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Preoperative electroacupuncture versus sham electroacupuncture for the treatment of postoperative ileus after laparoscopic surgery for colorectal cancer in China: a study protocol for a multicentre, randomised, sham-controlled trial

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ABSTRACT

Introduction Postoperative ileus (POI) is a postoperative complication that can cause lingering recovery after colorectal resection and a heavy healthcare system burden. Acupuncture aims to prevent postoperative complications, reduce the duration of POI, help recovery and shorten hospital stays. We hypothesise that preoperative electroacupuncture (EA) can promote POI recovery under the enhanced recovery after surgery protocol after laparoscopic surgery in patients with POI.

Methods and analysis This is a multicentre, randomised, sham-controlled trial. A total of 80 patients will be enrolled and randomly assigned to the EA or sham electroacupuncture (SA) group. The eligible patients will receive EA or SA for one session per day with treatment frequency starting on preoperative day 1 for four consecutive days. The primary outcome is the time to first defecation. The secondary outcomes include the time to first flatus, length of postoperative hospital stay, time to tolerability of semiliquid and solid food, postoperative nausea, vomiting, pain and extent of abdominal distention, time to first ambulation, preoperative anxiety, 30-day readmission rate, the usage of anaesthetics and analgesics during operation, length of postanaesthesia care unit stay. A mechanistic study by single-cell RNA sequencing in which postintervention normal intestinal tissue samples will be collected. The results of this study will provide evidence of the effects of acupuncture on POI and promote good clinical decision to millions of patients globally every year.

Ethics and dissemination This study has been approved by the ethical application of Beijing University of Chinese Medicine (2022BZYLL0401), Beijing Friendship Hospital Affiliated to Capital Medical University(2022-P2-368-02), Cancer Hospital Chinese Academy of Medical Science (23/175-3917), Huanxing Cancer Hospital (2023-002-02). The results will be published in a medical journal. In addition, we plan to present them at scientific conferences.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ A multicentre randomised controlled trial design enhances the study's richness and credibility.
⇒ Amsterdam Preoperative Anxiety and Information Scale provides an assessment.
⇒ Providing enhanced recovery after surgery to patients in the perioperative period is conducive to improving the speed and quality of postoperative recovery.
⇒ This study was undertaken in public hospitals in China, which demonstrates that it is feasible to undertake this trial in these settings, but the findings may not necessarily be generalisable to other settings.

Trial registration number ChiCTR2300077633.

BACKGROUND

Surgery remains the most commonly used treatment for colorectal cancer which is the third most common cancer worldwide.[1] Due to irritation of the intestine during the procedure, almost all patients have postoperative ileus (POI) which is one of the most common postoperative complications.[2] POI is characterised by delayed gastrointestinal (GI) recovery, including abdominal distension, delayed passage of flatus and stool, and inability to tolerate oral food.[3] Commonly, nasogastric tubes must be inserted in patients for GI decompression.[4] This increases the risk of associated postoperative morbidity and leads to prolonged hospital discharge.[5] This leads to an approximately double cost

of hospital admission as a consequence of a substantial economic burden, not only for individuals but also for the healthcare system.[6]

Many measures to reduce POI, including the use of a nasogastric tube for sputum aspiration, venous transfusion, parenteral nutrition and restoring GI motility through simple exercise, have been explored. Chewing gum and drinking coffee are cost-effective interventions, however, the evidence remains debatable.[4] The US Food and Drug Administration (FDA) approved the only drug for the treatment of POI, alvimopan, which is important for the management of POI. However, conflicting data on the efficacy and cost of alvimopan, as well as concerns about cardiovascular complications, limit its clinical use.[7] The enhanced recovery after surgery (ERAS) protocol as a strategy can be likely to translate clinical manifestations into better outcomes.[8] Even within an established ERAS protocol, the reported incidence of prolonged POI (PPOI) after colorectal surgery is high.[9]

Acupuncture is a potential treatment option for GI diseases.[10 11] Previous trials have predominantly focused on postoperative intervention with acupuncture.[10 12] Recently, our study also showed that electroacupuncture (EA) can reduce the duration of POI and the risk for PPOI compared with sham electroacupuncture (SA) in patients undergoing laparoscopic excision of colorectal cancer with the ERAS protocol.[12] Based on its effectiveness and safety,[10 12 13] acupuncture deserves to be promoted in the various phases of perioperative management, especially preoperative acupuncture which has unique advantages. It has been reported that preoperative EA can treat postoperative nausea and vomiting and promote the recovery of GI function.[14] In addition, preoperative preconditioning may reduce the pain associated with POI in advance and reduce the risk of intraoperative and postoperative disease. It has been reported that acupuncture can improve the patients' preoperative status and supplement anaesthesia to reduce the risk of intraoperative anaesthesia.[15] In addition, patients who receive preoperative acupuncture have greater acceptance and tolerance, moreover, do not have to worry about postoperative infection compared with patients who receive postoperative acupuncture.

Currently, no trials have provided clinical evidence of the effect of preoperative EA on POI. The clinical efficacy of preoperative EA in preventing POI under the ERAS protocol will be demonstrated as a matter of urgency. To evaluate the efficacy and safety of preoperative EA, we designed a multicentre, randomised controlled trial for POI after laparoscopic excision of colorectal cancer under the ERAS protocol.

