo laparoscopic surgery following the standard procedure of low anterior resection. The procedure of total mesorectal excision (TME) was performed using articulated instruments on one hand for at least 50% of the total TME time.

Management and assessment

The primary outcome of this study is to compare the positive rate of circumferential resection margin (CRM) in rectal cancer patients who were treated with low anterior resection using laparoscopic procedure and robotic procedure. As a secondary outcomes, this study compares the clinical, oncologic, and cost-effectiveness outcomes. After enrollment, patients will undergo preoperative evaluations, including general medical history, digital rectal examination, laboratory test, colonoscopy, and radiologic examination. TME feasibility score is recorded by the surgeon immediately after completing the surgery. The TME feasibility score quantifies the surgeon's evaluation of the dissection of the posterior, lateral, anterior, and deep posterior planes during total mesorectal excision (TME) surgery, ranging from 0 (impractical) to 10 (extremely easy). Oral intake will be started the day after surgery unless obstructive symptoms are reported. The timing of discharge from hospital will be determined by the surgeon, considering achievement of pain control without the need if intravenous or intramuscular analgesics, tolerance of soft diet, independent ambulation, and absence of significant complications or any other medical concerns. Investigators will check the clinical outcomes, total hospital cost, and surgical cost on the day of the patient's discharge. Moreover, investigators will check and record the pathologic outcomes including CRM and occurrence and severity of complications within one month after surgery. All patients will undergo regular outpatient follow-up observations for up to five years after surgery. We show the detailed schedule of the assessment in Fig. 2.

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	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Close-out
TIMEPOINT**	- t 1	0	t ₁ (peri-op)	t ₂ (1 mo after op)	t₃ (5 years after op)
ENROLMENT:					
Eligibility screen	х				
Informed consent	х				
Allocation		х			
INTERVENTIONS:					
Laparoscopic TME using ArtiSential®			х		
ASSESSMENTS:					
TME feasibility score			х		
Clinical outcome			Х		
Total hopital cost, Surgical cost			х		
CRM, Pathologic outcomes				х	
Complication				Х	Х
Survival data	1				X

op, operation; mo, month; TME, total mesorectal excision; CRM, circumferential resection margin

Fig. 2 Schedule of enrolment, interventions, and assessments

Sample size calculation

Based on a previous randomized clinical trial, we hypothesize that the positive rate of circumferential resection margin after robotic surgery would be 6.1% [7]. A trial with 157 patients contributing to the primary outcome analysis would have 80% power to declare non-inferiority with a 5.2% non-inferiority margin, assuming a 10% dropout rate.

Statistical analysis

The results were reported as means and standard deviations for continuous outcomes, and as frequencies and percentages for categorical outcomes. Categorical variables were analyzed using the chi-square test or Fisher's exact test and continuous variables were examined with a Student's *t*-test or Mann–Whitney *U* test. Logistic regression analysis will be performed to conduct univariate and multivariate analysis. Using the log-rank test for univariate analysis, the Kaplan-Meier method was used to examine the overall survival and the disease-free survival. To compare laparoscopic TME group and robotic TME group, we adjust for variables such as gender, T stage, N stage, sphincter saving status, and preoperative chemoradiation using propensity score matching. Additionally, patients will be classified into low, mid, and high rectal cancer groups based on tumor location, and further analyses will be conducted within each group to compare the differences between the two surgical methods and assess their feasibility and oncologic safety. A *P*-value of less than 0.05 was regarded as statistically significant. SPSS statistics software was used for the statistical analysis (version 25; IBM Corp., Armonk, NY, USA).

Data collection and monitoring

The researchers will perform the data collection. The data will be collected using an Access database by researchers and will monitor the included data. Independently on the findings of the present study, we intend to publish it in a peer-review journal. The local ethics committee does not require a data monitoring committee since only low-risk interventions will be performed. No interim analyses are planned. The only stopping guideline is when the planned sample size is reached.

