Modified ultrasound scalpel haemorrhoidectomy versus conventional haemorrhoidectomy for mixed haemorrhoids: A study protocol for a single-blind randomized controlled trial

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Research Article

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Abstract

Background: Haemorrhoids are common and frequently occurring diseases in the clinical setting, and severe haemorrhoids require surgical treatment. There are various surgical methods to treat haemorrhoids, but each has its advantages and disadvantages. In recent years, ultrasonic scalpels have been used in haemorrhoid surgery and have achieved good results. Ultrasonic scalpel haemorrhoidectomy is safer and more effective in the surgical treatment of grade III and IV haemorrhoids, with less intraoperative bleeding, less postoperative pain, and fewer complications than diathermic therapy, electrosurgical haemorrhoidectomy, the procedure for prolapse and haemorrhoids (PPH) and traditional haemorrhoidectomy. In previous reports, the majority of ultrasonic scalpel haemorrhoidectomies were performed as open procedures, with only the body of the haemorrhoid removed with the ultrasonic scalpel and the wound left open for drainage and natural healing. However, we performed a preliminary experiment with 12 patients who underwent open ultrasonic scalpel haemorrhoidectomy in the early stage. The results showed that 8 patients had different degrees of postoperative bleeding, and 4 of them required a second haemostatic surgery under anaesthesia. Therefore, we modified the open ultrasonic scalpel haemorrhoidectomy procedure by removing the mucosa of the internal haemorrhoid and closing the base of the incision with figure-of-eight penetrating sutures and designed this study protocol to evaluate its clinical efficacy and safety.

Methods: A randomized single-blind parallel-controlled trial was proposed for this project, and patients who meet the inclusion criteria will be divided into a test group and a control group, with 36 patients in each group.

The experimental group will be treated with modified ultrasonic scalpel haemorrhoidectomy, and the control group will be treated with Milligan-Morgan operation. The effectiveness of modified ultrasonic scalpel haemorrhoidectomy for haemorrhoids will be objectively evaluated, including incision healing time and the time for patients to return to normal activities, postoperative complications, evaluations of anal function 3 months and 6 months after surgery, an evaluation of quality of life 6 months after surgery, and an evaluation of the patient satisfaction rate 6 months after surgery. The safety assessment will consider all adverse and serious adverse events associated with the study treatment.

Discussion: The study was approved by the ethics committee. The first patient was registered on July 1, 2021. The purpose of the study will be to evaluate the clinical efficacy and safety of the modified ultrasonic scalpel haemorrhoidectomy procedure for the treatment of mixed haemorrhoids and to provide an evidence base for the clinical promotion and application of the procedure. A limitation of this study is that only the patients will be single-blinded, because the researchers and the patients cannot be blinded at the same time, which may produce certain bias in the results. In addition, the sample size of this study will be small, and the test results only represent the results of this clinical trial. In later stages, the sample size needs to be further expanded to improve the level of evidence. Despite its limitations, we hope the study will help provide a more optimized surgical approach in the selection of haemorrhoid surgery.

Trial registration: Chinese Clinical Trial Registry (Registration ID: ChiCTR2100047229). Registered on June 11, 2021.

Background

Haemorrhoids are a common and frequently occurring clinical disease, and the prevalence rate accounts for approximately 40% of the total population. The disease may occur in both men and women and may progressively worsen with age. Nonsurgical treatment does not significantly improve the symptoms of severe haemorrhoids, and they usually have irreversible pathological anatomy and physiological functions, so it is necessary to treat severe haemorrhoids by surgery. At present, the commonly used surgical methods include the Milligan-Morgan operation[1], procedure for prolapse and haemorrhoids (PPH)[2] and automatic haemorrhoid ligation (RPH)[3]. The Milligan-Morgan operation is a classic operation for the treatment of haemorrhoids; although it can significantly improve some clinical symptoms of patients, it causes greater tissue damage and more bleeding during the operation, and the incidence of complications such as wound edge oedema and pain is higher[4]. The PPH is a treatment method for haemorrhoids based on the theory of “anal cushion moves down“, which has the advantages of a short operation time, less intraoperative blood loss, less pain and fast wound healing[5]. It can reduce the clinical symptoms of mixed haemorrhoids to a certain extent, but the clinical effect of the PPH alone in the treatment of mixed haemorrhoids is not satisfactory. The PPH has the disadvantages of a high rate of recent short-term secondary operations, long-term recurrence, and residual skin tags[6], and also causes a postoperative risk of serious complications such as anal stenosis and rectal perforation. RPH surgery is mainly aimed at grade III internal haemorrhoids. Incomplete ligation of large haemorrhoids has the risk of postoperative haemorrhage.

