Comparison of surgical outcomes between end-to-side and side-to-side anastomosis after laparoscopic right hemicolectomy: a prospective randomized controlled trial

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Participant Information Sheet and Consent Form

Participant Screening Number:

Study Title: Comparison of surgical outcomes between end-to-side and side-to- side anastomosis after laparoscopic right hemicolectomy: a prospective randomized controlled trial

Principal Investigator: Professor Sung-Bum Kang,
Department of Colorectal Surgery,
Seoul National University Bundang Hospital

We sincerely invite you to participate in this research study. This study has been approved by the Institutional Review Board (IRB) of Seoul National University Bundang Hospital, which is responsible for protecting the rights of clinical trial participants.

Before you decide whether to participate in this study, it is important that you fully understand why this research is being conducted and what your participation will involve. The information below is provided to explain the details of this study, including its purpose, procedures, and any precautions involved. It also outlines your rights, including your ability to withdraw from the study at any time.

Please read this participant information sheet carefully and listen to the explanation provided by the research team before making your decision. If you choose to participate, you will receive a copy of this document, including the consent form, for your records.

If you have any questions, please feel free to ask the principal investigator or research staff before making your final decision about participating in this study.

1. The Clinical Trial is Conducted for Research Purposes

This clinical trial is conducted for research purposes and aims to compare two already validated and safe surgical (anastomosis) methods. It does not involve testing a new treatment method.

2. Purpose of This Clinical Trial

The purpose of this study is to compare two anastomosis (reconnection) methods—end-to-side anastomosis and side-to-side anastomosis—following the resection of the right colon, including the tumor, in right-sided colon cancer surgery. This study aims to determine which method provides better surgical outcomes.

The surgical procedure for right-sided colon cancer aims to achieve complete resection of the tumor, lymph nodes, and surrounding tissues. After the bowel resection, the remaining intestinal segments must be reconnected (anastomosed). Two widely used anastomosis techniques involve the use of a stapler: side-to-side anastomosis and end-to-side anastomosis (Refer to the diagram for anastomosis methods).

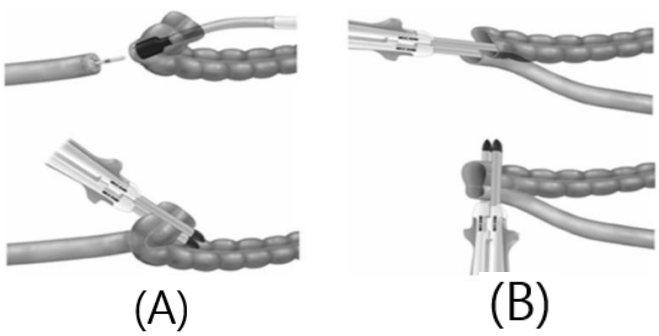

Figure. (A) end-to-side anastomosis (B) side-to-side anastomosis

The use of a surgical stapler for bowel anastomosis has been shown to significantly reduce the risk of anastomotic leakage, a severe complication of bowel anastomosis, compared to hand-sewn techniques. Both side-to-side and end-to-side anastomosis methods using a stapler are considered safe and widely accepted surgical techniques. However, no randomized controlled trials have been conducted globally to compare the surgical outcomes of these two stapled anastomosis techniques. Previous small-scale studies have failed to demonstrate a significant difference between the two methods.

Recently, with advancements in minimally invasive surgery, particularly laparoscopic surgery, postoperative hospital stays have been shortened, and early recovery programs have been more widely implemented compared to open surgery. As a result, questions have arisen regarding whether differences in anastomosis techniques could influence short-term surgical outcomes. However, no global studies have been conducted to compare these methods in this context.

While both anastomosis methods are internationally recognized as safe and standard procedures, it remains unclear which method provides superior outcomes. The primary objective of this study is to compare the short-term surgical outcomes, including recovery rates, failure rates of early recovery programs, and complication rates, between these two anastomosis techniques.