METHODS

Trial objectives

The primary objective is to estimate the efficacy of preoperative EA and SA in reducing the time to first defecation with the ERAS protocol. The secondary objectives of this study were to determine the possible effects have on time to first flatus, length of postoperative hospital stay, time to tolerability of semiliquid and solid food, postoperative nausea, vomiting, pain and extent of abdominal distention, time to first ambulation, preoperative anxiety, 30-day readmission rate, usage of anaesthetics and analgesics during operation, length of post-anaesthesia care unit (PACU) stay.

Trial design

This is a multicentre, sham-control, randomised trial. The patients and assessors will be blinded. Eligible patients will be randomly assigned by concealed allocation into preoperative EA or SA groups. Both groups will undergo ERAS. The trial has obtained ethical approval and registering the protocol (V.2.0 December 2021) was designed in accordance with the Standard Protocol Items: Recommendations for Interventional Trials[16] (online supplemental file 1). The trial flow diagram is shown in figure 1 and the schedules of the recruitment, intervention and assessment points are illustrated in figure 2.

Trial setting

We plan to recruit approximately 80 patients from three participating hospitals. The Beijing Friendship Hospital Affiliated to Capital Medical University (Beijing, China) is a general hospital and the Cancer Hospital Chinese Academy of Medical Sciences (Beijing, China) is a specialised hospital, both are government-funded, 'class A tertiary' hospitals and teaching hospitals. Huanxing Cancer Hospital(Beijing, China) is a specialised hospital.

Patients

In this trial, all patients diagnosed with colorectal cancer who have been scheduled for laparoscopic surgery will be recruited through hospital ward. Written informed consent will be obtained from eligible patients before randomisation (online supplemental file 2). A secondary screening will be performed after operation to ensure that 40 patients are included in each intervention group.

Inclusion and exclusion criteria

Patients who are going to undergo elective laparoscopic surgery for colorectal cancer will be recruited through inpatient wards. The clinical research coordinator will conduct the interviews to assess whether the participants meet the inclusion and exclusion criteria. Eligible patients will be informed of the trial before the surgery. Written informed consent will be provided by eligible patients before randomisation.

Inclusion criteria are as follows: (1) male or female patients aged >18 years; (2) patients diagnosed with colorectal cancer who have been scheduled for laparoscopic surgery; (3) patients with American Society of Anesthesiologists grades[17] I–III and (4) patients who sign the informed consent.

Patients who meet one or more of the following standards will be excluded. Exclusion criteria are as follows: (1) patients who received epidural anaesthesia; (2) patients whose laparoscopic surgery should be synchronised with other organs resection; (3) patients who required

