Effect of Preoperative CT Angiography Examination on the Clinical Outcome of Patients With BMI≥25.0kg/m2 Undergoing Laparoscopic Gastrectomy: Study Protocol for a Multicenter Randomized Controlled Trial

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Research Article

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Abstract

Background

Gastric cancer, which ranks the fifth most common malignant and causes the third oncological death, especially in east Asian countries, such as China, Japan and Korea, is still a serious global healthy issue that caused heavy financial burden for the government and family. To our knowledge, there is seldom reports of multicenter randomized control trial on the utilization of CT angiography (CTA)for the patients who are diagnosed histological gastric cancer before surgery. Therefore, we conduct this RCT to verify whether the utilization of CTA can possibly change the short- and long-term clinical outcome or not.

Method:

The GISSG 20 − 01 study is a multicenter, prospective, open-lable clinical study that emphasis on the application of the CTA for the patients who will undergo the laparoscopic gastrectomy to prove the clinical outcome of it. 382 patients that meet the inclusion criteria and not in accordance with exclusion criteria will be recruited in the study and randomly divided into two groups with a 1:1 ratio: CTA group(n = 191) and Non-CTA group (n = 191). Apart from both of the two groups receive the examination of upper abdomen enhanced CT, the CTA group receive the examination of CT angiography. The primary endpoint of this trial is the volume of blood loss, the second primary endpoints are retrieved number of lymph nodes, postoperative recovery course, hospitalization costs, length of hospitalization days, postoperative complications, 3 years OS and 3 years DFS.

Discussion

It is anticipated that the result of this trial can provide high-level evidence and have clinical value on the application of CTA in laparoscopic gastrectomy.

Trial registration:

ClinicalTrials.gov, NCT04636099, Registered November 19, 2020

Introduction

Background and rationale

Since the first report of laparoscopic assisted-distal gastrectomy was made by Kitano in 1994[1], it has been gained great acceptance both by the surgeons and patients who were diagnosed with surgical resectable gastric malignancy without bulky lymph node or lesion, due to its minimal invasive surgical procedure, enhanced recovery course, and comparable oncological efficiency compared with that of open

surgery that has been demonstrated by some large-scale multi-institutional randomized controlled trial[2–7]. Although the progress in terms of gastric cancer multimodal treatment has achieved a great improvement, such as chemotherapy, immunity therapy, which has showed significance oncological advantages for the curable advanced gastric malignant tumor, the surgery is still the mainstream of the curable treatment for the patients that diagnosed with gastric cancer.

Radical lymphadenectomy associated with gastrectomy is essential principle for the treatment of gastric cancer[8, 9]. The distribution of the lymph nodes is occurred with vessels. The number harvested positive lymph node is of great importance for the long-term survival of the patients, but even for the better-trained hands lymphadenectomy is a challenging and tricky task, not only for its technical factors in separating the lymph nodes from its surrounding tissues, but also to some circumstances its difficulty in distinguishing bulky lymph nodes from main perigastric artery, such as right gastric artery, common hepatic artery and spleen artery.

Because of the complexity of variation of perigastric vessels, apart from the necessary of familiar with normal anatomical perigastric vessels before surgery, the preoperative acquaintance of the aberrant anatomical of the vessels, and intraoperative reduction the of damage to the vessels, such as the left gastric artery and common hepatic artery, plays a utmost role during the surgery, which can reduce intraoperative blood loss, protect the liver from dysfunction, and fast postoperative recovery. [10]

Although digital subtraction angiography (DSA) is regard as the gold standard to detect the anatomical position and variations of the vessels[11], because of its invasive operation and relative high expense, it is replaced by the CT angiography (CTA) in the field of gastrectomy for the purpose of leaning the variation of the perigastric vessels before surgery which can provide the stereoscopic vision of the perigastric vessels[12, 13].

Some studies have already declared the useful application of the CT angiography before surgery. Iino et al. demonstrated that the preoperative learning the information of perigastric vessels may contribute to the safety dissection of the lymph node associated with laparoscopic gastrectomy[12]. According to the study of Natsume et al.[14], with the help of 3D CT images the surgeon may decrease the volume of blood loss during the surgery.

