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Central pancreatectomy combined with end-to-end anastomosis reconstruction versus conventional central pancreatectomy in robotic surgery: study protocol for a randomized clinical trial

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Study protocol

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Abstract

[EXSCINDED] Abstract Abstract Background Central pancreatectomy (CP) is an ideal surgery option for benign and low malignant potential lesions in the neck and body of pancreas. CP maintains pancreatic endocrine and exocrine function better than distal pancreatectomy and pancreaticoduodenectomy, but it has a higher risk of pancreatic fistula1. Up to now, CP reported by Dagradi and Serio2 is the standard procedure. But our four-year experience suggests CP with end-to-end anastomosis could reduce pancreatic fistula and other complication rates. The aim of the trial is to investigate whether the CP combined with end-to-end anastomosis reconstruction approach can reduce the fistula rate of patients with pancreatic neck and body benign and low malignant lesions compared with the conventional approach. We hypothesize that CP combined with end-to-end anastomosis could be an alternative procedure of conventional CP.Methods/design The trial is a single center, randomized controlled trial with two parallel research group. The trial compares the possible advantages of CP combined with end-to-end anastomosis to conventional CP in robotic surgery. One hundred and seventy patients with pancreatic neck and body benign and low malignant lesions in Chinese People's Liberation Army (PLA) General Hospital will be enrolled. The patients will be divided into two groups randomly. One group will choose CP with end-to-end anastomosis while the other group will use conventional CP. The primary endpoint will be postoperative pancreatic fistula (POPF) rate.Discussion There is no randomized clinical trial to estimate the advantages of CP with end-to-end anastomosis reconstruction. The CP with end-to-end anastomosis reconstruction in robotic surgery was first reported by Professor Liu in our department, and professional surgical techniques can reduce confounding factors and have high recruitment rate. For our research is a randomized clinical trial, we can provide high quality evidence on CP standard.

Introduction

Pancreatic neoplasms is a common disease in general surgery department. Pancreaticoduodenectomy and distal pancreatectomy are standard procedures for tumor located in the head or body-tail of pancreas respectively. However, CP is an ideal option for benign and low malignant potential lesions in the neck and body of pancreas, for pancreatic preserving surgery can optimize the quality of life with preservation of exocrine and endocrine pancreatic functions [3].

In 1982, Dagradi and Serio first reported CP with reconstruction of pancreas by oversewing the cephalic stump and performing an end-to-end pancreatojejunostomy for the distal pancreatic stump[2]. This procedure is considered safe and optimizes the quality of patients' life. Up to now, Dagradi and Serio' method is the conventional procedure in open and minimally invasive surgery[4–6].But it has a higher risk of pancreatic fistula[1]. Various studies indicate that the use of pancreatojejunostomy may lead the high risk of pancreatic fistula[7–8]. CP with end-to-end anastomosis reconstruction could solve this problem by keeping the pancreatic juice secreting from its original physiological structure and maintain the superiority of CP in selected patients[9].

We searched in PubMed and there are few studies comparing the short-term and long-term outcome of CP with end-to-end anastomosis reconstruction and conventional CP, for this new method was not commonly used worldwide. The new method of reconstruction was proved to be safe and feasible[10–11], but it was regarded the suboptimal technique because of the difficulties in anastomosis. With the development of minimally invasive surgery, surgeons can carry out more complex operation. Some studies showed the advantages of end-to-end pancreatic anastomosis in robotic CP[9,12], but their researches only contained few patients and did not compare with the conventional CP.

CP combined with end-to-end anastomosis reconstruction avoids the reconstruction of digestive tracts and keeps pancreatic juice secreting from its original physiological structure, so it could have lower risk of pancreatic fistula and better outcome. A randomized clinical trial can provide high quality evidence. If the trail suggests the new method has superiority in pancreatic fistula rate and postoperative morbidity rate, CP combined with end-to-end anastomosis reconstruction may become the optimal choice and patients with benign and low malignant potential lesions in the neck and body of pancreas will benefit from it.