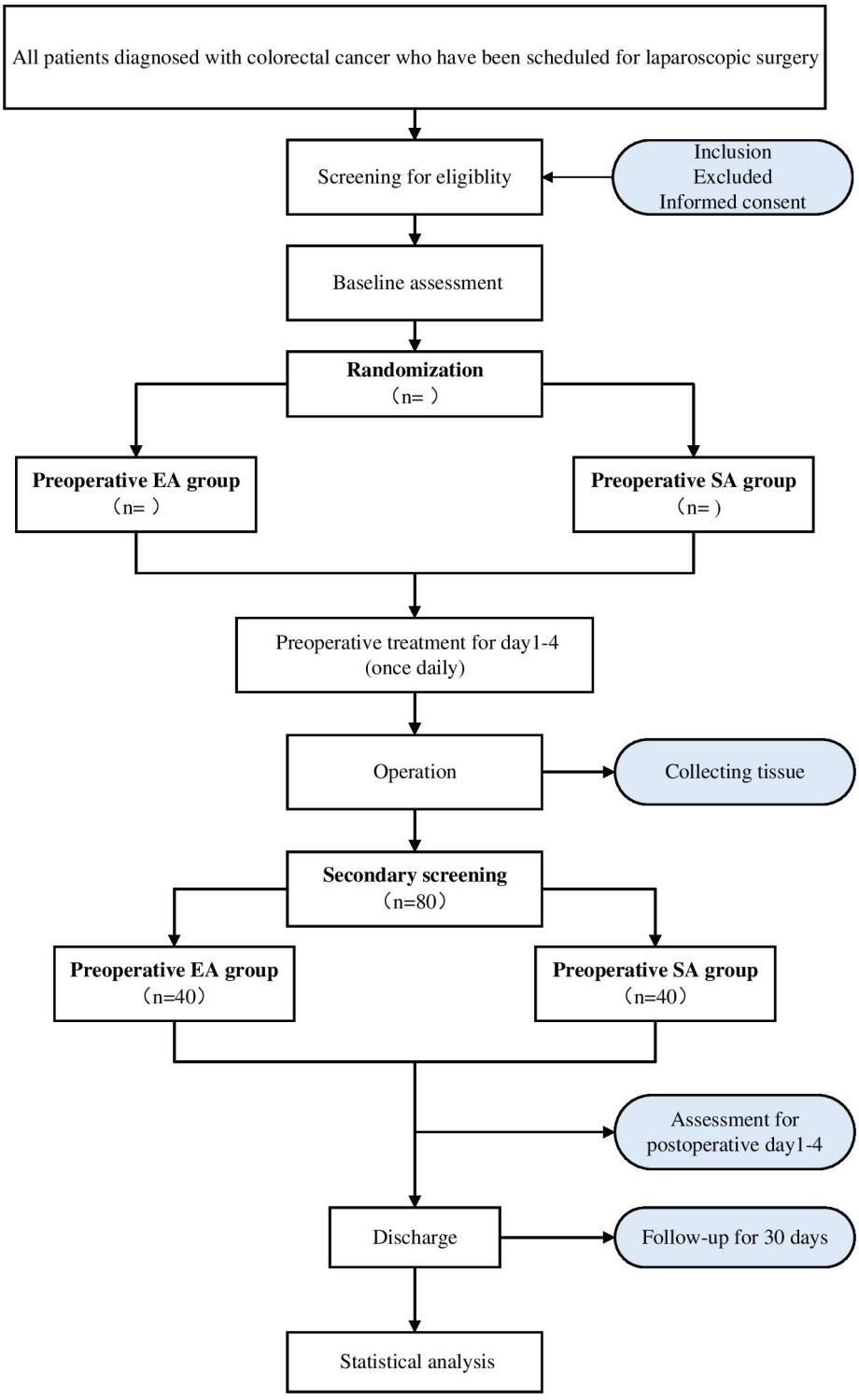

Figure 1 CONSORT diagram of the trial procedure. EA, electroacupuncture; SA, sham electroacupuncture; CONSORT, consolidated standards of reporting trials.

conversion from laparoscopic surgery to open surgery or underwent total colorectal resection; (4) patients with intraoperative and postoperative complications requiring long-term (>1 day) intensive care; (5) patients who require stoma creation; (6) patients with a history of mental disorders or alcohol or drug abuse; (7) patients who have been received acupuncture treatment within 1 month prior to the trial; (8) patients with electrical stimulation devices (eg, pacemakers or implantable defibrillators) and (9) patients who have participated in other clinical studies.

Randomisation and allocation

Eligible patients will be randomly assigned to receive preoperative EA or SA at a 1:1 ratio. A randomisation sequence, which is stratified by centres with block sizes, will be generated by an independent statistician using

The schedule of trial enrolment,interventions and assessments												
	Preoperative period					Operation	Postoperative period				Discharge	Follow-up
	Enrolment	Intervention					Intervention					30-day after discharge
Enrolment	**Day 0**	**Day 1**	**Day 2**	**Day 3**	**Day 4**		**Day 1**	**Day 2**	**Day 3**	**Day 4**		
Eligibility screening	○											
Informed consent	○											
Randomization	○											
Medical history	○											
Intervention												
EA		←	—	—	→							
SA		←	—	—	→							
Usual care		←	—	—	—	—	—	—	—	→		
Assessments												
Time to first defecation							←	—	—	→		
Time to first flatus							←	—	—	→		
Length of postoperative hospital stay											○	
Time to tolerability of semiliquid and solid food							←	—	—	→		
Postoperative nausea							○	○	○	○		
Postoperative vomiting							○	○	○	○		
Postoperative pain							○	○	○	○		
Postoperative extent of abdominal distention							○	○	○	○		
Time to first ambulation							←	—	—	→		
Preoperative anxiety					○							
30-day readmission rate												○
Usage of anesthetics and analgesics during operation.						○						
length of Post-Anesthesia Care Unit (PACU) stay						○						
Collecting samples						○						
Adverse events		←	—	—	—	—	—	—	—	→		

Figure 2 Schedule of trial enrolment, interventions and assessments. EA, electroacupuncture; SA, sham electroacupuncture.

SAS V.9.4 (SAS Institute). Randomisation numbers are retained by administrators who do not participate in trials, evaluation and statistics. Each time an eligible patient is included, the randomisation number is requested by telephone from the administrators by the screening officer. During the trial, the randomisation sequence should not be disclosed to other researchers who specialise in the subject in order to conceal the tasks. The acupuncturists who performed the trials are not blinded. Patients, outcome assessors and statisticians will be blinded to the allocation. A secondary screening will be performed after operation and the patients will be randomised.

Trial withdrawal

Patients are withdrawn if they withdraw their consent or do not complete the course and observation cycle provided for in the stated programme. When the patient is withdrawn, the investigator should, as far as possible, contact the subject to ask for reasons and refine the assessment point. No additional supplements are needed for the withdrawn patients.

Trial suspension

During the trial, patients will be terminated if any of the following conditions occur: patients with serious adverse reactions, serious complications (eg, infections, surgical site necrosis.) or requiring secondary surgery, fistula, etc. Physicians determine on a case-by-case basis the need to terminate the trial; patients should be treated as invalid cases when they have other characteristics affecting trial observation and acupuncture treatment cannot be completed; third, the implementation of clinical trials produces significant deviations from the protocol, and it is difficult to assess the effectiveness of acupuncture; and patients do not wish to continue the experiment and ask the appropriate physician to withdraw from the trial.

Trial intervention

Standardised care with ERAS

Standardised anaesthetic procedures and regular postoperative care protocols will be consistently applied to patients during the trial. On arrival in the operating room, the ECG, non-invasive blood pressure, pulse oxygen saturation, partial carbon dioxide pressure at the end of exhalation, double frequency index and body temperature are monitored using a standard anaesthesia monitor. The anaesthetist adjusted the concentration of the anaesthetic infusion according to the haemodynamic index and the double frequency index. Preoperative EA

and SA both which follow the Chinese consensus and clinical guidelines for ERAS.[18] The use of additional drugs is not prohibited during the trial.

