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Impact of a digital surgical workflow including Digital Device Briefing Tool on morbidity and mortality in a patient population undergoing primary stapled colorectal anastomosis for benign or malignant colorectal disease: protocol for a multicentre prospective cohort study

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ABSTRACT

Introduction With growing emphasis on surgical safety, it appears fundamental to assess the safety of colorectal resection involving primary stapled anastomosis. Surgical stapling devices can considerably foster patient safety in colorectal surgery, but their misuse or malfunction encompass a unique risk of postoperative complications. The Digital Device Briefing Tool (DDBT) is a digital cognitive aid developed to enhance safe use of the Ethicon circular stapling device during colorectal resection. The purpose of this study is to evaluate how a digital operative workflow, including DDBT, compared with routine surgical care, affects morbidity and mortality in patients undergoing left-sided colorectal resection with primary stapled colorectal anastomosis for colorectal cancer or benign disease.

Methods and analysis A multicentre, prospective cohort study will be conducted at five certified academic colorectal centres in Germany. It compares a non-digital with a Johnson & Johnson digital solution (Surgical Process Institute Deutschland (SPI))-guided operative workflow in patients undergoing left hemicolectomy, sigmoidectomy, anterior rectal resection and Hartmann reversal procedure. The sample size is set at 528 cases in total, divided into 3 groups (a non-digital and two SPI-guided workflow cohorts, with and without DDBT) in a ratio of 1:1:1, with 176 patients each. The primary endpoint is a composite outcome comprising the overall rate of surgical complications, including death, during hospitalisation and within the first 30 days after colorectal resection. Secondary endpoints include operating time, length of hospital stay and 30-day hospital readmission rate.

Ethics and dissemination This study will be performed in line with the Declaration of Helsinki. The ethics committee of the Charité—University Medicine Berlin, Germany, approved the study (No: 22-0277-EA2/060/22). Study Investigators will obtain written informed consent from each patient before a patient may participate in this study. The study results will be submitted to an international peer-reviewed journal.

Trial registration number DRKS00029682.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A strength of this study is that its primary endpoint is a composite outcome comprising 19 adverse events commonly associated with left-sided colorectal resection frequently seen after colorectal surgery.
⇒ Severity of the adverse events in patients undergoing left-sided colorectal resection using a non-digital and the SPI-guided operative workflow including Digital Device Briefing Tool will be objectively evaluated by scoring each of them according to the Clavien-Dindo classification of surgical complications.
⇒ An external full-service clinical research organisation will support and closely monitor the entire study execution in Germany, ensuring that all study activities will be fully compliant with national and international good clinical practice, data protection, data privacy and all regulatory requirements.
⇒ This multicentre observational study will be performed in real-world surgical settings, reflecting the standard of care of five certified academic colorectal centres in Germany, while contributing to better generalisability of surgical outcomes than single-centre studies would do.
⇒ The study might face difficulties in enrolling patients because emergency colorectal surgeries are excluded and patient inclusion is only possible if left-sided colorectal surgery, including primary stapled anastomosis, is performed with one specific circular stapling device.

INTRODUCTION

Colorectal cancer is one of the most prevalent malignancies worldwide, with more than 1.9 million new colorectal cancer cases and 935 000 deaths estimated to have occurred in 2020, mostly reported in Europe and North America.[1] Colorectal surgery is perceived as a potentially curative treatment for this malignancy, but concerns have emerged due to highly prevalent postoperative morbidity directly related to the colorectal resection, including but not limited to anastomotic leak, bleeding, wound or organ space infection and gastrointestinal motility complications such as ileus and bowel obstruction.[2 3] Evidence has shown that overall complication rates can go up to 35% and overall mortality rates range from 1% to 16.4% following colorectal surgery.[2–5] Therefore, it is crucial to reliably conduct the best surgical practices that improve the safety of colorectal resection, reducing the rate of preventable surgical complications and patient harm.[6 7]

Improvement in patient outcomes after rectal cancer resection was reported due to the implementation of the standardised surgical technique known as total mesorectal excision (TME).[8] Broad acceptance of the TME technique decreased the local recurrence rate of mid-low rectal cancer from 40% to less than 10% and was associated with a continuous improvement in patient survival.[8–10]