Methods/design

Aim of the trial

The aim of trial is to find out the possible advantages of CP combined with end-to-end anastomosis reconstruction in robotic surgery. We hypothesize that the new method has lower pancreatic fistula rate and could reduce the occurrence of postoperative complications.

Primary and secondary endpoints

Primary endpoint is postoperative pancreatic fistula which is the essential indicator for pancreatic surgery. The definition and grading of postoperative pancreatic fistula are based on the 2016 update of the International Study Group[13]. We will examine the amylase level in abdominal drainage fluid and blood in the first, third, fifth and seventh day after operation.

Secondary endpoints care about the postoperative morbidity rate and mortality rate, including the rates of lymphatic fistula, postoperative hemorrhage, DGE (delayed gastric emptying), infection and reoperation. Lymphatic fistula is based on the definition of the International Study Group of Pancreatic Surgery (ISGPS) 2017[15] and Postoperative hemorrhage is based on the definition of ISGPS 2007[16]. Reoperation will be performed when severe complication happens, and it could not be solved by normal treatments. DGE is based on the definition of ISGPS 2007[17], Clavien–Dindo Grade will be used to estimate the severity of complications[18]. Moreover, readmission rates, days of hospital stay and days of stay in intensive care unit will also be assessed in our study. The definition of the endpoints is shown in Table 1.

Design/setting/participants

The trial is designed as Chinese single center randomized clinical trial. The feature of this trial design is a randomized study. Randomization will reduce confounding factors, and PLA General Hospital is a big center with enough number of participants and advanced surgery technique. Single center research guarantees all the patients received equal level treatments during their hospitalization. The primary and secondary outcomes are objective indicators, so our results could hardly affect by subjective factors. The schedule of the trial is showed in Fig.1.

The randomized clinical trial will be conducted in Second Department of Hepatopancreatobiliary Surgery, PLA General Hospital. One hundred and seventy patients with benign and low malignant potential lesions in the neck and body of pancreas will be included. The exclusion criteria can be limited to tumors do not invade the main pancreatic duct and suitable for enucleation, distant pancreatic stump shorter than 5cm and suspected high malignant lesions. All the candidates should fully aware of the trial and could give informed consents before the randomization. The inclusion and exclusion criteria are showed in Table 2.

The follow-up for each patient will be 3 months, and all the data will be documented properly. We will give suggestion and suggestion to the patients to guarantee follow-up rates. The patient data is documented in Table 3. The schedule of enrolment, interventions and assessment is planned in standard form[14].

Intervention

We will compare the outcome of two different types of CP in selected patients. All the operations will be performed by an experienced team. Operation initiates by establishing pneumoperitoneum and putting trocars. The placement of ports is shown in Fig.2. Then open lesser sac and expose pancreas. Neoplasms and the relationship with blood-vessel are identified with the use of intraoperative ultrasonography. The superior mesenteric, portal, and splenic veins are separated smoothly from the pancreas and the middle pancreas is dissected by ultrasonic scalpel. After the resection is the reconstruction. The procedures of two kinds of CP is different from now on. For conventional CP, the cephalic portion ligates with suture and single layer pancreatojejunostomy anastomosis is performed at distant part of pancreas. A pancreatic stent should be placed into the main pancreatic duct and two drainage tubes are left close to the anastomosis and cephalic stump respectively. As for CP combined with end-to-end anastomosis reconstruction, the main pancreatic duct of two parts is identified and a temporary pancreatic stun is placed in it. The superior and inferior margins of two stumps are oversewn and the sections of pancreas suture in U-shaped way. Then the cephalic and distant parts are pulled together, and the anastomosis is completed by continuous suture of posterior and anterior parts respectively. Two drainage tubes are placed close to the posterior and anterior parts of anastomosis. The operation is accomplished without other reconstruction of digest tract.