With the rapid development of minimally invasive medicine and the continuous improvement of medical instruments, ultrasonic scalpels were applied in clinical surgery in 1992. Their working principle is to make the metal cutter head oscillate at a frequency of 55.5 kHz through an ultrasonic frequency generator so that the water molecules in the tissue are vapourized, the hydrogen bonds of proteins are broken, and cells can disintegrate to cut the tissue and coagulate the blood vessels. Ultrasonic scalpels convert electrical energy into mechanical energy without electrical conduction and have high safety. Compared with traditional electric scalpels, ultrasonic scalpels cause the least damage to tissues (causing thermal damage to an area 1-3 mm wide), have less smoke, and do not cause neuromuscular stimulation[7-8]. In recent years, ultrasonic scalpels have been gradually used in haemorrhoid operations and have shown good results. Some scholars compared ultrasonic scalpel haemorrhoidectomy with diathermy therapy[9], Ferguson's with electrosurgical haemorrhoidectomy (FEH)[10], PPH[11] and traditional haemorrhoidectomy[12-13]. The results showed that ultrasonic scalpel haemorrhoidectomy was safer and more effective in the surgical treatment of grade III and IV haemorrhoids, with less intraoperative bleeding, less postoperative pain and fewer complications. Domestic scholars Yuan Xiaoqian et al. [14] applied ultrasonic scalpel haemorrhoidectomy combined with band ligation therapy to treat mixed haemorrhoids, and the results showed that the combination was safe and effective in the treatment of

mixed haemorrhoids, with the advantages of a short operation time, less intraoperative bleeding, less postoperative pain and fast wound healing. Shen Jianyong et al. [15] used a nonligating ultrasound scalpel to treat 57 cases of circular mixed haemorrhoids. The clinical effect was obvious and there were few complications.

An ultrasonic scalpel can directly remove haemorrhoids, coagulate blood vessels and tissues, and avoid the disadvantages of massive bleeding during the ligation shedding period and postoperative recurrence after traditional surgery. However, in the preliminary experiment we found that when only an ultrasonic scalpel was used to remove haemorrhoids without suturing the incision after the operation, the increase of intra-abdominal pressure and pressure in the anal canal due to normal defaecation activities would increase the tissue tension in the anal area. Under repeated stimulation from stool, the solidified tissues easily crack and bleed, causing incision infection and secondary healing. Therefore, based on the previous literature and clinical studies, we designed the modified ultrasonic scalpel haemorrhoidectomy procedure and will evaluate its clinical efficacy and safety, aiming to provide an evidence basis for the promotion and application of the procedure in the clinical setting.

Objectives

A randomized controlled blind study is planned to objectively evaluate the efficacy of modified ultrasonic scalpel haemorrhoidectomy in the treatment of haemorrhoids. The healing time of the incision and the time for patients to return to normal activities, postoperative complications, evaluations of anal function 3 months and half a year after surgery, an evaluation of the quality of life at half a year after surgery and an evaluation of the patients' satisfaction rates half a year after surgery will be measured.

To assess safety, the incidence of adverse events (AEs) and serious adverse events (SAEs) between the two study groups will be compared to show the potential risks for patients.

Methods

Design

Setting

This will be a randomized, single-blind, parallel controlled study. Patients who meet the inclusion criteria will be divided into a treatment group and a control group, each with 36 patients. The treatment group will undergo modified ultrasonic scalpel haemorrhoidectomy, and the control group will undergo Milligan-Morgan operation and internal ligation injection. The study will be conducted at Shangjin Hospital of West China Hospital of Sichuan University.

Participants

Eligible participants who meet the diagnostic criteria for haemorrhoids in the Clinical Diagnosis and Treatment Guidelines for Hemorrhoids (2006 edition), formulated by the Colorectal and Anal Surgery

Group of the Chinese Medical Association Surgery Branch and the Anorectal Branch of the Chinese Society of Traditional Chinese Medicine, will be enrolled. All the participants will have been treated and hospitalized by the Department of Integrated Traditional Chinese and Western Medicine of West China Hospital of Sichuan University. Recruitment began on July 1, 2021 and is expected to last for 24 months.

The trial was approved by the Ethics Committee on Biomedical Research at West China Hospital of Sichuan University (Approval code: NO. 2020-367). It was also registered in the Chinese Clinical Trial Registry (Registration ID: ChiCTR2100047229).