Similarly, notable improvements in surgical outcomes for colon cancer patients were found after implementing the surgical technique known as complete mesocolic excision (CME).[11–13] By using the standardised CME technique, the local 5-year recurrence rate in colon cancer was reduced from 6.5% to 3.6% and the colon cancer-related 5-year survival rate in patients resected for cure increased from 82.1% to 89.1%.[11]

Furthermore, the introduction of enhanced recovery after surgery (ERAS), discharge and home follow-up, as well as hospital infection prevention protocols, resulted in a significant reduction of postoperative morbidity, including overall and superficial surgical site infection rates and hospital readmission rates associated with colorectal surgery.[14–20]

Latest evidence has identified that reliability of surgical care could be further increased by automating and digitalising operative workflows in operating theatres (OT). One study reported that a novel Johnson & Johnson digital solution (Surgical Process Institute Deutschland GmbH (SPI)), developed for use in OT, can support the creation of reliable operative workflows and guide operating teams in a step-by-step fashion through surgery, reducing unwarranted variation of the applied surgical technique.[21] The SPI software allows OT teams to also include important safety checks into the digital operative workflow, such as the surgical safety checklist (SSC).[21 22]

The SSC was earlier developed to improve surgical care adherence, teamwork and communication.[23–25] Utilisation of the SSC resulted in a 47% reduction in overall mortality and a 36% reduction in overall complication rates after major surgery.[23] Other studies confirmed that the SSC and similar cognitive aids may foster patient safety by acting against the negative consequence of surgeon's emotional stress, unproductive teamwork and the inability to remind the surgical team in the everyday clinical practice of all evidence-based actions required in case of critical events.[26–28]

Nowadays, different types of checklists to reduce postoperative complications are frequently used in colorectal surgery, such as those described here.[29–34] They are increasingly imposed through a variety of professional and regulatory mandates, especially in North America and Europe, serving as evidence of due diligence and performance of care teams with respect to prevention of patient harm.[26–28] However, concerns have emerged since behavioural compliance to checklists has been shown to be highly variable, with inconsistent performance occurring notably when the checklist becomes a trivial exercise in 'checking the box'.[24]

This has coincided with recent reports from established healthcare agencies pointing out that the misuse of surgical stapling devices or their malfunction additionally represent a unique risk of major morbidity after colorectal surgery.[35 36] The Food and Drug Administration issued a warning letter to healthcare providers emphasising the risks of unsafe use of surgical stapling devices, as their malfunctions or misuse can result in serious surgical complications including death.[36] Accordingly, a generic medical device briefing tool was developed for use in surgical settings as a powerful communication tool, particularly to improve quality of first-time use of different types of medical devices in OT through improved teamwork and timely preparation of surgical teams.[37]

Ultimately, it seems that further reducing overall postoperative morbidity after colorectal surgery might be accomplished by using synergistic benefits of digital technology, combining a digital operative workflow with behavioural aids, to create a more reliable care process for the entire surgical team in OT.[21–28]

Study objectives

This study aims to evaluate whether implementing the SPI-guided operative workflow, including the cognitive aid for surgical stapling named Digital Device Briefing Tool (DDBT), compared with the routine surgical care, impacts postoperative morbidity and mortality in patients undergoing left-sided colorectal surgery with primary stapled anastomosis for colorectal cancer or benign disease. The DDBT was specifically designed for deployment within the SPI-guided operative workflow to enhance safety of primary stapled colorectal anastomosis. A secondary aim is to evaluate the postoperative economic outcomes including operating time, length of hospital stay and 30-day readmission rate.