Randomization

All the patients will be randomized after they are diagnosed as pancreatic neck and body benign and low malignant lesions compared. The randomization with variable block length will be performed with a 1:1 ratio before the CP. All the patients will be randomized to either the new CP group or the conventional CP group basing on computer-generated random list. The randomization and assignment will be performed by scientific secretary of Second Department of Hepatopancreatobiliary Surgery, PLA general hospital, and the allocation results will be informed to surgeon before the CP. If the operation method changes due to the patient's condition, the patient will be excluded from this research. Study design flow chart is shown in Fig.3.

Blinding

Patients do not know the anastomosis method after operation, for it is difficult for patients to know the operation method without the help of CT or MRI. The surgeons will not know the anastomosis method and remain blinded before the CP. The treatments after operation will be decided and carried out by doctors blinded to the anastomosis procedure. If patients are in serious conditions and blinding could affect the treatment, the doctors will be unblinded. The data of patients will be documented and analyzed by doctors and secretaries blinded to allocation group.

Statistical analysis

A systematic review which contained 94 studies involving 963 patients indicated that the POPF rates of traditional CP were 30.8%[25]. A retrospective study of PLA general hospital showed that the POPF rates of CP combined with end-to-end anastomosis reconstruction were 65.6%[9]. The required sample size (Z-Pooled normal approximation; power 80%; alpha 0.05) will be seventy-eight per group. We will recruit eighty-five patients per group to reduce influence of loss of follow-up.

A data collection group will develop the plan of statistical analysis and carry out it. The continuous variables will be showed as mean ± SD, and it will be compared by using Student's t test or the Wilcoxon rank-sum test. The categorical data will be analyzed with x^2 test or Fisher's exact test. Ranked data, including age, POPF, Clavien-Dindo grade, will be compared in Wilcoxon signed-rank test. $P<0.05$ is statistically significant and we will use two-sided statistical tests to calculate P value. A midterm test will be planned during the research. The data of enrolled patients, including blood loss, POPF rate, complication rate, will be analyzed by investigators in midterm test.

Data management

All the data will be collected and recorded in case report forms (CRFs) by investigators. The patients' demographic, baseline clinical and outcome data will include in CRFs. Only authorized people have access to the data. To protect patients' privacy, each person will have a unique number in CRFs. All the data will be documented in an electronic database by two responsible researchers to ensure the accuracy of data, and the data will be analyzed by investigators who do not know the allocated groups.

Monitoring

Monitoring will be performed in the entire study by our research secretaries. The duty of them is to ensure that all the procedures of the study are following the protocol. Furthermore, they will supervise the data and solve problems developed during the trail. To evaluate the safety of the trial, a midterm analysis will be performed when half of the participants enrolled in the study.

Safety

All the complications will be uploaded to the database immediately, and serious adverse events will be evaluated by safety monitor group. The study will be stopped if patients have high risks of complication caused by intervention. A midterm analysis will be made, and the trial will be adjusted or canceled if the results indicate the high risk of CP combined with end-to-end anastomosis reconstruction. Patients could withdraw from the study at any time and they will be excluded from the trail.

Ethics

The study will be conducted in accordance with the Declaration of Helsinki. The trial has been approved by the Ethics Committee of PLA General Hospital (S2016–098–02). All the patients will be informed the purpose, method, risk of the study and their rights to withdrew. They will sign their names with fully aware of the trial voluntarily.

Discussion

Radical resections of pancreatic malignant tumors were common performed worldwide to achieve high R0 resection rates[20]. However, radical resections were not the optimal choices for benign and low malignant potential lesions in the neck and body of pancreas[21], and CP is enough to deal with these lesions[22,23]. Though CP has a higher risk of pancreatic fistula, it maintains pancreatic endocrine and exocrine function better than distal pancreatectomy and pancreaticoduodenectomy. Pancreas preserved operation provides better long-term outcomes[1].