Inclusion criteria

1. Patients with the clinical manifestation of mixed haemorrhoids with the symptoms of internal haemorrhoids and external haemorrhoids existing at the same time. Among them, internal haemorrhoids should be manifested as stage II (grade) or higher;
2. Patients aged 20-70 years without obvious surgical contraindications;
3. Patients who provide informed consent, with good compliance, and are able to cooperate to complete all clinical research content.

Exclusion criteria

1. Patients with haemorrhoids combined with anusitis;
2. Patients with haemorrhoids combined with inflammatory bowel disease;
3. Patients with suppurative infection around the anorectal canal;
4. Patients with intestinal infectious diseases (e.g., dysentery);
5. Patients diagnosed with outlet obstructive constipation.

Withdrawal criteria

1. During the study, subjects have poor compliance, which can affect the effectiveness evaluation;
2. Those who have serious adverse events, complications and special physiological changes and are not able to continue the experiment;
3. Those who quit on their own during the study;
4. Patients who withdraw from the trial, are lost to follow-up or die due to various other reasons;
5. Those who have incomplete data which affect the validity judgement.

Recruitment and trial timeline

Researchers will recruit participants from the inpatient wards of the Department of Integrated Traditional Chinese and Western Medicine. After screening patients who met the inclusion and exclusion criteria, the researcher will inform the participants of the different treatment methods available for their condition,

provide information about the study, and have the participants sign a written informed consent form. A copy will be kept by the participant, and the original will be kept in the hospital.

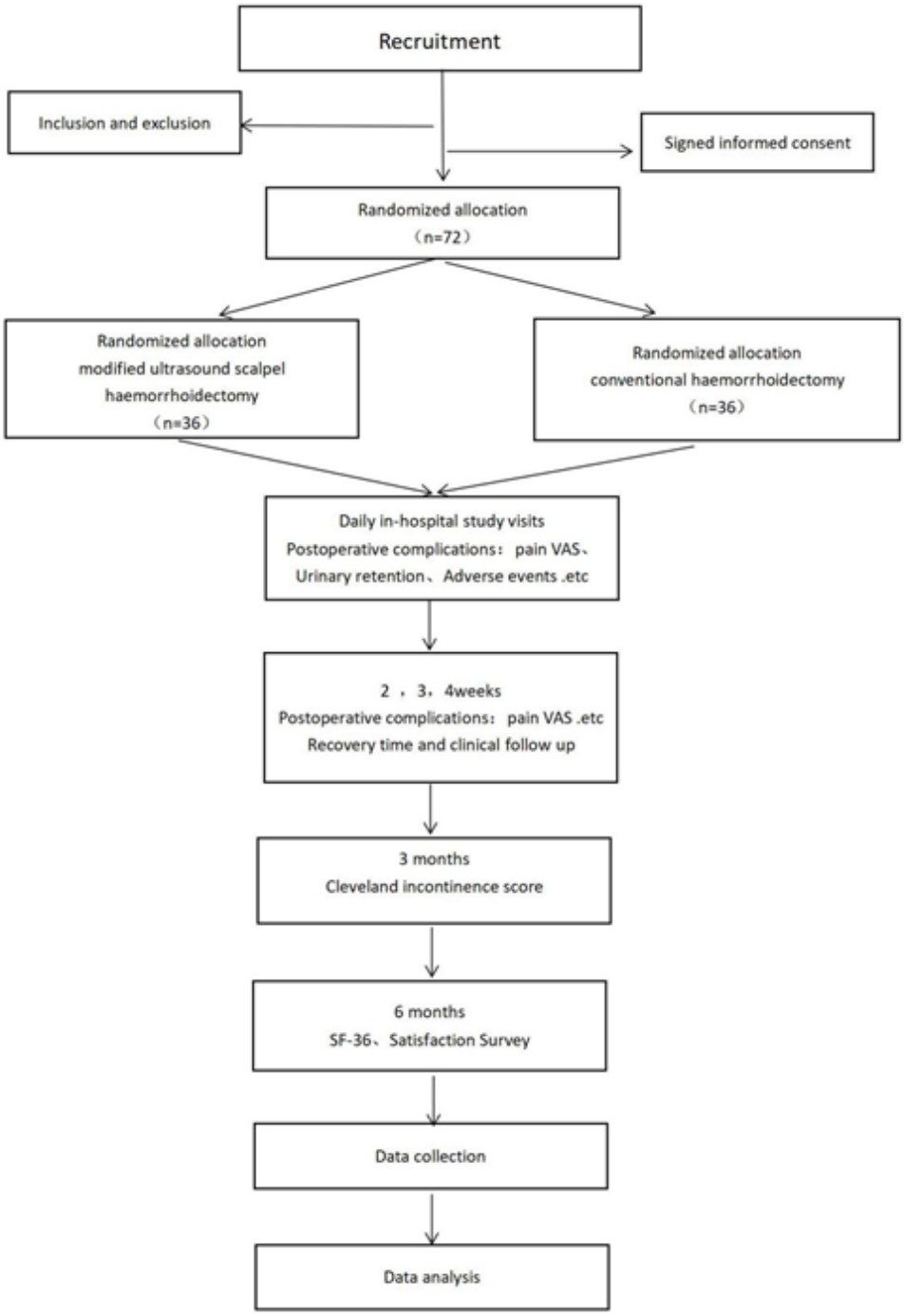
The participants who meet the criteria will be registered, the baseline data and clinical features of the participants will be collected before the operation, and measurements will be taken at each observation time node according to the CRF form after the operation (Table 1). Participants who met the withdrawal criteria shall strictly follow the criteria and provide records. The registration process, the intervention and evaluation schedule and the study flow chart are shown in Tables 1 and 2.