METHODS AND ANALYSIS

Study design

A multicentre, prospective, observational cohort study will be conducted at five certified colorectal centres, including four university medical centres and one

academic teaching hospital in Germany: Charité—University Medicine Berlin, Campus Benjamin Franklin; University Medicine Marburg, Campus Fulda; Otto-von-Guericke University Magdeburg, University Hospital Magdeburg; Friedrich-Alexander-University Erlangen-Nürnberg, University Clinic Erlangen and the Klinikum Magdeburg. These colorectal centres will be appropriate study sites based on their characteristics regarding the standardisation of the operative workflows, including both digital and non-digital workflow settings, in which colorectal surgery is performed. A principal investigator (PI) at each site will be appointed to lead the project locally and the hospital administration will support the intervention. A local data collector will be determined at each site and will receive training and supervision from the primary investigators in the identification and classification of surgical complications and process measures.

Study population

A total of 528 consecutive adult patients will be enrolled within 48 months from study start, establishing three different study cohorts with 176 prospectively enrolled patients each: A, B, C. Inclusion will start at the first hospital in December 2022. Inclusion will continue until the number of required patients is reached. All patients will undergo a left-sided colorectal surgery with primary stapled anastomosis for colorectal cancer or benign disease, comprising left hemicolectomy, sigmoidectomy, anterior rectal resection and Hartmann reversal procedure, according to the centres' standard of care. Colorectal resections will be performed using either laparoscopic, open or robotic surgical techniques and equipment, including the Ethicon circular stapler (Johnson & Johnson, USA) used for primary stapled colorectal anastomosis. A representative patient sample will be recruited from investigators' available local patient population.

Setting

The study environment involves the routine, non-digital operative workflow at the two colorectal centres in Magdeburg and at the three remaining colorectal centres, their SPI-guided operative workflow with and without a DDBT. At study start, the two colorectal centres performing left-sided colorectal surgery with non-digital operative workflows will build the study cohort A, enrolling 176 consecutive patients (figure 1). Contemporaneously, the three other colorectal centres performing surgery using the SPI-guided operative workflow, will build the study cohort B, by enrolling 176 consecutive patients undergoing left-sided colorectal resection (figure 1). After collecting real-world baseline data within the digital and non-digital surgical settings, all five colorectal centres will be given information about identified process characteristics, intraoperative and postoperative complications and their differences. Thereafter, the three colorectal centres previously performing surgery using the SPI-guided operative workflow will implement the digital cognitive aid for surgical stapling, DDBT, into their SPI-guided operative