CP combined with end- to-end anastomosis reconstruction was recognized as unreliable because of its high POPF rates[24], especially in normal pancreatic texture without pancreatic duct dilated. Robotic

system provides a perfect platform for minimal invasive surgery, and precise surgical performances become easier with the help of robotic system. We could relieve pancreatic tails connection with around tissue and pull pancreatic head and tail together in robotic surgery with less anastomosis time and blood loss. The efficiency of this method was proved by postoperative MRCP.

PLA general hospital is a high-volume center and a great number of patients will be enrolled in the trial to ensure the representation of population. Patients with benign and low malignant potential lesions in the neck and body of pancreas and suitable for CP will be included in the study. It is a randomized clinical trial, and the results will be applied to clinical practice and CP combined with end-to-end anastomosis may become a standard procedure of CP.

The primary endpoint concerns the major problem in pancreatic surgery: postoperative pancreatic fistula. Postoperative pancreatic fistula often relates serious complication after the operation and longer recovery time of patients. Secondary endpoints consider the postoperative morbidity rate and mortality rate, including the rates of lymphatic fistula, postoperative hemorrhage, DGE, infection and reoperation. Long-time outcome is also considered in our study, and a one-year follow-up will evaluate the efficiency of end-to-end anastomosis reconstruction.

The single center clinical trial reduces confounding factors caused by different surgeons and treatment of hospitals. All the endpoints are objective indicators which reduce the impact of investigators. Moreover, a midterm analysis will be conducted to estimate the safety of the study.

PLA general hospital is a high-volume center and our team has finished more than 1010 robotic pancreatic surgery in the past six years which guarantee the enough number of participants in our study[19].

CP combined with end-to-end anastomosis reconstruction was proved to be safe and feasible[10–11], and retrospective study indicated the superior of CP combined with end-to-end anastomosis reconstruction in our center[9,12].

Though CP combined with end-to-end anastomosis reconstruction are adopted by several centers, there are no randomized prospective researches to compare new CP with conventional method. The results of our trial will be published in journal. This will provide high-quality evidence to consensus and may become an alternative of conventional CP.

Trial Status

This trial protocol is published using version 1.0 on 18 December 2018 approving by Ethics Committee of PLA General Hospital (S2016–098–02). The recruitment will be started on 1 August 2019 and it is estimated to be completed in October 31, 2019.

Abbreviations

CP: central pancreatectomy; PLA: People's Liberation Army; POPF: postoperative pancreatic fistula; ISGPS: International Study Group of Pancreatic Surgery; CRFs: case report forms; DGE: delayed gastric emptying; ASA: American Society of Anesthesiologists; LOS: length of stay; BMI: body mass index; ICU: intensive care unit. CRFs: Case Report Forms.

Declarations

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Availability of data and materials

Not applicable.

Authors' contributions

RL drafted the trial. He is the principle investigator for the study. FW integrated the definition and background. GZ and HZ performed the randomization and provided the statistical analysis for the trial. FH recruited the patients and collected the data. JL monitored the trial and guaranteed the quality of study. LZ wrote most part of the article. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The trial protocol was approved by the Ethics Committee of PLA General Hospital (S2016–098–02). Before enrolled in the trial, patients will be informed the purpose, method, risk of the study and their rights to withdrew. Patients must be at least 18 years old and fully understand the trail. Patients' informed consent form with signature will be documented. The trial will be conducted in the accordance with the Declaration of Helsinki.

Consent for publication

Not applicable.

Competing interests

The authors deny have any competing interests.