Table 1: Schedule of the registration process, the intervention, and evaluations

Measures	Preoperative	Daily in-hospital study visits							Follow-up				
		POD 0	POD 1	POD 2	POD 3	POD 4	POD 5	POD ≥6	W2	W3	W4	M3	M6
Incision healing time									X	X	X		
Recovery time									X	X	X		
Pain VAS		X	X	X	X	X	X	X	X	X	X		
Urinary retention		X	X	X	X	X	X	X					
Postoperative bleeding		X	X	X	X	X	X	X	X	X	X		
Postoperative oedema		X	X	X	X	X	X	X	X	X	X		
Anal stenosis	X	X	X	X	X	X	X	X	X	X	X	X	X
Cleveland incontinence score	X	X										X	X
SF-36	X	X											X
Satisfaction survey		X											X
Adverse events		X	X	X	X	X	X	X	X	X	X	X	X

POD= postoperative day; W= week; M= month; VAS= visual analogue score; SF36= 36-Item Short Form Health Survey

Table 2: Flow chart of the research phases.



VAS= visual analogue score; SF-36= 36-Item Short Form Health Survey.

Sample size

The number of cases in this test were estimated based on the count data of the test unit (n):

$$n = \frac{(U_\alpha + U_\beta)^2 2P(1-P)}{(P_1 - P_0)^2}$$

According to the loss to follow-up rate of 15%, the ratio of the control group and treatment group was 1:1, with 36 participants per group.

Randomization and blinding

A third party statistician will use Excel software (Kingsoft Office Software Co. Ltd. China) to randomly assign participants to the two study groups in equal proportions. Only one data administrator will be able to access the table of random numbers in the computer. Participants will be registered by the research assistant in the order of entry time. The data administrator will use the random number table for grouping. The two groups will receive different surgical methods, and the operator and observer must know which group the patient is assigned to, so they cannot be blinded. However, the patients and statisticians will be blinded to the allocation of the participants.

Intervention description

The treatment group

The external haemorrhoids in the mother haemorrhoid area at points 3, 7 and 11 will be removed by ultrasonic scalpel in a V-shape;

The internal haemorrhoids will be clamped with forceps to be removed, the superior haemorrhoids artery will be ligated with No. 0 mousse thread "8", 1 ml of Xiaozhilin will be injected under the ligation proximal sticking mould, and then the haemorrhoid will be removed it slowly with an ultrasonic scalpel along the clamp mark at the base;

The carbonization (fixation) range of the incision will be checked, the free carbonized tissue will be removed at the incision, a needle will be inserted at the edge of the solidified tissue to suture the incision with the figure of "8" slightly above the tooth line, and then the incision epithelium will be sutured near the tooth line with the modified "8" suture method. When there is no obvious bleeding from the wound, the operation will be complete.

The control group

The top of the external haemorrhoids will be clamped and gently pulled outward to expose the internal haemorrhoids. A V-shaped incision will be made on the external haemorrhoids, and the subcutaneous tissue will be stripped to 0.2 cm on the tooth line. The stripped external haemorrhoids and the base of the internal haemorrhoids will be clamped with middle-curved forceps. No. 0 silk thread will be used to run through the base root of the suture clamp. Part of the internal haemorrhoid tissue will be removed, without letting the suture slip off.