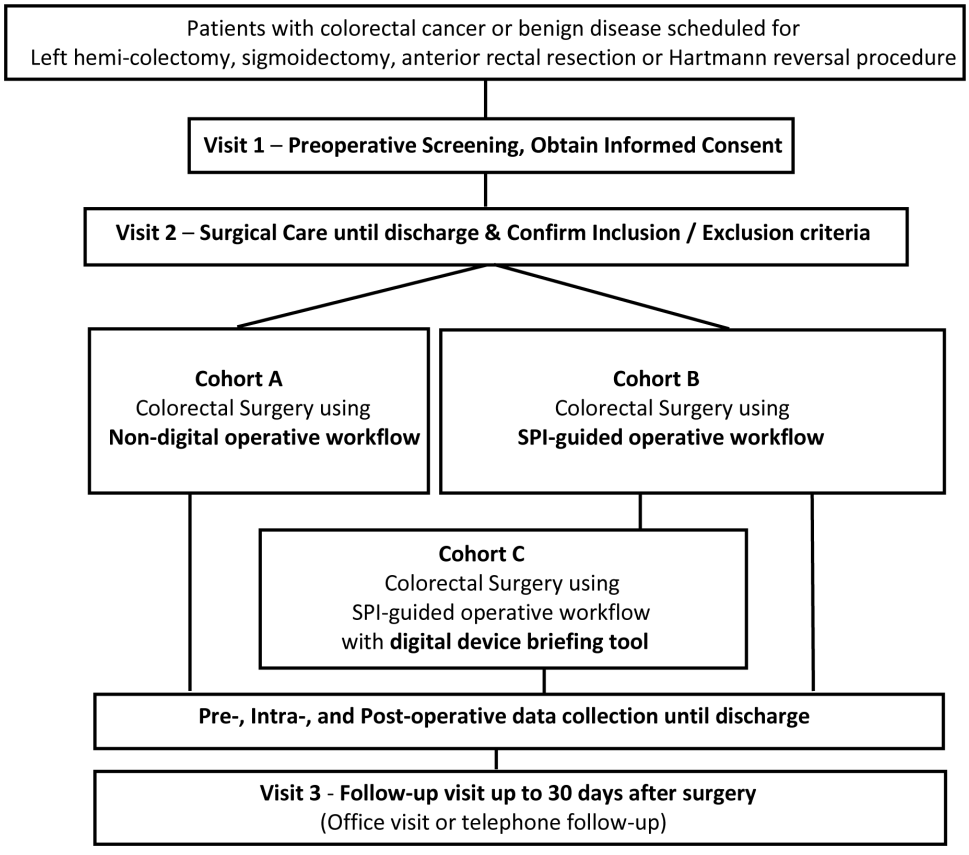

Figure 1 Trial scheme. SPI, Surgical Process Institute Deutschland.

workflow, hereby establishing cohort C, by enrolling another 176 consecutive patients undergoing left-sided colorectal resection with primary stapled colorectal anastomosis (figure 1).

Inclusion criteria

Patients satisfying the following criteria will be considered eligible for enrolment in this study:

1. Adult patients undergoing left hemicolectomy, sigmoidectomy, anterior rectal resection or Hartmann reversal operation for benign disease or colorectal cancer where open, laparoscopic or robotic technique will be performed and the Ethicon circular stapler is used for colorectal anastomosis.
2. Willingness to give consent to and comply with all evaluations and visit schedule that are part of the study centres' standard of care.

Exclusion criteria

Patients meeting the following criteria will be considered ineligible for enrolment in this study:

1. Preoperative.
   a. Physical or psychological condition which would impair study participation.
   b. The procedure is a revision/reoperation for the same indication or same anatomical location.
   c. The procedure is an emergency colorectal surgery.
2. Intraoperative.
   a. Non-restorative surgery (colorectal anastomosis not made).
   b. Study stapling device (Ethicon circular stapler) not attempted.

Comparison groups

Cohort A: non-digital operative workflow

In the control cohort A, patients will undergo left-sided colorectal resections performed according to the colorectal centres' standard of care, including a routine, non-digital operative workflow.

Cohort B: SPI-guided operative workflow

In the study cohort B, patients will undergo left-sided colorectal surgery performed with the SPI-guided operative workflow, helping OT teams to prepare, coordinate, evaluate and document surgery. It guides the care team through surgery in a step-by-step fashion by displaying the sequences of the workflow on dedicated OT screens and shows the previous, the current and the next surgical procedure step, as well as the actual and predicted ending time of surgery, including interaction possibilities to advance to the next workflow segment. Unwarranted deviations from the predefined operative workflow, such as management of possible adverse events, are noticed and entered into the system, based on the care teams' professional medical judgement. All sequences of the operative workflow are contemporaneously visible to all team members in real time, ensuring behavioural compliance to all steps of the applied surgical technique. At any time, the surgical crew retains final authority to execute the steps of the SPI-guided operative workflow, according to their expertise, medical judgement and patient safety needs. After surgery, operative workflow notes and comments documented within the SPI software will be used to generate the surgical report. This offers OT teams the possibility to retrospectively evaluate surgical techniques and trace any deviation from the applied surgical approach, enabling future surgeries to be carried out reliably, with less workflow interruption.[15]

Cohort C: SPI-guided operative workflow including DDBT for stapled colorectal anastomosis

In the study cohort C, patients will undergo the left-sided colorectal surgery performed with the SPI-guided operative workflow containing the DDBT. The DDBT is a digital cognitive aid developed to enhance safe use of the Ethicon circular stapler. It is deployed within the digital

Table 1 Digital Device Briefing Tool (DDBT)

