A Prospective Randomized Controlled Trial of the Effect of Different Pancreaticojejunostomy After Pancreaticoduodenectomy on Postoperative Pancreatic Fistula Based on the Position of the Pancreatic Duct in Pancreatic Section Informed Consent

Dear Participant

We invite you to participate in the research project "**A Prospective Randomized Controlled Trial of the Effect of Different Pancreaticojejunostomy After Pancreaticoduodenectomy on Postoperative Pancreatic Fistula Based on the Position of the Pancreatic Duct in Pancreatic Section**", which has been approved by West China Hospital of Sichuan University. This study will be conducted at West China Hospital of Sichuan University, and 974 participants will be able to participate. This study was reviewed and approved by the Biomedical Ethics Review Board of West China Hospital of Sichuan University.

1. Why conduct this research? (Introduction to research background and purpose)

Pancreaticojejunostomy is currently a common operation in pancreatic surgery, and the incidence of pancreatic fistula after surgery is as high as 45%. In this study, we propose to perform intraoperative measurements (A: short distance from the center of the pancreatic duct to the edge of the pancreas) and (B: pancreatic thickness) and classify the pancreatic duct during the operation according to the intraoperative measurements and then implement the corresponding pancreaticojejunostomy. The incidence of perioperative pancreatic fistula and other relevant parameters were collected from patients for data analysis. To establish a universal and effective "West China standard" for the anatomical classification of pancreatic duct positions in pancreatic cross-section and as an important basis for the method of pancreaticojejunostomy (number of layers). Exploring the different types of pancreatic ducts. To study the effects of the location of the pancreatic duct and the layers of pancreaticojejunostomy on the occurrence of postoperative pancreatic fistula and attempt to establish a risk prediction model for the occurrence of postoperative pancreatic fistula based on the classification of the pancreatic duct.

2. What do you need to do if you participate in research?

(1) Sign the informed consent;

(2) Randomly divide the participants into an experimental group and a control group;

(3) Participants need to complete preoperative imaging, biochemical and other examinations in our hospital and cooperate with our surgical treatment;

(4) In the experimental group, pancreas cross-sectional measurement was performed to select the corresponding pancreaticojejunostomy method; the control group did not have intraoperative measurements and underwent traditional anastomosis.

(5) Three days after the operation, the drainage fluid of the participant was collected for amylase determination, and imaging, biochemical and other examinations were reviewed after the operation.

3. What are the treatment options available?

Alternative treatment options for participants:

1. Conservative treatment;
2. Routine surgery and anastomosis.

4. Who does not need to participate in this study?

1. If you do not need pancreaticojejunostomy, you do not need to participate in this study.

2. Except for pancreaticoduodenectomy, there are other pancreatic operations and injuries. and patients undergoing other organ surgery at the same time.

5. What are the risks of participating in the study?

Please fully inform participants about the risks associated with the study, including the risks of study drugs, examinations, devices, and procedures.

The risk of this study is comparable to routine pancreaticojejunostomy. There are some risks including pancreatic fistula, infection, and bleeding after surgery, and it may be necessary to retain the drainage tube for a long time or need a second operation.

Treatment plan for major postoperative complications:

(1) Postoperative intra-abdominal infection treatment plan and process

1.Fever occurred after abdominal surgery, if blood routine suggested that white blood cells significantly increased, and clear infections, such as pulmonary infection and surgical incision infection, were excluded. Imaging examinations suggested subdiaphragmatic and intra-abdominal infection was considered.

2. After the diagnosis of intra-abdominal infection, corresponding broad-spectrum antibiotics should be given according to the possible pathogenic bacteria. If there is a drainage tube, the bacterial culture of the drainage fluid and drug sensitivity should be performed immediately, and the antibiotics should be adjusted in time according to the culture results.

3. Maintain smooth drainage. Attention should be given to postural drainage.

4. Appropriate nutritional support treatment and small and multiple blood transfusions can be used to improve physical fitness and enhance immunity.

5. If encapsulated effusion has been formed, percutaneous aspiration or percutaneous catheter drainage under the guidance of ultrasound or CT can be attempted.

6. If the site is deep, the puncture is difficult or the puncture and drainage are not complete, and the intra-abdominal infection is difficult to control, an appropriate path for surgical drainage can be selected.

7. Anti-inflammatory and systemic treatment should be continued after surgery, and attention should be given to maintaining smooth drainage. Regular imaging examinations are used to understand the improvement of effusion to determine the timing of catheterization.