The trial is managed by a coordinating center, which ensures adherence to the study protocol. A Trial Steering Committee provides strategic oversight, ensuring ethical and scientific integrity. The coordinating center is responsible for protocol implementation, site coordination, data management, and regulatory compliance. To maintain effective governance, weekly meetings are held to monitor trial progress, address operational challenges, and ensure data integrity. Additionally, a monthly newsletter will be distributed to all researchers to share updates on the current trends and progress of the study.

A Trial Monitoring Unit, led by the PI, convenes regularly to audit trial procedures and report findings. This

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structured governance framework facilitates efficient trial execution, enhances data reliability, and promotes transparent communication among all participants of the study.

Safety evaluation and reporting of adverse event

Adverse events and serious adverse events should be reported to protect the patients. Serious adverse events which could result in death or life-threatening will be reported within 24 h from the detection by investigators. If the treatment in the clinical trial causes any side-effects, compensation will be made to the patients according to the prescribed rules.

Protocol amendments

Any changes to the protocol will follow a structured notification process. The PI will notify all participating centers about the changes. A copy of the revised protocol will be provided to the PI, who will ensure that it is appropriately added to the investigator site file at each site. Additionally, any deviations from the approved protocol will be fully documented using a breach report form to ensure transparency and compliance with regulatory requirements. Furthermore, all protocol amendments will be updated in the clinical trial registry to maintain accuracy and ensure that all participant of the study have access to the most current version of the study protocol.

Confidentiality

All study-related information will be stored safely using a locked file cabinet in an area with limited access.

Reporting of the study results

The results of the study will be released to the participation investigators and patients. The study will be published, regardless of the magnitude or direction of the effect.

Discussion

Robotic TME offers significant technological advantages compared to laparoscopic TME using straight and rigid laparoscopic instruments, especially in the narrow bony pelvis. Furthermore, robotic platform can provide the steady camera motion, tremor filtering, endo-wrist function and enhanced 3-dimentional view leading to make precise anatomical dissection with less blood loss and tissue injury. These theoretical benefits of robotic platform suggest that robotic TME could make superior outcomes compared to laparoscopic TME. Indeed, many studies have reported better clinical outcomes in patients undergoing robotic TME, including lower complication rates, shorter hospital stays, and improved quality of life, while maintaining similar oncologic outcomes to

laparoscopic TME [16–18]. However, most of these studies are non-randomized, retrospective, and either single or multi-institutional, leading to some controversies in their findings. Furthermore, some randomized controlled studies were conducted for comparing the two platforms for TME, but there were still controversies to results. REAL trial reported that robotic surgery was associated with the less CRM involvement and better short-term outcomes compared to laparoscopic surgery [19]. However, ROLARR trial failed to show the reduced risk of conversion to open laparotomy and positivity of CRM [6]. Recently, Park et al. reported in multi-center randomized controlled trial (COLRAR trial) that the rates of complete TME, positivity of CRM and complication rates were not different between the robotic and laparoscopic group [20].

Several laparoscopic articulated instruments have been developed as viable alternatives to robotic systems in minimally invasive surgeries [21]. These instruments, which can be flexed or curved into an arc shape, allow for enhanced joint movement control via handle manipulation. This feature, operated by the user's thumb, either through a joystick or ball, has historically led to technical challenges and limited their widespread adoption. However, the ArtiSential® is a pistol-handle instrument that possesses a comprehensive articulating function akin to the human wrist, along with an intuitive controllability. Some studies recently reported the clinical application of laparoscopic articulated instruments in various surgical fields. Kang et al. reported that laparoscopic gastrectomy using articulated instruments was significantly associated with shorter total operation times and faster bowel recovery than conventional laparoscopic gastrectomy using straight laparoscopic instruments [22]. Zubarevich et al. used the instruments for cardiac surgery including mitral, aortic and tricuspid valve procedure, closure of atrial septum defect, and myxoma resection to maintain a sufficient range of motions due to narrow surgical field [23]. Giovanni el al. novely applied the ArtiSential® for pediatric surgery including thoracoscopic thymectomy and hepatic lymphagnioma debulking [24].