If our study identifies a superior anastomosis method with better short-term outcomes, it could provide valuable guidance for selecting the optimal anastomosis technique in right-sided colon cancer surgery, ultimately improving patient care.

3. Probability of Random Assignment

A total of 130 participants are expected to enroll in this clinical trial. Each participant will be randomly assigned to one of two groups—either the end-to-side anastomosis group or the side-to-side anastomosis group—through computer-generated randomization. The probability of being assigned to either group is 50%.

4. Procedures and Examinations, Including Invasive Interventions

This clinical trial does not involve any additional tests or procedures beyond standard medical care. All preoperative and postoperative examinations and treatments will be conducted in the same manner as for non-participating patients. The only difference between study participants and non-participants is the random assignment of the anastomosis method.

5. Participant Responsibilities

If you decide to participate in this clinical trial, you are expected to comply with the following guidelines:

- You will not be entitled to any special privileges or rights different from those of non-participating patients.
- Medical treatment will be provided without discrimination, and there will be no unreasonable decisions regarding your care. We expect you to follow the medical team's guidance accordingly.

6. Comparison of Two Established Surgical Methods

This clinical trial does not aim to test a new surgical (anastomosis) technique. Instead, it compares two existing, well-established, and standard anastomosis methods that are already considered safe and effective.

7. Expected Risks or Discomfort for Participants

There are no additional risks or discomforts expected for participants compared to non-participating patients. Since this study compares two standard and widely used anastomosis techniques, the level of risk remains the same as in routine clinical practice.

8. Lack of Direct Benefit to Participants

Participants in this clinical trial should be aware that they may not receive any direct benefits from their participation. This study is conducted for research purposes to compare two standard anastomosis techniques, and individual participants may not experience any additional advantages compared to standard treatment. However, the findings of this study may contribute to improving surgical outcomes for future patients.

9. Alternative Treatment Options and Their Potential Risks and Benefits

Surgery is the primary treatment for colon cancer, and this clinical trial aims to compare two already validated anastomosis techniques. Choosing not to participate in this study will not result in an alternative treatment approach. Regardless of participation, all patients will undergo the same laparoscopic right hemicolectomy, and the potential risks and benefits of the procedure remain the same.

10. Compensation and Treatment for Potential Injuries Related to the Clinical Trial

During the clinical trial, the medical team will make every effort to ensure your safety. In the event of a serious adverse reaction, appropriate and prompt medical interventions will be provided to minimize any potential harm.

If any harm occurs as a result of this study, the principal investigator, Professor Sung-Bum Kang, will take full legal responsibility. Compensation will be provided in accordance with applicable regulations, and all necessary medical treatments will be administered using the best available methods to address the adverse reaction.

11. No Financial Compensation for Participation

Participants in this study will not receive any financial compensation for their participation.

12. Expected Costs for Participants

There will be no additional costs associated with participating in this study. Participants will be responsible for standard medical expenses, such as surgical fees, hospitalization costs, and treatment fees, which are similar to those incurred by non-participating patients.

13. Voluntary Participation and the Right to Refuse or Withdraw

Before or during the study, you have the following important rights:

- The right to be fully informed about all aspects necessary to make an important decision regarding participation in the study.
- The right to receive medical treatment without discrimination.
- The right to refuse participation in the study at any time.
- The right to withdraw from the study at any time.

Your participation in this study is entirely voluntary. You have the right to decline participation, and you may withdraw your consent and discontinue your participation at any time without any disadvantage or penalty. Regardless of your decision, you will continue to receive the same standard of care from the same medical team.Additionally, your consent to participate in this study does not waive any of your legal rights. In the event of a medical dispute, your participation in this study will not be used against you or negatively impact your rights as a patient.

14. Confidentiality of Participant Information

All records containing identifiable personal information will be kept strictly confidential. If the results of this clinical trial are published, your personal information will remain protected and will not be disclosed.