Electroacupuncture

EA will be performed by licensed acupuncturists with at least 3 years of treatment experience. All the acupuncturists will receive standardised training prior to the trial. The eligible patients will receive one session of EA per day with treatment frequency starting on preoperative day 1 for four consecutive days. Acupuncture starts on the first day after admission if surgery occurs less than 4 days after admission. The stimulation will continue for 30 min. The intervention will be reported following the Standards for Reporting Interventions in Clinical Trials of Acupuncture guidelines.[19]

EA will be provided with *Zusanli* (ST36, bilateral), *Shangjuxu* (ST37, bilateral), *Neiguan* (PC6, bilateral), *Zhongwan* (RN12) and *Tianshu* (ST25, bilateral) as treatment acupoints. According to traditional Chinese acupuncture theory, the selected acupoints are associated with GI function. Locations of the acupoints were in accordance with the WHO Standard Acupuncture Locations.[20] The locations of the acupoints are presented in figure 3 and table 1.

After disinfection of the surrounding skin, suitable-size acupuncture needles will be inserted perpendicular to the skin. Twirling and rotating, and lifting and thrusting manipulations will be applied for 30 s at each acupoint until '*de qi*' sensation (soreness, numbness, distension or heaviness) is achieved.[21] Bilateral ST36 will receive electric stimulation (22Hwato SDZ-II) acupoint nerve stimulator, Suzhou Medical. The paired electrodes from the EA device will be attached to the needle handles. The frequency of the electrical stimulation will be set at 10 Hz. The intensity at the needle handle appears slightly trembling and the patient tolerates as appropriate.

Sham electroacupuncture

In the SA group, superficial skin (2–3 mm in depth) is needed to penetrate the patient. The acupuncturists do not perform any manipulations on the needles. The locations of the five non-acupoints are shown in figure 3 and table 2.

Bilateral non-acupoint 4 will receive electrical stimulation but has no current flow. The frequency of treatment is the same as that in the EA group.

Safety monitoring

During the trial, the patients will be required to report any adverse events (AEs), including acupuncture and non-acupuncture AEs. Bleeding, subcutaneous haematomas, numbness, bloating after the end of acupuncture treatment and other adverse effects will be recorded during acupuncture treatment. All AEs will be treated symptomatically as prescribed. Those who cannot be treated by the acupuncturist must be consulted and treated by the doctor of the corresponding discipline.

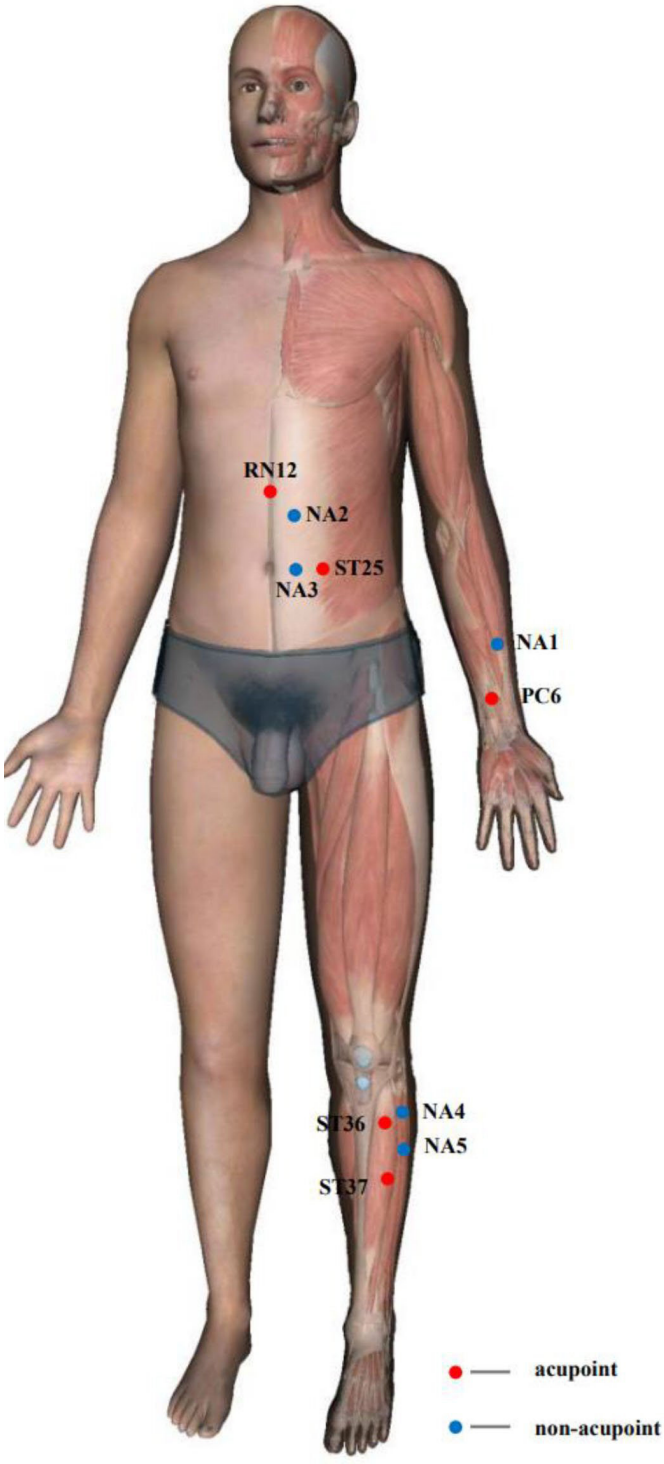

Figure 3 Locations of acupoints and non-acupoints. NA, non-acupoint.