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Tables

Table 1 The definition of endpoints

Endpoints	Definition
Pancreatic fistula	A drain output of any measurable volume of fluid with an amylase level >3 times the upper limit of institutional normal serum amylase activity, associated with a clinically relevant.
Lymphatic fistula	Output of milky-colored fluid from a drain, drain site, or wound on or after postoperative day 3, with a triglyceride content ≥110 mg/dL (≥1.2 mmol/L)
DGE	The inability to return to a standard diet by the end of the first postoperative
Estimated blood loss	week and includes prolonged nasogastric intubation of the patient
Operating time	The total time from the start of surgery to the end of surgery.
Length of hospital stay	Days from operation to discharge
Mortality	Death during the follow-up period

Table 2 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Benign or low malignant potential lesion	Tumors do not invade the main pancreatic duct and suitable for enucleation
Lesion located in the neck and body of pancreas	Distant pancreatic stump shorter than 5cm
No more than 1 lesion	Suspected high malignant lesions
Undergoing robotic surgery	ASA ≥ 4
Age≥18 years and≤75 years	Participation in another interventional trial
Aware of the trial	Pregnant women
Giving informed consents	Severe mental disorder
Body mass index (BMI)≤30 kg/m^2	Previous abdominal surgery
American Society of Anesthesiologists (ASA)≤3	Combined with other malignant lesions

Table 3 Demographic and Outcomes of two groups

	CP combined with end-to-end anastomosis reconstruction	Conventional P CP
Preoperative characteristics		
Age		
Sex(F)		
BMI		
ASA score		
Operative characteristics		
Operative time, min		
Estimated blood loss, ml		
Intraoperative blood transfusion		
Soft pancreatic gland		
Dilated pancreatic duct(≥4mm)		
Outcomes		
Major complication		
POPF		
DGE		
Wound infection		
Pathology		
ICU length of stay (LOS)		
Hospital LOS		
Readmission		
Mortality		

Figures

	study period								
	Enrolment		Surgery	Follow-up					Close-out
TIMEPOINT	t-x	t-<72h	t0	POD1	POD3	POD5	POD7	POD30	POD90
ENROLMENT:									
Eligibility screen	X								
Informed consent	X								
Randomization		X							
Allocation			X						
INTERVENTIONS:									
New CP			X						
Conventional CP			X						
ASSESSMENTS:									
Demography	X								
Intraoperative data			X						
Pathology							X		
Pancreatic fistula				X	X	X	X		
Operative time			X						
Postoperative morbidity				X	X	X	X	X	X

Fig.1 Enrollment, interventions, and assessment schedule of the trial (modified SPIRIT figure)

Figure 1

Enrollment, interventions, and assessment schedule of the trial (modified SPIRIT figure)

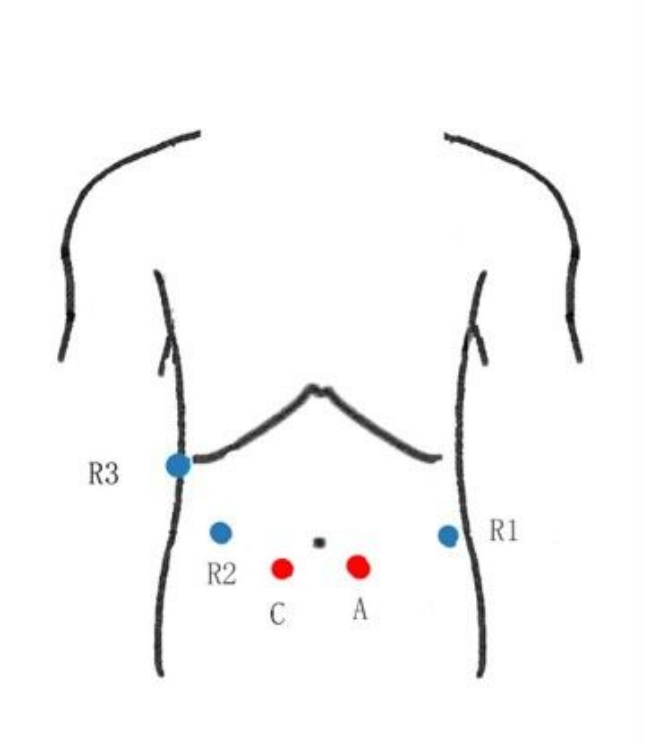


Fig.2 Ports locations in CP. R1-3: ports of robotic arms, A: assistant port, C: camera port.