Process: intra-abdominal infection→antibiotics and supportive care→adjusted antibiotics according to bacterial culture results → percutaneous aspiration or catheter drainage → surgical drainage→continued anti-inflammatory and systemic therapy

(2) Postoperative pancreatic fistula treatment plan and process

1. The drain output of any measurable volume of fluid with an amylase level >3 times the upper limit of institutional normal serum amylase activity is associated with a clinically relevant development/condition, which can be diagnosed as pancreatic fistula.

2. The imbalance of water, electrolyte and acid-base was corrected, and low potassium, low sodium and dehydration were detected in a timely manner.

3. Use drugs that inhibit the secretion of pancreas, 3 mg of statin or somatostatin for 12 h infusion, twice a day.

4. The drainage of the abdominal cavity should be maintained smoothly, and leakage of pancreatic juice should be avoided to activate and corrode the internal organs of the abdominal cavity.

5. Infection was actively prevented and treated, systemic nutritional support treatment was provided, and the changes in blood oxygen partial pressure, blood creatinine and blood urea nitrogen were monitored.

6. Those who have not recovered by active nonsurgical treatment can be considered for surgical treatment. According to the situation, different surgical methods, such as partial pancreatectomy and Roux-en-Y anastomosis of the jejunum and sinus, can be selected.

Process: Pancreatic fistula → inhibit pancreatic secretion → maintain smooth drainage → systemic support therapy → surgical treatment for patients who has persistent pancreatic fistula more than 6 months.

(3) Treatment plan and process of gastric emptying disorder

1. For patients undergoing upper abdominal surgery, a daily increase in the amount of gastric juice

aspirated during gastrointestinal decompression or abdominal distension and persistent vomiting after eating after removing the gastric tube is considered gastric emptying disorder.

2. Once gastric emptying disorder is diagnosed, water should be fasted to reduce gastric secretion and gastric content retention.

3. Gastrointestinal decompression can further reduce gastric retention, relieve gastric mucosal edema, restore the tone of the stomach wall muscles, and relieve abdominal distension, vomiting and other symptoms.

4. Intravenous nutritional support therapy to maintain water, electrolyte and acid-base balance. Albumin was applied when necessary to reduce gastrointestinal anastomotic edema.

5. Application of drugs to promote gastrointestinal motility, such as metoclopramide, morphine, and mosapride.

6. For those who are ineffective after nonsurgical treatment, gastroscopy can be used to understand the anastomosis, and if necessary, reoperation can be performed to perform partial or total gastrectomy.

Process: gastric emptying disorder → fasting and gastrointestinal decompression → intravenous nutritional support treatment → application of drugs to promote gastrointestinal motility → gastroscopy → reoperation

(4) Postoperative bile leakage treatment plan and process

1. Bile-like fluid is drained from the abdominal drainage tube after surgery, the daily drainage volume is 100-300 ml or more, and postoperative bile leakage is considered.

2. The primary treatment is effective drainage, ensuring smooth drainage and flushing if necessary. Most bile leaks can heal on their own within 2 weeks to 2 months.

3. Ultrasound examination should be performed in time when there are signs of subdiaphragmatic infection, and if necessary, ultrasound-guided percutaneous drainage should be performed, supplemented by antibiotics and systemic supportive therapy.

4. The persistent bile leaks can be reoperated, the liver section is fully sutured, and the drainage is continued after the operation.

Process: postoperative bile leakage → smooth drainage → percutaneous drainage if necessary → reoperation

(5) Treatment plan and process of stress ulcer bleeding

1. Prevention is the mainstay: for patients with major abdominal surgery, persistent low-grade fever after operation, high blood count, postoperative infection or infection that has not been effectively controlled, while actively treating the primary disease and eliminating stress factors, it should be given early.

Prophylactic drugs such as antacids, H2 receptor antagonists, proton pump inhibitors, etc.

2. When stress ulcer bleeding occurs, gastrointestinal decompression should be given to remove gastric juice and bile fluid and reduce further damage to the gastric destruction.

3. Antacids, such as proton pump inhibitors, should be used, and somatostatin should be applied to reduce portal blood pressure.

4. Actively control infection, replace sensitive antibiotics, and eliminate the further promoting effect of infection factors on stress ulcers.

5. Systemic support therapy to correct water, electrolyte and acid-base balance disorders.

6. Endoscopy should be given in a timely manner to clarify the location, scope and morphological characteristics of the lesion, and hemostasis should be given under the microscope.