Complications following surgery should be estimated by the Clavien-Dindo (online supplemental file 3) classification,[22] including anastomotic fistula (by imaging diagnosis such as enhanced scanner or secondary surgery judged); wound infection; intestinal adhesion and; PPOI (defined as if two or more of the following criteria are met on the fourth postoperative day: (1) nausea or vomiting,

Table 1 Locations of acupoints for the EA group

Acupoints	Locations
Tianshu (ST25)	2 cun* directly to the side of umbilicus.
Zhongwan(RN27)	In anterior median line, 4 cun directly above umbilicus.
Zusanli (ST36)	3 cun directly below *Dubi* (ST35), 1 finger-breadth lateral to the anterior border of the tibia.
Shangjuxu (ST37)	6 cun directly below *Dubi* (ST35), 1 finger-breadth lateral to the anterior border of the tibia.
Neiguan (PC6)	2 cun directly above wrist, the line between *Quze* (PC3) and *Daling* (PC7), and between the long tendon of the palm and the flexor tendon of the wrist on the radial side.

*1 cun (≈20 mm) is defined as the width of the interphalangeal joint of patient's thumb.
EA, electroacupuncture; PC, pericardium; ST, stomach.

(2) inability to tolerate an oral diet over last 24 hours, (3) abdominal distension and (4) radiologic confirmation).

AEs, including occurrence, duration, severity (symptoms and signs) and corresponding solution, will be immediately recorded in the patients' medical record. Serious AEs will be reported to the principal investigator (PI) and ethics office within 24 hours. Costs incurred for AEs related to interventions during trials will be addressed in accordance with applicable laws and regulations.

Outcome measures

Primary outcome

The primary outcome is the time to first defecation. It is defined as time interval between the first defecation and the end of laparoscopic surgery. Patients will be assessed daily by the outcome assessors and will be assisted by patients or their family members until the first defecation occurs. The final data will be recorded for minutes in case report forms by the outcome assessors as soon as possible. (online supplemental file 4)

Table 2 Locations of acupoints for the SA group

Non-acupoint	Locations
Non-acupoint 1	5 cun* directly above wrist, 2 cun directly lateral to *Ximen* (PC4).
Non-acupoint 2	3 cun directly above belly button, 1 cun on the left side of the front middle line.
Non-acupoint 3	1 cun directly lateral to the belly button.
Non-acupoint 4	In the middle of *Yanglingquan* (GB34) and *Zusanli* (ST36).
Non-acupoint 5	3 cun directly below *Yanglingquan* (GB34).

*1 cun (≈20 mm) is defined as the width of the interphalangeal joint of the patient's thumb.
GB, gallbladder; PC, pericardium; SA, sham electroacupuncture; ST, stomach.

Secondary outcomes

In order:

1. Time to first flatus: It is defined as the time to first flatus refers to the time from the end of laparoscopic surgery to the first passage of exhaust. Recording in the same way as the time to first defecation (online supplemental file 4).

2.Length of postoperative hospital stay: It is defined as continuous days spent in hospitalisation from the day of colorectal resection to the day of discharge to the community. It has six clinical criteria[18]: (1) proper functioning organs with the ability of free movement, (2) oral analgesics with good analgesia, (3) ability to tolerate a semiliquid diet, (4) wound healing well, no sign of infection, absence of other postoperative complications, (5) with home care and (6) the patients' agreement on discharge (online supplemental file 4).

3. Time to tolerability of semiliquid and solid food: It is defined as no symptoms of nausea and vomiting within 4 hour of eating semiliquid (ie, rice porridge, egg, soup and chicken custard) and solid food after laparoscopic surgery. If the event does not occur during hospitalisation, the patients should record the time and report to the assessors in a convenient way (online supplemental file 4).

4. Postoperative nausea, vomiting, pain and extent of abdominal distention: We will measure the degree of nausea, vomiting, pain and extent of abdominal distention over the previous 24 hours using Numerical Rating Scale[23 24] (online supplemental file 4) with scores ranging from 0 (no nausea at all) to 10 (worst nausea). It will be evaluated once per day from postoperative day 1 to day 4.

5. Time to first ambulation: The time to first get out of bed and ambulation after the operation will be recorded (online supplemental file 4).

6. Preoperative anxiety: We will measure the degree of preoperative anxiety using Amsterdam Preoperative Anxiety and Information Scale[25] (online supplemental file 5). It should be graded on a 5-point Likert scale from 1 (no anxiety at all to 5 (extremely anxiety)

7. 30-day readmission rate: To assess whether the patients have been readmitted within 30 days due to postoperative complications, the outcome assessor will be followed by telephone.

8. Usage of anaesthetics and analgesics during operation: The dosage and route of administration of the anaesthetics and analgesics used during the operation will be recorded accurately and in detail.