In the same way, the other haemorrhoids will be removed and ligated, and 3~55 ml of 1:1 Xiaozhiling (1 part Xiaozhiling stock solution, 1 part normal saline) will be injected into the mucosa of the superior haemorrhoid artery area where the haemorrhoids are ligated under an anoscope to prevent bleeding. When there is no obvious bleeding from the wound, the operation will be complete.

Perioperative management, discharge, and follow-up

After the operation, a fluid diet will be given for 1 day, and appropriate fluids will be supplemented. Nonsteroidal anti-inflammatory drugs or opioid central analgesics will be given for postoperative pain according to the VAS pain score. For postoperative urinary retention, catheterization will be determined by the ward doctor on duty after evaluating the patient's symptoms and signs. The patient's catheter will be removed on POD 2. For postoperative defecation, lactulose oral solution will be used to soften the stool on the first day after the operation. If the patient still has difficulty with defecation, a glycerine enema can be given to help the patient defecate. If the symptoms still cannot be alleviated, a warm normal saline can be given to clean the enema.

Twenty-four hours after the operation, the anal canal dressing will be removed, and the patient can defecate on their own. After defecation, the patients will be treated with heat-clearing and detoxifying traditional Chinese medicine sit-baths, iodophor disinfection, indomethacin and furazolidone embolization of the anus, and dressing changes every day after defecation. The patient's wound recovery, stool smoothness and blood in the stool will be evaluated to decide to arrange for discharge. After discharge, the patient will be advised not to exercise vigorously, continue perianal disinfection and dressing changes, and participate in regular outpatient follow-up. Wound healing and surgical complications will be observed 1, 2, 3 and 4 weeks after the operation.

Each participant will be followed up 12 and 24 weeks after the operation via WeChat, telephone, video and outpatient clinics. At 3 months and 6 months after the operation, the Cleveland Clinic Florida Fecal Incontinence Score (CCF-FI) will be used to evaluate the anal condition of the patients and to evaluate whether the patients have postoperative anal incontinence. The simple SF-36 quality of life questionnaire (self-made) will be used to evaluate the patients half a year after operation.

For the schedule of the trial, please see Table 1.

Outcome measures

Primary outcome measures

The primary outcome measures are postoperative incision healing time and recovery time of the patients, calculated in days (d).

Efficacy evaluation: Efficacy will be evaluated according to the efficacy evaluation of mixed haemorrhoids in the 2017 Standard for Diagnosis and Efficacy of TCM Diseases and Syndromes as

follows: Cured: the symptoms and haemorrhoids disappear; Improvement: the symptoms improve and the haemorrhoids shrink; and Unhealed: there are no changes in symptoms and signs.

Secondary outcome measures

Postoperative complications: pain: A visual analogue scale (VAS) will be used to observe the patients' pain 4 h, 8 h and 24 h after operation and the pain from defecation for 7 consecutive days after the operation in the two groups. Urinary retention will be assessed by the "with" and "without" method. Postoperative bleeding will be assessed as follows: 0 points: no bleeding; 1 point: blood on the paper; 2 points: drops of blood; 3 points: ejection of blood; and 4 points: Massive bleeding that requires surgery to stop the bleeding. Postoperative oedema will be assessed as follows: 0 points: no oedema; 1 point: oedema in 1/4 of the anal margin incision; 2 points: oedema in 1/2 of anal margin incision; 3 points: oedema in 3/4 of the anal margin incision; and 4 points: oedema around the perianal incision. Anal stenosis will be assessed by the "with" and "without" method.

Anal function evaluations 3 months and 6 months after operation: Anal function evaluation will be assessed by the CCF-FI as follows: normal continence: the anus controls stool, intestinal fluid and intestinal gas is normal; partial anal incontinence: the anus cannot control intestinal fluid, intestinal gas, loose stools, or the pollution of underwear or the anus has a sense of dampness; and Complete incontinence: the anus cannot control forming stool.

Evaluation of quality of life half a year after the operation: The simple SF-36R quality of life questionnaire (self-made) will be used for evaluating the quality of life.

Evaluation of patient satisfaction rate half a year after the operation: The self-designed patient satisfaction questionnaire will be used, which is divided into very satisfied, satisfied, general and no opinion, and calculates the percentages of the 4 levels.