Based on a retrospective propensity score matching study[15], we proposed a novel classification of the perigastric vessels according to the processing of image of CTA, which indicates that the utilizing of it can enhance the short clinical recovery course, especially for the patient whose BMI was not less than $25kg/m^2$. As far as we know,there is seldom literature about multi-center randomized controlled prospective research that focus on the application of CTA for the patients who are diagnosed with gastric cancer before underwent laparoscopic gastrectomy yet.

To a further research, we conducted this multicenter controlled trial which was named after GISSG 20 – 01 to verify whether the using of CTA can improve the short and long clinical outcome for the patients who underwent laparoscopic or robotic gastrectomy.

Methods/design

Objective

The aim of GISSG20-01 study is to explore the short clinical recovery course and long-term oncological effects by application of the CTA for the patients who will undergo the laparoscopic or robotic gastric cancer radical surgery.

Trial design

The GISSG20-01study is a multicenter, prospective, open-lable clinical study that the patients who meet the inclusion criteria was randomly assigned into experimental group (CTA Group) and control group (Non-CTA Group) with a 1:1 ratio. Apart from a certain routine examination in both groups, the patient in the CTA group will receive the examination of upper abdomen enhanced CT and CT angiography while the Non-CTA group received the upper abdomen enhanced CT only.

Participant selection

The patients who are diagnosed with gastric cancer and underwent laparoscopic or robotic gastrectomy were enrolled from 14 centers which include The Affiliated Hospital of Qingdao University, Qilu Hospital of Shandong University, Shandong Provincial Hospital, Shandong Province Qianfoshan Hospital, Yantai Yuhuangding Hospital, The Affiliated Hospital of Weifang Medical University, Weifang People's Hospital, Shandong Jining No.1 People's Hospital, Weihai Municipal Hospital, Weihai Central Hospital, Dongying People's Hospital, Rizhao People's Hospital, Liaocheng People's Hospital and People's Hospital of Jimo District, Qingdao. The launching conference was held online which was used to inform the details of the GISSG 20 – 01 trial. The enrollment of the first patient was started in November 2020, while it is anticipated that the deadline of recruitment of the patient in November 2021. In the end,382 patients that meet the inclusion criteria would be included in this trial. The study protocol and informed consent was approved by the ethics review board in all research hospital before the enrollment of the patients.

The flowchart that demonstrates the procession of enrollment of patients is shown in Fig. 1, the study protocol was revised to 1.3 version in December 2020. An integral checklist of items in accordance with SPIRIT (Standardized Protocol Items: Recommendations for Intervention Trials) (2013 version) was supplied in the additional file 1.

Inclusion criteria and exclusion criteria

The inclusion criteria are listed in the following: 1) patients with pathological diagnosis of gastric adenocarcinoma by gastroscopy;2) patients age between18 and 75 years old; 3) patients with BMI (Body Mass Index) not less than 25.0kg/m^2; 4) the tumor clinical stage that evaluated by CT image is T1 ~ T4a, N0 ~ 3, M0; 5) patients with Eastern Cooperative Oncology Group

(ECOG) score 0–1 points;6) the surgical approach is laparoscopic or robotic surgery;7) patients who are willing to participate in the study and sign the informed consent form.

The exclusion criteria are listed in the following: 1)patients whose tumors clinical stage are conformed to be T4b or M1 and the tumor is found to be unresectable during the operation; 2) patients who are suffering from the history of other malignant tumors, tumors of low malignant potential (such as giant cell tumor of bone, pseudomyxadenoma of appendix, invasive fibroma); 3)patients who have serious other system diseases and cannot tolerate the trauma of surgery; 4)patients with non-adenocarcinoma type malignant tumors verified by pathology after surgery; 5)patients with residual gastric cancer; 6)patients who are allergic to iodine contrast agents; 7) patients who have received neoadjuvant therapy before surgery; 8)pregnant or lactating female patients; 9)patients who are participating in other clinical trial.