No.	Steps of the DDBT
a) Team briefing	
1	Verbally confirm the stapling device to be used: 'During this operation, we're going to use the Ethicon circular stapler, which is intended to perform the colorectal anastomosis. Are the team members aligned?'
2	Verbally confirm review of the stapling device Instruction for Use: 'I confirm that I've reviewed the materials for the Ethicon circular stapler and that I have no questions about the use or setup of the Ethicon circular stapler? Have you reviewed them?'
3	Verbally confirm stapling device readiness for use: 'Is the Ethicon circular stapler prepared appropriately and ready to use?'
4	Verbally confirm readiness of the team members to speak-up: 'If you have any questions or concerns during the operation, please speak up'
b) Surgeon's Do-Confirm Checklist	
1	Surgeon confirmed: 'Set the device to the correct range (green area)?'—(yes/no)
2	Surgeon confirmed: 'Closed stapler till snug?'—(yes/no)
3	Surgeon confirmed: 'Waited for a minimum of 15 s?'—(yes/no)
4	Surgeon confirmed: 'Retightened the stapler after the 15 s waiting?'—(yes/no)
5	Surgeon confirmed: 'Completed full firing sequence?'—(yes/no)
6	Surgeon confirmed: 'Cut-washer auditive sign noticed?'—(yes/no)
7	Surgeon confirmed: 'Correctly opened and removed the stapler?'—(yes/no)
8	Surgeon confirmed: 'Complete anastomotic donuts?'—(yes/no)

Table 2 Surgical complications assessed in the primary endpoint

Surgical procedure-related intraoperative and postoperative adverse events	General clinical complications associated with colorectal surgery
Anastomotic leakage	Cardiac arrest requiring cardiopulmonary resuscitation
Anastomotic bleeding	Coma of 24 hours duration or more
Anastomotic stenosis	Death
Bleeding (any haemorrhagic complication)	Deep vein thrombosis
Bleeding requiring the transfusion of four or more units of red cells within the first 72 hours after surgery	Myocardial infarction
Burst abdomen/wound dehiscence	Pneumonia
Postoperative ileus including obstruction (colon obstruction, rectal obstruction, small bowel obstruction)	Pulmonary embolism
Sepsis	Stroke
Surgical site infection (any)	Unplanned intubation
Unplanned returns to the operating theatre	

operative step named colorectal anastomosis time out. The first part of the DDBT includes four briefing points related to the colorectal anastomosis and the necessary OT team preparation tasks (table 1). The second part includes a surgeon's Do-Confirm Checklist, providing a cognitive aid for the operating surgeon related to the critical handling steps of the stapling device according to its instructions for use (table 1). Thus, the DDBT assists both the surgical team and the operating surgeon to successfully carry out primary stapled colorectal anastomoses, aiming to improve safe use of the stapling device. Behavioural compliance to all standardised steps of the DDBT are documented within the SPI software.

Outcome measures

The primary endpoint of the study is a composite outcome comprising the overall rate of surgical complications, including death, during hospitalisation and within the first 30 days after colorectal surgery with primary stapled colorectal anastomosis. PIs at all study centres will assess the severity of surgical complications by rating each of them as mild, moderate or severe and by scoring each of them according to the Clavien-Dindo classification.[38] For this study, a surgical complication is defined as any deviation from the normal postoperative course, including any undesirable clinical event that may be attributable to the surgical procedure or specifically to the stapling device used to create the colorectal anastomosis and which might be expected during the left-sided colon resections and up to 30 days after colorectal surgery. This comprises all surgical procedure-related intraoperative and postoperative adverse events commonly associated with left-sided colectomy procedures as well as general clinical complications frequently seen after colorectal surgery (table 2).

Secondary endpoints consist of operating time (measured from surgical incision to the end of suture in minutes), length of patient hospital stay (in days) and 30-day readmission rate (in per cent).