Safety and reporting of serious adverse events

In this study, adverse events will be defined as any treatment-related medical event, including any adverse and unexpected signs, symptoms or illnesses associated with the treatment. Adverse events will be evaluated according to the Standard for General Terminology for Adverse Events (V4.03). Within 24 hours after the occurrence of adverse events, the researchers and relevant experts will evaluate and classify the events and deal with them in a timely manner according to the condition. We will collect, evaluate, and report any spontaneously described adverse events that occur among the participants. Adverse event data regarding the severity of the occurrence, duration (signs and symptoms) of the adverse reactions, and how to resolve (or not) them during treatment will be recorded. If the participants experience serious adverse events, they will be reported to the principal investigator and the Ethics Committee of West China Hospital of Sichuan University (IEC) and it will be decided whether blindness is removed and if they withdraw from the study.

Study organization

Data collection and management

The case report form (CRF) includes observation time points, outcome measurements, adverse events, and safety assessments. The evaluators of the results will follow the requirements of the CRF and fill in relevant information in a timely and accurate manner. Data collection and entry will be carried out independently by two staff members and completed by a third staff member. The principal investigator will not be involved in data collection. Data will be obtained from the CRF, and only trial group members will be able to access the CRF and perform dual data entry. The organization of the test is as follows. The steering committee will fully oversee the design of the study. The investigators of the Data Management Safety Committee (DMSC) will supervise and confirm that the CRF is completed correctly and that the data are consistent with the original data. If there are any errors or omissions, the investigator will immediately correct them. We do not intend to collect personal information about potential or registered participants other than that typically collected during hospitalization. For confidentiality, the electronic health information will be encrypted in accordance with the hospital’s protocol. After the trial, personally identifiable information will be omitted and placed in a separate database for data analysis.

Statistical analysis

Data analysis: We will use SPSS software version 17.0 (IBM, Armonk Company, New York, USA) for data analysis. Demographic and baseline data will be analysed using standard descriptive statistics. For categorical variables, Fisher's exact test will be used. For continuous variables, Student's t test or the Mann–Whitney U test will be used. The entire data analysis process will be performed by statisticians who are independent of the research team and are blinded to the set. The acceptable level of significance for all analyses will be $p < 0.05$.

Audits

The ethics committee will locally monitor the quality of the trial after the first batch of patients is registered. The trial management team will meet every 3 months to check the implementation of the study, including the recruitment rates, the data quality and adverse event reporting.

Plans for communicating important protocol amendments to relevant parties

The protocol, statistical analysis plan, data safety management plan, informed consent, and recruitment materials were reviewed and approved by the Biomedical Research Ethics Committee of West China Hospital of Sichuan University. Any subsequent modifications will be submitted for review, and annual safety and progress reports will be submitted. In addition, the online trial registration form will be updated accordingly. The data can be obtained through the research centre upon reasonable request.

Communication plan

The research results will be disseminated through peer-reviewed publications and speeches at industry academic conferences. A summary of the research results will be released through WeChat, Weibo and

other social media platforms.

Discussion

There are many surgical methods for haemorrhoids, but each has its own advantages and disadvantages. Therefore, it is particularly necessary to explore a surgical method that not only does not damage anal sphincter function but can also restore the normal shape of the anus.