Randomization

In this trial, eligible patients are randomized assigned to either CTA group or Non-CTA group with a 1:1 ratio. A central dynamic, stratified strategy is adopted for the aim of randomization. The sequence of randomization is generated by a certain doctor who is independent of this trial using the method of Pocock-Simon minimization by SAS 9.3 (SAS Institute Inc, Cary, NC, USA), and stratified by participating site (14 hospitals) and surgical approach (laparoscopic or robotic). The above information provided by participating centers would be submitted to the date center, at the Department of Gastrointestinal Surgery, Affiliated Hospital of Qingdao University, China, where the central randomization was executed. Consequently, the allocation information is sent to each participating site. The allocation procedure was not blinded for investigators or patients, but mask for data collection and analysis.

Sample size computation

Based on the precious retrospective study which shows that the mean ± standard deviation of the estimated blood loss during the operation in CTA group and Non-CTA group was 72.5 ± 66.4ml and 93.5 ± 88.4ml, respectively[15]. we calculate that 382 patients are enquired to participate in this study (191 patients in the experimental group and 191patients in the control group) providing that a significant level of $\alpha = 0.05$ using a one-sided two-sample t-test, the power of $1-\beta = 80\%$,and the maximum dropout rate is about 10%. The sample size computation was performed using PASS 11(NCSS, LLC. Kaysville, Utah, USA).

Outcomes

The primary endpoint of this trial is the volume of blood loss which occurs during the manipulation of the surgery. The second primary endpoints are: 1) the harvest number of lymph node is defined as the dissection number of lymph node through the standard extend of lymph node dissection which is compiled with the principal of lymph node dissection guided by the 2018 version of Japanese Gastric Cancer Treatment Guidelines, 2)postoperative recovery course which refers to the items of time to first ambulation, flatus, liquid diet and so on, 3) hospitalization costs is defined as the total expenses during the hospitalization brought on by the treatment and care,4)length of hospitalization days that is defined as from the day of surgery to the day of discharge, 5) the severity of postoperative complications that include anastomotic leakage, pancreatic fistula, pulmonary or abdominal infection are evaluated by the

classification of Clavien–Dindo. The complications should be recorded when it is more than Grade II. Moreover, 3 years OS (Overall Survival) and 3 years DFS (Disease Free Survival) are also should be followed-up and recorded.

Interventions and CTA protocol

Both the procedure of laparoscopic or robotic gastrectomy associated with the standard extend of lymph node dissection was performed by reference to the 2018 version of Japanese Gastric Cancer Treatment Guidelines[8], and the rection range of stomach that is based on the Japanese Gastric Cancer Association classification is according to lesion location and size that is described in gastroscopy reports[16]. Although there are three classic type of digestive tract reconstruction which is named after Billroth I, Billroth II and Roux-en-Y, the last type was recommend in this study. The TNM staging system is adopted from the eighth version of American Joint Committee on Cancer (AJCC). Mandatory abdominal enhanced CT scan was performed in both experimental group and control group to evaluate the clinical stage of tumor. Moreover, Compared with Non-CTA group, the patients in the CTA group was enquired to perform the examination of CTA once they are randomly assigned to the experimental group.

Abdominal enhanced CT is performed using 64-detector row CT scanner in this study, while the type of CT equipment is according to each participating center. The operation procedure of abdominal enhanced CT is set to ensure the same standard for the reconstruction of perigastric arteries. Fasting no less than 8 hours before examination is necessary for the patients and the injection of 10 mg anisodamine is for the purpose of reducing the gastric distention and motility 10 minute before the examination. Non-ionic iodinated contrast material is used as the contrast agent that is injected at a speed of 4.0 ml/s by an automatic injector, and the volume of it is based on the weight of patient, such as for patients weighing 60 kg or less, the lower limit is 120 ml, and for patients weighing more than 75 kg, the upper limit is 150 ml.

Quality control

For qualification of surgeons

To ensure the quality of the clinical trial and guarantee the safety of patients, some essential principle should be achieved before the surgeon participate in the study. Apart from the surgeon should perform at least 100 laparoscopic or robotic gastrectomy, which means that the learning curve was went through, two raw surgical videos are also required to submit to surgical treatment quality control committee that consist of two senior surgeons independently of the trial

to verify that the surgeon meets the research requirements.