7. If the hemostasis of the drug is ineffective and the blood pressure is difficult to maintain, subtotal gastrectomy, total gastrectomy, or vagotomy plus pyloroplasty can be performed at the right time.

Process: prevention first → early gastrointestinal decompression and antacid therapy → active infection control and systemic support therapy → endoscopic hemostasis → surgery

(6) Treatment plan and process of postoperative abdominal hemorrhage

1. Prevention is the main priority: the first is strict hemostasis during the operation.

2.Postoperative patients with unstable circulation or decreased blood pressure should be given hemostatic drugs in addition to the routine infusion rate and blood transfusion, and bleeding may stop automatically in some patients.

3.If the appeal cannot stop the bleeding, surgical exploration should be performed to stop the bleeding if necessary.

4.When the patient's condition and conditions permit, arteriography can be considered to clarify the cause and location of bleeding. If arterial bleeding is confirmed, interventional embolization can be implemented to stop the bleeding.

Process: prevention first → active fluid replacement and blood transfusion → combined use of hemostatic drugs → interventional embolization for hemostasis → surgical exploration to stop bleeding if necessary.

6. What are the possible benefits of participating in research?

It is possible that your condition will improve by taking part in this study, and this study may also help determine which treatment is safer and more effective for other patients with similar conditions.

All patients participating in this study will be examined and treated by doctors with rich clinical experience, answer your questions, and provide you with timely and thoughtful medical services. To fully

protect your rights, we have formulated a detailed clinical trial plan, which has been reviewed and approved by the hospital ethics committee, and we will implement clinical trials in strict accordance with the protocol. Participating in this clinical study, your disease may be relieved or it may not be relieved, or even progress. You may not benefit directly from receiving this study treatment, but we hope that the information you gain from your participation in this study will benefit patients with the same condition as you in the future.

If you do not agree to participate in this study, you will still receive the usual care given by your doctor. You will not be unfairly treated, or your interests will not be harmed. If you drop out of the study, your study doctor will give you follow-up treatment advice according to the reason for your withdrawal, and please contact your professional doctor to determine the follow-up treatment plan.

7. Do I need to pay any fees for participating in the study?

There was no charge for participants in the study, and the extraction of clinical data was for analysis purposes only.

Corresponding reductions and compensations will be given to the participants in this study: the fees for the amylase test of the postoperative drainage fluid are reduced or exempted according to the corresponding proportion of the research funds.

Participants entering into the study will provide corresponding treatment and compensation in accordance with relevant national regulations in the event of research-related injury.

8. Is personal information confidential?

Your study materials will be kept in West China Hospital of Sichuan University, and your medical records can be accessed by investigators, research authorities, and ethics review committees. Any public reporting of the results of this study will not disclose your personal identity. We will make every effort to protect the privacy and personal information of your personal medical data to the extent permitted by law.

9. Do I have to participate in the study?

Participants in this study are completely voluntary, and you can refuse to participate in the study or withdraw from the study at any time during the trial without discrimination and retaliation, and your medical treatment and rights will not be affected. If you decide to withdraw from this study, please contact your doctor so that the disease can be properly managed.

Participant Statement: I have read the above introduction to this study. The investigator has fully explained and explained to me the purpose of this study, how it operates, and the possible risks and potential benefits of participating in this study and has answered all relevant questions. Voluntary participation in this study.

Agree□ or **Reject**□ Studies other than this one have utilized my research data and biological specimens.

Participant print name：

Participant signature：_____ Date：__ __ __ __ __ __

Participant contact number：_____ Phone number：

Legal representative print name：_____ （If applicable）

Relationship with participant ：

Signature of legal representative：_____ Date：__ __ __ __ __

Reason for signing by legal representative：

Witness print name：_____ （If applicable）

Witness signature：_____ Date：__ __ __ __ __

Reasons for a witness's signature：

Investigator Statement: I have explained the relevant details of the study to the above volunteer who participated in this study and provided him/her with an original signed informed consent form. I confirm that I have explained the situation of this study to the subjects in detail, especially the ethical principles and requirements, such as the possible risks and benefits, freedom and compensation, damage and compensation, voluntariness and confidentiality of participating in this study.

Investigator signature：_____ Date：__ __ __ __ __

Investigator contact number：

Biomedical Ethics Review Committee of West China Hospital of Sichuan University

Contact telephone number: 028-85422654, 028-85423237