The choice of surgical instruments for mixed haemorrhoids should not only take into account the different symptoms and morphological characteristics of patients with mixed haemorrhoids lesions but also local related haemodynamic changes, microcirculation control disorders and haemorheological pathophysiological changes; the concept of "minimally invasive" should be used as much as possible to achieve a good therapeutic effect and protect the fine functions of the anus, such as defecation control. The metal head of the ultrasonic scalpel is sharp and conducive to fine anatomy and is of great value in the operation of mixed haemorrhoids. Ultrasonic scalpel haemorrhoidectomy was reported to be applied in the clinic by Jane [16] and other reports in 2001, and research has shown that ultrasonic scalpel haemorrhoidectomy can reduce the pain and postoperative bleeding of patients. Mushaya [17] et al. conducted a meta-analysis of the comparison between ultrasonic haemorrhoidectomy and traditional haemorrhoidectomy, and the results showed that the ultrasonic scalpel group had lower pain scores, a lower complication rate and a faster recovery than the traditional surgery group. Research by Ravi Kumar [18] et al. showed that compared with the Milligan-Morgan operation, ultrasonic haemorrhoidectomy resulted in less blood loss (19.4 and 6.1 ml, respectively). Compared with the Milligan-Morgan method group, the ultrasonic scalpel group had lower VAS pain scores on the first day, and the first and the second week after the operation. There were more complications, such as postoperative bleeding and urinary retention, in the Milligan-Morgan group. In a case study of 25 patients (ultrasound scalpel group) by Tariq Ahmed Mala [19], the average operation time was 17.68±2.84 minutes, and the average operation time of the control group was 28.44±3.69 minutes. The average blood loss of the ultrasonic scalpel group and the control group were 8.96±2.15 ml and 31.72±3.28 ml, respectively. VAS pain scores on the first day after surgery in the ultrasonic scalpel group were 5.92±0.70 and 8.52±0.84 in the control group. The ultrasound scalpel group had a lower analgesic dose, earlier walking and returned to normal work faster. In previous research reports, the vast majority of ultrasonic scalpel haemorrhoidectomy were open operations, only using an ultrasonic scalpel to remove the haemorrhoids; the wound was left open and drained and healed naturally. Only two studies mentioned that the incision was closed [16,20]. Another study showed that closing the incision is not beneficial; it is not conducive to drainage of the incision and may actually slow the healing process [21]. Before the start of this study, we conducted a preliminary study: 12 patients with mixed haemorrhoids were treated with open ultrasonic scalpel resection. Unfortunately, 8 of the 12 patients had blood in the stool 5-16 days after the operation, mainly dripping blood and jet-like bleeding, and the amount of bleeding was ≥5 ml each time. Among them, 4 patients had postoperative bleeding > 50 ml. All 4 patients underwent a second haemostatic operation under anaesthesia. During the operation, the wounds were found to have ulcers and erosions and extensive

bleeding after ultrasonic scalpel resection. After inquiring about the medical history, the 8 patients with bleeding had no primary underlying diseases (hypertension, heart disease, blood system diseases, etc.) and no history of long-term anticoagulant drug use. The reasons may be as follows: if only the ultrasonic scalpel is used to remove the haemorrhoids without suturing the incision, normal defecation activity after the operation will increase the abdominal pressure and anal pressure, which will increase the tissue tension in the anal area. Under the repeated stimulation from stool, the coagulated tissues easily crack and bleed, causing incision infection and delayed healing. Therefore, we modified the open ultrasonic scalpel haemorrhoidectomy procedure. While removing the internal haemorrhoid mucosa, we sutured the base of the incision with a figure of eight and designed this research plan to evaluate its clinical efficacy and safety.

A limitation of this study is that only the patients will be single-blinded; the researchers and patients could not be blinded at the same time, which may have a certain bias on the results. In addition, the sample size of this study will be small, and the results will only represent the results of this clinical trial. The sample size needs to be further expanded in later stages to improve the level of evidence. Despite its limitations, we hope this trial will help provide a more optimized surgical approach in the selection of haemorrhoid surgery.

Trial status

Participants are still being recruited. Enrolment began in July 2021, and the trial is expected to be completed by July 2023.

Abbreviations

PPH Procedure for prolapse and haemorrhoids RPH Automatic haemorrhoid ligation FEH Ferguson's with electrosurgical haemorrhoidectomy AEs Adverse events SAEs Serious adverse events VAS Visual analogue score SF-36 36-Item Short Form Health Survey CCF-FI Cleveland Clinic Florida Fecal Incontinence Score CRF Case report form

Declarations

Acknowledgements

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Authors' contributions

JW obtained funding for the project and conceived the study. KQY designed the study and drafted the manuscript. HBH helped to design the study. PX, HJL, ZDX and MHT will perform this study. JW will perform the statistical analysis. The authors read and approved the final manuscript.

Ethics approval and consent to participate

The Ethics Committee on Biomedical Research, West China Hospital of Sichuan University, approved the study protocol (Approval code: NO. 2020-367). The study was also registered in the Chinese Clinical Trial Registry (registration ID: ChiCTR2100047229). Before randomization, all participants will be asked to provide written informed consent.

Competing interests

The authors declare that they have no competing interests.