For quality of CTA image

The scanning range of abdominal enhanced CT was from the upper abdomen, from the top of diaphragm to the level of inferior mesenteric artery, and the region of interest (ROI) was at the level of celiac artery. Since the quality of CTA is of utmost importance in this trial, we set up a criterion to ensure the image

quality which are listed as following: 1) There was no bundle sclerosis artifact produced by metal foreign body in vitro which obviously affected the display effect of artery;2) There is no motion artifact caused by motion displacement;3) MPR, VR, MIP and other three-dimensional reconstruction techniques can display the perigastric artery clearly. After the reconstruction of the CTA, the anatomy of perigastric arteries is captured to evaluate the origin and branch of it, such as celiac artery and the hepatic artery, by two senior radiological specialists.Besides, in order to decrease the potential damage to perigastric arteries ,the surgeon and his team should have a good acquaintance of anatomy of the perigastric arteries, and the perigastric artery type which was divided into seven types based on our previous proposal for a novel classification of perigastric arteries is recorded in the CRF.

Adverse events

Adverse events, which is defined as an unfavorable and negative clinical outcome happens when the patients received medical care, occur after the examination of CTA and surgery was recorded and treated properly. To ensure the high quality of the trial, an independent date and safety monitoring committee (DSMC) which consist of two senior surgeon, one statistician and one medical ethics expert has been set up and has privilege to check all of the statistics related to the trial without any permission.

Postoperative Care

The patients are assessed by the doctor in charge twice a day, any discomfort or surgical complications should be appropriately explained and handled, moreover, these management is recorded in the CRF. The patients should be discharged from the hospital when meet the criteria listed in the following: postoperative pain is well controlled with or without oral analgesics, the body temperature is no more than 37 ℃, the postoperative complications are well managed, and the oral semiliquid food is tolerated that can sustain daily walking activity.

Follow-up

A Specified follow-up team is arranged for the patient after surgery at each participated center,the mainly follow-up method including outpatient, telephone or mail. Postoperative recovery course that includes short-term course and long-term oncological effects and adjuvant therapy will be assessed, as is shown in Fig. 2. For the first year after surgery, the patient needs to be reviewed every three months, for the 2–3 years, the patient needs to be reviewed every six months, the follow-up program includes physical examination, laboratory test that consist of blood routine, liver and kidney function, electrolytes, digestive tract tumor markers(including the examination of CEA, CA125,CA199 and CA724), moreover, the gastroscope and chest and abdominal CT was performed once a year and every six months, respectively. MRI or PET-CT need to be executed when tumor recurrence or metastasis is suspected, besides, the survival status of patients is noted in the CRF, the patients received follow-up of 36 months is essential for the study.

Date collection and analysis

A designed and coincident case report form (CRF) was used to record the information required by the study, such as baseline characteristics, laboratory data, perioperative clinical recovery course, and long-term oncological outcome, meanwhile, a designated clinical investigator is responsible for the collective of date in each center. Moreover, in order to keep track of changes in date, any corrective of the raw date need to sign date and the investigator's name.

A monthly data check that includes data summarized by each center, abnormal data, and delayed data in progress tracking, is required during the trial period. The check content.

Continuous variables will be presented as the mean ± standard deviation, meanwhile classification variables will be are described as number(N) and percentage (%) to express the difference between two groups. To compare continuous variables for the two groups, the Student's t test or Mann–Whitney U test are performed, and categorical variables are calculated by the $\chi 2$ test or Fisher's exact test. The OS and DFS, which is respectively defined that the time from the surgery to death and that the time from surgery the recurrence of the tumor, are assessed by the methods of Kaplan–Meier with log-rank test that are adopted to analyze the difference in the survival curves. Cox proportional hazards regression model with 95% confidence interval will be used to perform regression analysis in univariate and multivariate analyses. P value less than 0.05 is set down the result as statistical significance. The 25th version of SPSS (SPSS Inc., Chicago, IL, USA) will be used to analysis the required date.