Table 3 Schedule of activities per visit

Activity	Visit 1 Screening visit (−56 to −1 days)	Visit 2 Procedure (day 0)—discharge	Visit 3 Postprocedure follow-up visit (day 30)
Informed consent	X		
Demographics and baseline characteristics	X		
Review of inclusion/exclusion criteria	X	X	
Surgical data collected for evaluation		X	
Concomitant procedures conducted		X	
Digital Device Briefing Tool used		X	
Procedure-related adverse events		X	X
General clinical complications		X	X
Patient completion/discontinuation			X
Readmission			X

Table 4 Demographics and baseline characteristics

Category	Preoperatively collected patient data
General demographics and characteristics	Age, sex, ethnicity, body weight, body height, smoking status, immunosuppressive therapy
Physical status	American Society of Anaesthesiologists Physical Status Classification System
Cancer staging	American Joint Committee on Cancer TNM Classification System
Comorbidities	Cardiac disease, defined as a history of congestive heart failure, myocardial infarction, angina within 1 month of surgery, percutaneous coronary intervention or cardiac surgery
	Pulmonary disease, defined as dyspnoea with moderate exertion or at rest, history of severe chronic obstructive pulmonary disease or current pneumonia
	Liver diseases (any)
	Preoperative renal failure, defined as acute renal failure in the 24 hours prior to surgery or preoperative acute or chronic haemodialysis
Comorbidity index	Charlson Comorbidity Index
Laboratory values	White and red blood cell count, creatinine, platelet count, haematocrit

Patient visits and follow-up

According to the centres' standard of care, consecutive patients will be screened and consented anytime during a period of 8 weeks prior to the date of planned colorectal surgery and will be followed prospectively until discharge or for 30 days after performed colorectal resection, whichever came first, for postoperative complications and death. All activities performed at each patient visit are listed in table 3.

Data collection and data management

All preoperative (table 4), intraoperative and postoperative (table 2) research parameters will be collected prospectively. Data will be collected using an electronic database capture system, which will be used by the study centres' personnel to transfer study data from the study centres source records such as electronic health records into common electronic case report forms (eCRFs). Each eCRF will be completed by the local PI or PI's designee. A unique ID number will identify each patient and will be visible on each eCRF. At no time will the patient's name appear on the eCRFs. The collection, use and disclosure of all personal data, including patient health and medical information, will be maintained in compliance with applicable personal data protection and security laws and regulations that govern protected health information and the informed consent given by each study patient. By collecting and processing personal data, appropriate measures will be taken to maintain the confidentiality of patient health and medical information and to prevent access by unauthorised persons. The study centre PI will review and approve each completed eCRF. The study centres will allow the sponsor or its representatives (such as the external clinical research organisation) as well as other governmental regulatory agencies to inspect all study records, eCRFs and corresponding portions of the patient's office and/or hospital medical records at regular intervals during the study. These inspections aim to verify adherence to the protocol and integrity of the data being captured on the eCRFs, including data quality assurance steps which will be taken to assure the accuracy and reliability of the data as well as compliance with applicable regulations. The entire research project execution, including data collection and management, will be supported, and closely monitored by an external full-service clinical research organisation to ensure that all study activities will be compliant with national and international good clinical practice, data protection, data privacy and all regulatory requirements.

Statistical analysis

Overall, 3 comparisons are planned for the primary endpoint, as well as each of the 3 secondary endpoints (12 comparisons in total). The comparisons include cohort A versus cohort B, cohort B versus cohort C and cohort A versus cohort C. For the surgical composite outcome and hospital readmission, a risk difference will be calculated, while for operating time and hospital length of stay mean differences will be calculated. Given the possibility of confounding, interpretation of all

Table 5 Sample outcome table

Outcome	Cohort A (n=xxx)	Cohort B (n=xxx)	Cohort C (n=xxx)	Cohort B–cohort A (95% CI)	Cohort C–cohort A (95% CI)	Cohort C–cohort B (95% CI)
Composite surgical complications	Events (%) xx (xx.x%)	Events (%) xx (xx.x%)	Events (%) xx (xx.x%)	xx.x% (xx.x% to xx.x%)	xx.x% (xx.x% to xx.x%)	xx.x% (xx.x% to xx.x%)
Hospital readmission	Mean (SD) xx (xx.x%)	Mean (SD) xx (xx.x%)	Mean (SD) xx (xx.x%)	xx.x% (xx.x% to xx.x%)	xx.x% (xx.x% to xx.x%)	xx.x% (xx.x% to xx.x%)
Operating time (min)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx)	xxx.xx (xxx.xx to xxx.xx)	xxx.xx (xxx.xx to xxx.xx)	xxx.xx (xxx.xx to xxx.xx)
Length of stay (days)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx)	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)	xx.xx (xx.xx to xx.xx)