Figure 2

Ports locations in CP. R1-3: ports of robotic arms, A: assistant port, C: camera port

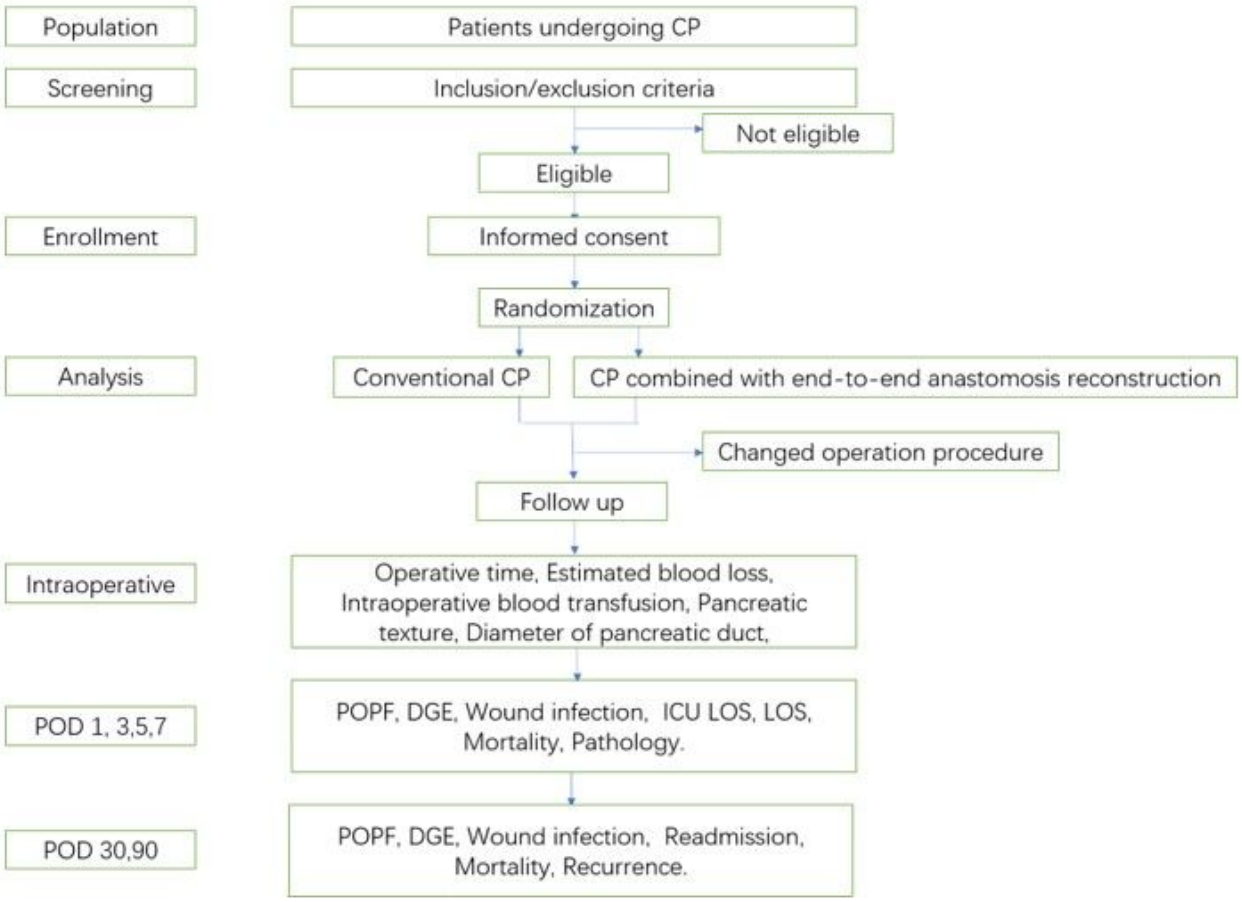


Fig.3 Study design flow chart

Figure 3

Study design flow chart

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