Strengths and limitations

The strength of study is that this is the first multi-center randomized controlled trials to evaluate the feasibility and benefits for the application of CTA on the short clinical recovery course and long-term oncological effects for the patients who will underwent laparoscopic-assisted radical resection for gastric cancer. The subjective consciousness of the surgeon may lead to deviations in the results for this is an open-lable trial.

Discussion

Minimally invasive surgery, such as laparoscopic and robotic technique, has gained great popularity for its minimal trauma in the treatment of gastric cancer in these decades[3, 17–19]. However, laparoscopic surgery is lack of obtaining the three-dimensional anatomical vision and distinguishing relationship between intra-abdominal organs and vessels in spatial conformation compared with open surgery. Meanwhile, the local magnifying effect of laparoscopic makes it easy for the surgeon to lose the overall judgment of the adjacent relationship of perigastric tissues, and it is difficult to dissect the celiac artery and its branches accurately.

CT angiography (CTA), which is noninvasive and easy to operate, is the combination of CT enhancement technology and thin-layer, large-scale, fast scanning technology[20, 21]. It can clearly show the details of blood vessels in all parts of the body through reasonable post-processing of reconstruction. It is of great value for vascular variation, vascular diseases and displaying the relationship between lesions and

vessels[22–24]. Through this technology, we can clearly understand the anatomical conditions of gastric blood vessels and related blood vessels and provide better and more detailed lesion information for gastric cancer surgery.

Overall, the application of CTA before surgery can provide the information of the variation of perigastric vessels, contribute to the make a surgical formula in advance and guide the lymph node dissection, which is expected that the result of this trial can provide evidence and have clinical value on the application of CTA in laparoscopic gastrectomy, meanwhile this is consistent with the precise surgery.

Trial Status

The patients' recruitment is still ongoing that are still at the stage of collecting data at each participating site. In order to better execute this trial and ensure the safety of the patients, the study protocol was modified to the version of 1.3.

Abbreviations

CT
Computed tomography; CTA:CT angiography; MRI:Magnetic resonance imaging; PET-CT:Positron emission tomography CT ;CRF:Case report form; OS:Overall survival; DFS:Disease-free survival

Declarations

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Authors' contribution

YZ, SC and CM designed the study. CM, SC and YZ drafted the manuscript and modified the study protocol. YZ, LL, QH, LX, HW, SH and CM contributed to study coordination. HZ, XL, ZL, GL, ZJ, QW and CM made substantial contributions to patient recruitment. YZ, LL and QH contributed to obtaining funding and supervision. All authors have read and approved the version to be published and have agreed to be responsible for all aspects of the work. All authors have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature. All authors have read and approved the latest version of manuscript to be published.

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Availability of data and materials

The relevant date has not been available since datasets are currently not generated or analyzed yet.

Ethics approval and consent to participate

The study was approved by the ethics committee of the Affiliated Hospital of Qingdao University (QYFYKYLL 791311920) and will be performed to coincide with the principles of the Declaration of Helsinki and Good Clinical Practice guidelines. The written informed consent was obtained before the enrollment of patients. This study has already been registered at the ClinicalTrials.gov: NCT04636099, November 15, 2020.

Consent for publication

Not applicable

Competing interests

The authors declare that there are no conflicts of interest among each other.