9. Length of PACU stay: The length of patients staying in PACU needs to be recorded.

Collecting samples

During the procedure, the biological samples of the intestinal tissues and blood of the participants will be used for further analysis. The samples of intestinal tissue retained

are normal tissues from the intestinal segments removed during the operation. The fresh samples will be immediately sent to the laboratory and subsequently analysed by single-cell RNA sequencing to provide new evidence of improvement in POI by EA. All patients will sign informed consent form prior to sample collection.

Blinding

Only the acupuncturist in the trial can be aware of the group allocation. The outcome assessors and data analysts will be blinded. Random numbers will be kept by the administrator who are not involved in the trial. On inclusion of an eligible patient, screening officer will request a random number from the administrator by telephone. Patient expectations and masking will be assessed after the first treatment. Revealing blinding after all data analysis. Patient masking (online supplemental file 6) and expectations (online supplemental file 7) will be assessed after the first treatment.

Data availability and management statement

On completion of the trial, the database will be preserved for at least 5 years after publication and made available for readers and reviewers if requested. Sharing raw data via ResMan platform of China's clinical trial registry within 6 months of trial completion. Patient information, including name, age and telephone number, will remain hidden. Due to the lack of intermediate analysis and high acupuncture safety, data monitoring committee will not be needed.

Quality control

The study protocol has been revised and reviewed by experts in acupuncture, surgeons, statistics and methodology. Before modification, the study protocol will be submitted to the ethics committee. The trial will be monitored at a frequency of 12 months by researchers from the Beijing University of Chinese Medicine.

Statistical analysis

Sample size

We based our sample size calculations on previous study.[12] According to previously published articles on postoperative EA for the treatment of POI, the median time to first defection which is the primary outcome, was 90 hours in the EA group and approximately 76 hours in the SA group, with a difference of 14 hours between the two groups. On the basis of a statistical power of 80% at a two-sided significance level of 5 %, the calculated number of subjects is 32 in each group. With the consideration of a 10% drop-out rate, eight additional subjects will be recruited to offset the potential attrition. Hence, we expect to enrol a target number of participants of 80 (40 per group).

Statistical methods

Based on intention-to-treat (ITT) analysis basis, including all randomly assigned patients. The measurement data are expressed as the mean±SD (M±SD) or as the median and IQR. The counting data are expressed as the number of frequencies, the composition ratio and the percentage. Patient characteristics will be analysed by analysis of variance or the χ^2 test.

All time-related items in outcomes, such as the time to first defecation and flatus, postoperative hospital stay, tolerability of semiliquid and solid food, first ambulation and patients staying in PACU, will perform as Kaplan-Meier curves to analyse differences in time-event variables. Statistical significance was calculated using a logarithmic rank test.

Independent sample t-tests or rank sum tests will be performed for differences in secondary outcomes, including analysis for nausea, vomiting, pain, extend of abdominal distension, preoperative anxiety, the dosage of anaesthetics and analgesics during the operation between the two groups.

AE rates will be compared between preoperative EA and SA by the χ^2 test. Missing data will be completed for the primary outcome by multiple interpolation. For secondary outcomes, missing data are not taken into account and actual observations are used for analysis. Multiple linear regression analysis will be performed to determine independent predictor of primary outcome. The surgical site (left half of the colon, right half of the colon and rectum) of the patients in the predefined subgroups will be analysed.

A bilateral test will be used with a test level of 0.05, a $p<0.05$ will be considered to indicate a statistically significant difference. The statistical analysis will be carried out using SPSS statistics version 27 .

Patient and public involvement

The trial results will be published in a peer-reviewed journal and presented at international conferences. Neither the patients nor the public will be involved in the design, conduct or reporting of the trial. The trial results will be shared with all patients at the end of the trial.

Trial status

This trial is currently underway. Recruitment for this trial started on 15 November 2023 and will be completed on 31 December 2024.

DISCUSSION

This trial provides the first high level of evidence for the possible benefit of preoperative acupuncture in reducing POI after laparoscopic surgery for patients with colorectal cancer patients. This trial will be conducted within a pragmatic protocol in which all other perioperative care is routine. Therefore, our findings will be highly generalisable to most hospitals worldwide.

The diversity of indications for acupuncture[26] is a potential benefit for its participation in preoperative ERAS interventions. Safety, efficacy and patient acceptance are important elements in a clinical practice. Acupuncture is generally safe.[27] Patients would benefit from being able to reasonably apply acupuncture prior

to surgery. Preoperative acupuncture can optimise the perioperative conditions of patients, and promote postoperative recovery.[14] Preoperative anxiety is related to the occurrence of AEs such as postoperative pain, postoperative nausea and vomiting, etc.[27 28] Therefore, we will assess whether preoperative anxiety relief has an impact on POI and postoperative recovery.