References

1. MILLIGAN E T, MORGAN C N, JONES L E, et al. Surgical anatomy of the anal canal, and the operative treatment of haem orrhoids[J]. Lancet, 1937, 2(1): 1119-1124.
2. LONGO A. Treatment of haemorrhoid disease by reduction in mucosal and haemorrhoidal products with a circular stapling de vice-new procedure[C]. Proceedings of the 6thWorld Congress of Endoscopic Surgery, Rome, Italy 3-6 June 1998.
3. Su Liang,Jia Xiaoqiang,Cao Weiwei.The efficacy and safety of RPH and PPH in treatment of mixed haemorrhoids:a meta-analysis [J].Chinese journal of anorectal diseases,2019,39(3):19-24.
4. YANG J, CUI P J, HAN H Z, et al. Meta-analysis of stapled hemorrhoidopexy vs ligasure hemorrhoidectomy[J]. World J Gas troenterol, 2013, 19(29): 4799-4807.
5. TJANDRA J J, CHAN M K Systematic review on the proce dure for prolapse and hemorrhoids (stapled hemorrhoidopexy)[J]. Dis Colon Rectum, 2007, 50(6): 878-892.
6. COSENZA U M, MASONI L, CONTE S, et al. Stapled hemor rhoidopexy as a daysurgery procedure[J]. Am surg, 2011, 77 (5): 552-556
7. Khanna, R. Khanna, S.Bhadani, S.et al.Comparison of ligasure hemorrhoidectomy with conventional Ferguson's hemorrhoidectomy[J].Indian J Surg, 2010 Aug; 72(4): 294–297.
8. A.A. Abo-hashem, A. Sarhan, A.M. Aly, Harmonic scalpel compared with bipolar electrocautery hemorrhoidectomy: a randomized controlled trial[J].Int J Surg,2010,(8) :2437
9. Jatin G. Bhatt, Arvind Ranwa, Jignesh P. Dave,etc. A Prospective Randomised Study of Comparing Diathermy and Ultrasonic Scalpel Haemorrhoidectomy[J]. Int J Res Med. 2017; 6(1); 7-10.
10. Hakan Bulus,Adnan Tas,Ali Coskun,etc.evaluation of two haemorrhoidectomy techniques: Harmonic scalpel and Ferguson’s with electrocautery[J].Asian Journal of Surgery.2014,37:20-23.
11. Yusuf Bilgin,Semih Hot.Short-and long-term results of Harmonic scalpel haemorrhoidectomy versus stapler hemorrhoidopexy in treatment of hemorrhoidal dieseae[J].Asian Journal of

Surgery.2015,38:214-219.
12. Dae Ro Lim, Dae Hyun Cho, Joo Hyun Lee,etc,Comparison of a Hemorrhoidectomy With Ultrasonic Scalpel Versus a Conventional Hemorrhoidectomy[J]. Ann Coloproctol 2016;32(3):111-116.
13. Atul Philipose, Murtaza Akhtar, Divish Saxena, Harmonic scalpel versus conventional haemorrhoidectomy for grade III and IV haemorrhoids: a randomized controlled trial[J]. Int Surg J. 2017 May;4(5):1627-1631
14. Yuan Xaioqian,Lu Jingen,Cao Yongqing.Clinical study of ultrasonic scalpel combined with ligation therapy in the treatment of mixed haemorrhoids [J].Hebei traditional Chinese medicine.2017,39(1):63-65.
15. Shen Jianyong He Lingbo. 57 cases of circular mixed haemorrhoids treaded by ultrasonic scalpel without ligation[J]. Chinese journal of Integrated Traditional and Western Medicine Surgery, 2017 ,23(6):680-681
16. Jane J.Y. Tan, F. Seow-Choen,Prospective, Randomized Trial Comparing Diathermy and Harmonic Scalpel ® Hemorrhoidectomy[J]. Dis Colon Rectum, May 2001:677-679
17. C. D. Mushaya ,P. J. Caleo,et al. Harmonic scalpel compared with conventional excisional haemorrhoidectomy: a meta-analysis of randomized controlled trials [J]. Tech Coloproctol,2014,18:1009–1016.
18. Ravi Kumar G. V, Madhu B. S,et al. Harmonic scalpel compared with conventional open (Milligan-Morgan) method in surgical management of symptomatic haemorrhoids [J]. Int Surg J. 2017 Jun;4(6):2010-2013.
19. Mala T A, Mala S A,et al. Comparative study of harmonic scalpel haemorrhoidectomy versus conventional (Milligan and Morgan) haemorrhoidectomy [J]. J Surg Arts (Cer San D), 2018(1):7-12.
20. Ramadan E, Vishne T, Dreznik Z.Harmonic scalpelhemorrhoidectomy: preliminary results of a new alternative method [J]. Tech Coloproctol ,2002,6:89–92.
21. Ho YH, Buettner PG. Open compared with closed haemorrhoidectomy: meta-analysis of randomized controlled trials [J]. Tech Coloproctol,2007, 11:135–143.

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