Recent randomized controlled trials have also focused on the cost-effectiveness of robotic TME compared to laparoscopic TME. Feng et al. reported that the total hospital and surgical costs were higher for robotic TME than for laparoscopic TME. Similarly, Park et al. showed that robotic rectal cancer surgery costs were 2.3 times higher than laparoscopic surgery, primarily because robotic surgery is not reimbursed by the National Health Insurance Service [20]. This results in a direct patient payment of approximately US \$6000–8000 more for robotic rectal excision compared to laparoscopic procedures.. However, there are no studies on

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the cost-effectiveness of comparing articulated laparoscopic surgery to robotic surgery in colorectal cancer surgery. Lee et al. reported the cost-effectiveness of laparoscopic gastrectomy with articulated instruments compared with robotic gastrectomy (operation cost, USD, 6303 \pm 96 vs. 7546 \pm 149, p< 0.001) [25]. With lower medical costs for patients compared to robotic surgery, it reduces the financial burden on households, and more effective surgery compared to conventional linear instruments, leading to higher recovery rates and decreased complications. Therefore, we anticipate that the study could contribute to the stability of the nation's healthcare insurance finances.

A prospective randomized controlled study could be the most ideal. However, due to the expensive cost of robotic surgery, there are several anticipated challenges in realistically conducting research. Despite investing substantial costs over an extended period, the ROLARR trial failed to demonstrate the superiority of robotic TME over laparoscopic TME [6]. Therefore, we aim to establish a prospective arm cohort for laparoscopic TME using articulated instruments and retrieve a retrospective cohort for previously conducted robotic TME for historical comparison. To minimize potential selection bias, we plan to perform propensity score matching through a literature review to identify factors influencing CRM, such as gender, T stage, N stage, sphincter saving status, and preoperative chemoradiation. While various options exist for selecting the primary endpoint, considering the historical strength of CRM as an oncologic surrogate marker and the fact that many institutions report the CRM, we have taken CRM into account [26, 27].

In conclusion, we expect to validate the scientific evidence supporting the clinical significance of an articulated instrument in laparoscopic TME for rectal cancer and establish its clinical validity.

Trial status

This is version 5.5 of the protocol and was registered on CRIS (KCT0008896) on November 24, 2024. Patient recruitment started in August 2023, and 25 patients have been enrolled to date. Recruitment is expected to be completed by March 2027, and all participants will complete the follow-ups by March 2028.

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-025-08847-1.

Supplementary Material 1.

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None

Patient public involvement

In the ATOME trial, patient and public involvement was not explicitly included in the protocol design. However, recognizing the increasing importance of patient-centered care and the active participation of patients and the public in clinical research, future studies may consider incorporating structured involvement. Including patient perspectives in protocol development can enhance study relevance, improve participant engagement, and strengthen overall research outcomes.

Informed consent materials

These are available from the corresponding author on request.

Authors' contributions

Conceptualization, formal analysis, methodology: SUB, KEK, SKB, SHL, DRL, HKH, JK, SIK, GMS, SYL, CHK, KHL, GWH, HJK, WBJ, WKJ, WRK. Data curation: SHK, NSS, JHK, TGL, MJK. Writing—original draft: KEK, SUB. Writing—review and editing: HSR, SYP, KEK, SUB. The authors read and approved the final manuscript.

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Data availability

The datasets analyzed during the current study and statistical code are available from the corresponding author on reasonable request, as is the full protocol

Declarations

Ethics approval and consent to participate

The protocol was approved by the Institutional Review Board of Keimyung University Dongsan Medical Center (IRB No. DMC-2023–06-034). This clinical trial was registered in the Clinical Research Information Service (CRIS registration KCT0008896).

Consent for publication

We hereby provide consent for the publication of the manuscript detailed above, including any accompanying images or data contained within the manuscript that may directly or indirectly disclose our identity. We understand that this information will be freely available online, and accessible to the general public. We understand that under the Trials terms of publication, this information may be reproduced and used for other purposes, including commercial uses. We acknowledge that this will reduce our actual privacy to the extent of the content of the manuscript. We confirm that I have been given the opportunity to view the manuscript prior to publication, and we understand that once published, it cannot be removed from the published record except in exceptional circumstances.

Competing interests

All authors have no competing interests to declare.

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