Acupuncture has been widely used for GI disease.[29] Surgical manipulation of the intestine can stimulate innate immune cells and cause an inflammatory response, leading to an inflammatory state in POI.[30] In our previous study, we found that EA improved GI transit by protecting smooth muscle cell layer to reduce local inflammation in mice model of POI.[31] Furthermore, EA suppressed the intestinal manipulation-induced inflammation via activating the α7nAChR-mediated JAK2/STAT3 signalling pathway and exciting the vagal nerve in mice model of POI.[32] Preoperative preconditioning with the α7nAchR agonist AR-R17779 can reduce postoperative inflammatory cell aggregation to prevent POI by activating STAT3 signalling.[33] Preoperative administration of the 5-HT4 receptor agonist prucalopride also inhibited myenteric macrophage activation and shortened the time to POI in mice via α7nAChR and was validated in human mechanistic experiments, where prucalopride reduced the expression of IL-6 and IL-8 in human intestinal myenteric tissues, resulting in faster recovery of GI function in the postoperative period of patients.[34] The evidence for these preoperative applications of medications to treat POI is similar to the mechanism of acupuncture, so we hypothesised that acupuncture could prevent POI. In addition, for more direct evidence in humans, we will choose to obtain normal tissue samples from intestinal segment that are removed during surgery to observe the inflammatory response. The whole process is in accordance with ethics.

We are aware of the inevitable limitations of our trial. First, we did not design a group with postoperative EA for comparison with preoperative EA. The main consideration is that the lack of blinding patients may affect the results of the trial. We will pay attention to whether differences in the effectiveness of preoperative acupuncture and sham-EA, exist to clearly identify the placebo effect, which is our primary goal. Second, this study was undertaken in public hospitals in China, which demonstrates that it is feasible to undertake this trial in these settings, but the findings may not necessarily be generalisable to other settings.

The results of this trial will provide evidence of the effect of acupuncture on POI and promote good clinical decisions to millions of patients globally every year.

ETHICS AND DISSEMINATION

This protocol has been approved by the Medical Ethics Committee of Beijing University of Chinese Medicine (2022BZYLL0401) and registered on Chinese Clinical Trials Registry (ChiCTR2300077633), Beijing Friendship Hospital Affiliated to Capital Medical University(2022-P2-368-02), Cancer Hospital Chinese Academy of Medical Science(23/175-3917) and Huanxing Cancer Hospital (2023-002-02). The participants' information will be kept anonymous and confidential and can decide to withdraw from the trial at any time. The findings will be shared in peer-reviewed publications irrespective of final results.

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Contributors C-ZL, Y-CY and YW conceived the idea behind the trial. C-ZL, YW, Y-CY, WP and JZ designed the study. YW is responsible for the statistical analysis. Y-CY, WP, JZ, JZ, G-YL, SL, CW, L-WW, Y-TY and N-NY helped with the implementation of the study. YW and Y-MF drafted and strictly revised the manuscript for important intellectual content. CZ-L sought funding. Y-CY, WP and JZ obtained the ethical approval. All authors have read and approved the final manuscript.

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SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Page
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, plans for seeking research ethics committee/institutional review board (REC/IRB) approval trial acronym	1-2
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	2
	2b	All items from the World Health Organization Trial Registration Data Set	2
Protocol version	3	Date and version identifier	5
Funding	4	Sources and types of financial, material, and other support	18
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	18
	5b	Name and contact information for the trial sponsor	1
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	18
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	not applicable

Introduction

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	3-4
	6b	Explanation for choice of comparators	3-4
Objectives	7	Specific objectives or hypotheses	4
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	5

Methods: Participants, interventions, and outcomes

Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	5
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	7-10
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	7
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	not applicable
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	7-8

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11-12
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	Figure 2
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	14
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	not applicable
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	6-7
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	6-7
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	6-7
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	6-7,13

	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	13
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	Supplementary file 3-7
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	12
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	14
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	14
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	14
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	13

	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	7
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	10-11
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	13
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	18
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	13
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	5-6
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	13
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	13
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	19
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	13

Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	8
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	18-19
	31b	Authorship eligibility guidelines and any intended use of professional writers	not applicable
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	not applicable
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary file 2
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	13

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

Supplementary file 2: Informed Consent

Informed Consent

Dear patient:

If you were diagnosed with colorectal cancer who have been scheduled for laparoscopic surgery, we invite you to participate in this study aiming to evaluate the efficacy of preoperative acupuncture for management of POI. You need to decide whether you want to participate or not. It is helpful for you to introduce about the study aim, procedures, benefits and risks of the study, inconvenience and potential discomforts during the study. This study is supported and funded by National Science Foundation for Distinguished Young Scholars (NO.81825024). Carefully read the following and feel free to ask the study doctor any question which you may have.

Why is this study being done?

Postoperative ileus (POI) which is one of the most common postoperative complications. POI is characterized by delayed gastrointestinal (GI) recovery, including abdominal distension, delayed passage of flatus and stool, inability to tolerate oral food. Many measures to reduce POI have been explored, including nasogastric tube for sputum aspiration, venous transfusion, parenteral nutrition and restoring gastrointestinal motility through simple exercise. But there are problems

with these treatments, such as side effects. Acupuncture is traditional Chinese medicine, which dates back more than 3,000 years. In recent years, the use of acupuncture as a treatment to the management of various gastrointestinal motility problem has gained increasing popularity worldwide.

Aim of the study

The aim of this study is to estimate the efficacy of preoperative electroacupuncture (EA) and sham electroacupuncture (SA) in reducing the time to first defecation with the ERAS protocol.

You will randomly be allocated to one of two groups:

A) Electroacupuncture Protocol

B) Sham electroacupuncture Protocol

Who should be in this study?

Patients who meet the criteria will be included in this study if they have the following:

(1) male or female patients aged>18 years.

(2) patients diagnosed with colorectal cancer who have been scheduled for laparoscopic surgery.