All data collected in this study will be strictly confidential and protected to ensure patient privacy. If you agree to participate in this study, the data collected will be handled anonymously. Even if the study results are published, the personal information of participants will remain confidential and protected. Additionally, please be assured that your data will not be used for any purposes other than research and medical care.

15. Notification of New Information That May Affect Participation

If any new information that may influence your decision to continue participation in this study becomes available, the investigator will promptly inform you or your legal representative.

16. Access to Medical Records for Study Monitoring and Regulatory Compliance

During and after the clinical trial, authorized personnel, including monitors, inspectors, the Institutional Review Board (IRB), and the Ministry of Food and Drug Safety, may review your medical records to verify the procedures and data reliability of the clinical trial. This review will be conducted within the scope permitted by confidentiality regulations.

By signing the consent form, you or your legal representative acknowledge and agree that these authorized personnel may access relevant medical records for verification purposes while ensuring the protection of your personal information.

17. Contact Information for Study-Related Inquiries and Reporting Adverse Events

You or your legal representative may contact the following individuals at any time for inquiries, concerns, or in the event of any study-related injury:

- **Principal Investigator:** Professor Sung-Bum Kang, Department of Colorectal Surgery, Seoul National University Bundang Hospital
- **Study Coordinator:** Seong-Il Kang, Fellow, Department of Colorectal Surgery, Seoul National University Bundang Hospital
    - **Contact:** +82-31-787-6451 (Note: The study coordinator may change annually.)
- **IRB or Clinical Research Ethics Center Contact for Concerns Regarding Participant Rights:**
    - **Contact:** +82-31-787-8801~8804

18. Reasons for Discontinuation of Participation in the Clinical Trial

Your physician may decide to withdraw you from the study if you fail to follow the study protocol, if there are medical reasons, or for any other reason deemed necessary by the investigator. Possible reasons for discontinuation include:

- You or your legal representative request to withdraw from the study.
- You undergo additional surgery, take medications, or use other medical devices that may significantly affect the evaluation of safety or efficacy.
- A serious adverse event occurs.
- You fail to comply with the investigator's instructions or with the conditions outlined in the consent form, impacting the reliability of the study results.
- You become unavailable for continuous observation due to non-participation.
- You pass away due to reasons unrelated to the clinical trial.
- Any other circumstance in which the investigator determines that continuing the trial is not feasible.

19. Estimated Duration of Participation in the Clinical Trial

If you participate in this clinical trial, your involvement will last approximately one month after surgery. No additional outpatient visits or examinations beyond standard care will be required.

20. Estimated Number of Participants in the Clinical Trial

This study is a single-center clinical trial conducted at Seoul National University Bundang Hospital, with a total of 130 participants expected to enroll.

21. Additional Information

- If you decide to participate in this study after reviewing the provided information, you will be required to sign a separate consent form, including your name and date in handwriting.
- You will receive a copy of both the participant information sheet and the signed consent form for your records.

Participant Consent Form

Study Title: Comparison of surgical outcomes between end-to-side and side-to- side anastomosis after laparoscopic right hemicolectomy: a prospective randomized controlled trial

Participant Screening Number:

- I have received a verbal explanation about this clinical study, read the provided participant information sheet, and discussed the study in detail with the research staff.
- I have been informed about the potential risks and benefits of this study and have received satisfactory answers to all my questions.
- I voluntarily agree to participate in this study.
- I understand that I can refuse to participate or withdraw from the study at any time without affecting my future medical treatment and that my decision will not result in any disadvantage or harm to me.
- By signing this information sheet and consent form, I agree that my personal information may be collected and processed by the researchers within the scope permitted by applicable laws and regulations for medical research purposes
- I understand that I will receive a copy of this participant information sheet and consent form.

I hereby agree to participate in this study of my own free will.

	Name	Signiture	Date
Participant			year month day
Participant's Legal Representative (if applicable)			year day
	Relationship to Participant : _____ Detailed reasons: _____		
Principal Investigator (or Co-Investigator)			year month day

If applicable

	Name	Signiture	Date
Witness			year month day