effect estimates will be based on covariate balanced data (results for unbalanced data will be presented as well for descriptive purposes). Point estimates as well as two-sided 95% CIs will be presented. The general approach to covariate balancing is to balance each pair of groups being compared. Therefore, for each pairwise comparison, we first identify a treatment and control group, with the convention that groups labelled treatment contain the surgical process component of interest. Therefore, we have: cohort A (control) versus cohort B (treatment), cohort B (control) versus cohort C (treatment) and cohort A (control) versus cohort C (treatment). For each pairwise comparison, we fit a propensity score model in which the outcome is treatment group assignment, and the predictors are the measured confounders. We then assign weights to patients to estimate the average treatment effect on the treated. Generally, patients in the treatment group all receive weights of 1 and patients in the control group receive weights not equal to 1 that make them resemble the treatment group with respect to the measured covariates. Balance on measured covariates is evaluated prior to and after propensity score weighting using absolute standardised differences. A weighted outcome analysis is used to estimate the risk differences and mean differences in this study. In this approach, the treatment group estimate is based on unweighted statistics (mean, proportion) and the control group estimate is based on weighted statistics (weighted mean, weighted proportion). The difference between the treatment and control group is the point estimate of the treatment effect. A variance of this treatment effect is based on the sum of variances in the two groups being compared. In the treatment group, the variance is based on conventional methods for estimating a variance (asymptotic variance for a proportion) and in the control group a variance is based on a non-parametric bootstrap (500 replicates). Subgroup analyses will be performed on each of the four colorectal study procedures, considering which of the standard surgical technique was used. Table 5 lays out how the statistical analysis will be presented.

Sample size justification and level of significance

The sample size required to achieve adequate study power was considered. For the primary composite endpoint, the proportion of safety events in the control group is assumed to be 0.40 and 0.26 in the intervention group. This large effect was observed in a previous study regarding the SSC.[23] With 80% power and an alpha=0.05 (two sided), based on a two-sample test for a difference in proportions using a Pearson χ^2 test (implemented in PROC POWER in SAS, V.9.4), the minimum required sample size is 176 in each group for a pairwise comparison. The level of significance is set at p=0.05.

Patient and public involvement

None.

ETHICS AND DISSEMINATION

Ethics approval

Ethical approval for this study was obtained from the ethics committee (EC) of the Charité—University Medicine Berlin, Germany, (No: 22-0277-EA2/060/22) on 7 October 2022. Additionally, local ethical approval will be obtained at each participating centre. This study will be conducted in compliance with Good Clinical Practice and in accordance with the Declaration of Helsinki, as well as other applicable local and country regulatory requirements.

Patient information and consent

The EC of Charité—University Medicine Berlin approved informed consent documents (ICDs), which will be used in this study. Study investigators will obtain written informed consent from each patient before a patient may participate in this study. All patients in this study will be completely informed about the purpose, risks, benefits and other pertinent details of this study. The ICD will be presented in native, non-technical language that is understandable to the patient. The patient will be provided a copy of the signed ICD. The ICD will be revised whenever new information becomes available that may be relevant to their willingness to participate or continue participation in this study. Revision to the ICD and other written materials will receive EC approval before implementation.

Publication and dissemination

The study results will be submitted to an international peer-reviewed journal. The Strengthening the Reporting of Observational Studies in Epidemiology checklist for cohort studies will be used as a reporting guideline for the final manuscript.[39] The findings will also be disseminated through relevant international meetings and conferences and will be used for further research and technology development as well as possible change in clinical practice.

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Contributors JL, KB and PMC: Conceptualisation, methodology, validation, writing—review & editing. CL: Conceptualisation, methodology, validation, writing—review & editing, funding acquisition. GR: Conceptualisation, methodology, validation, writing—original draft, writing—review & editing, visualisation, project administration. AH, RSC, KR, CK and MK: Conceptualisation, validation, writing—review & editing. All authors approved the study protocol for publication in its present form.

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