(3) patients with American Society of Anesthesiologists grades18 I-III.

(4) patients who sign the informed consent.

Patients will not be included in this study if you have the following:

(1) patients who received epidural anesthesia.

(2) patients whose laparoscopic surgery should be synchronized with other organs resection.

(3) patients who require conversion from laparoscopic surgery to open surgery or underwent total colorectal resection.

(4) patients with intraoperative and postoperative complications requiring long-term (> 1Day) intensive care; patients who require stoma creation.

(5) patients with a history of mental disorders or alcohol or drug abuse.

(6) patients who have been receiving acupuncture treatment within 1 month prior to the study.

(7) patients with electrical stimulation devices (pacemaker or implantable defibrillator).

(8) patients who have participated in other clinical studies.

How many POI patients will participate in the study?

We plan to recruit 80 patients.

Do you agree to biological sample collection during operation?

A) Yes

B) No

What risk effects may happen to me by participating in the study?

Acupuncture is a relatively safe procedure and few side-effects have been reported. You may feel nausea, dizziness and fainting during or after acupuncture treatment. Bleeding, hematoma, and other phenomena may occur after acupuncture treatment, but these phenomena will release and disappear after a few days of acupuncture treatment. If you feel any discomforts during the treatment, you need to tell your doctor about your conditions immediately and then the doctor will evaluate the condition and give you appropriate medical treatment.

What benefits can I expect?

Patients may benefit from a reduction in POI symptoms and promote postoperative recovery after EA treatment. The information will be beneficial in the management of other patients with a similar condition in the future. If you decide to participate in the study, you will get the study treatment for free during the study period.

Can I refuse to be in the study?

Whether you participate in this study or not is depending on your desire totally. You can choose not to take part in the study, or you can drop out at any time without your doctor permission during the study. If you quit the study, you will receive the standard treatment as other patients at our department clinic.

Confidentiality and privacy

All information about patients will be kept confidential by the research group members. Only the clinical research members who responsible for the study may have access to your medical records. Your name will not appear in any publication or report related to this study. We will make every effort to protect the privacy of your personal information.

How to acquire correlative information of the study?

If we notice any new information that may affect your decision to continue participating in the study, the doctor will keep you informed.

If you have any questions related to the study, please contact to Doctor * (Tel: ********).

If you have any questions related to your personal benefits, you can consult the Ethics Committee of *** Hospital (Tel: ****

I have read and understood this consent form. All my questions have been answered. I volunteer to take part in this study.

Patient's signature Patient's name Date

_____ _____ _____

Site Investigator’s signature Site Investigator’s name Date

_____ _____ _____

Supplementary file 3: Classification of Surgical Complications (Clavien-Dindo)

Grade	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic or radiological intervention
Grade IIIa	Intervention not under general anesthesia
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU
Grade IVa	Single organ dysfunction (including dialysis)
Grade IVb	Multiorgan dysfunction
Grade V	Death of a patient
Suffix “d”	If the patient suffers from a complication at the time of discharge (see examples in Table 2), the suffix “d” (for “disability”) is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

*Brain hemorrhage, ischemic stroke, subarrachnoidal bleeding, but excluding transient ischemic attacks.

CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.

Supplementary file 4: Daily assessment form during postoperative hospitalization

Daily assessment: from operation day to discharge day					
Pain	NRS_____				
Abdominal distension	NRS_____				
Nausea	NRS_____			frequency _____	
Vomiting	NRS_____			frequency _____	
Flatus	____h		Defecation	____h	
Tolerability to liquid	____h	Tolerability to semiliquid	____h	Tolerability to solid diet	_____h
Out of bed	_____h		Discharge	_____h	
Postoperative complications			Adverse events		

Supplementary file 5: The Amsterdam Preoperative Anxiety and Information Scale (APAIS)

1.I am worried about the anesthetic.

2.The anesthetic is on my mind continually.

3.I would like to know as much as possible about the anesthetic.

4.I am worried about the procedure.

5.The procedure is on my mind continually.

6.I would like to know as much as possible about the procedure.

The measure of agreement with these statements should be graded on a five-point Likert scale from

1 = not at all to 5 = extremely.

Supplementary file 6: Blinding Questionnaire

Blinding Questionnaire
Which one acupuncture treatment do you think you accepted?
□ Acupuncture
□ Sham acupuncture

Supplementary file 7: Credibility/ Expectancy Questionnaire

Credibility/ Expectancy Questionnaire (CEQ)

1. At this point, how logical does the therapy offered to you seem?

   1 2 3 4 5 6 7 8 9

   not at all logical somewhat logical very logical

2. At this point, how useful do you think this treatment will be in reducing your trauma symptoms?

   1 2 3 4 5 6 7 8 9

   not at all useful somewhat useful very useful

3. How confident would you be in recommending this treatment to a friend who experience similar problems?

   1 2 3 4 5 6 7 8 9

   not at all confident somewhat confident very confident

4. By the end of the therapy period, how much improvement in your trauma symptoms do you think will occur?

   0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

5. At this point, how much do you really *feel* that therapy will help you to reduce your trauma symptoms?

   1 2 3 4 5 6 7 8 9

   not at all somewhat very much

6. By the end of the therapy period, how much improvement in your trauma symptoms do you feel will occur?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%