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Figures

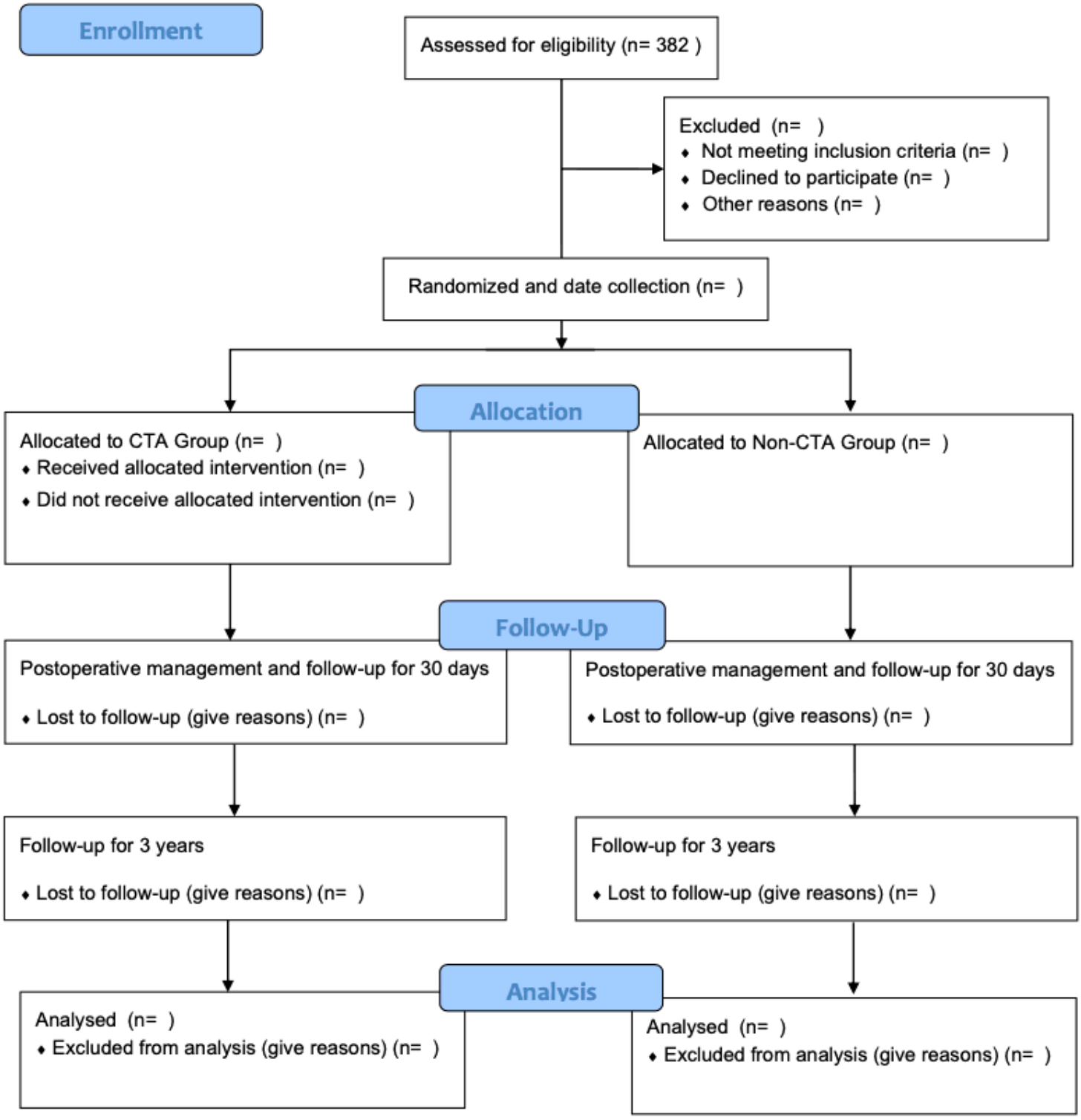

Figure 1

Study flowchart. Abbreviations: CTA CT angiography.

	STUDY PERIOD											
	Enrolment	perioperative	Chemotherapy 1-8 circle	Follow-up								
TIMEPOIT*	-1	0	1	2	3	4	5	6	7	8	9	10
ENROLMENT												
Inclusion/exclusion screen	×											
Informed consent	×											
Demographic	×											
Allocation	×											
INTERVENTIONS												
CTA intervention		×										
Non-CTA intervention		×										
ASSESSMENTS:												
Health checkup	×	×		×	×	×	×	×	×	×	×	×
Blood examination	×	×		×	×	×	×	×	×	×	×	×
Image material	×			×	×	×	×	×	×	×	×	×
Gastroscopy	×					×		×		×		×
Operation record		×										
Pathological report		×										
Postoperative recovery course		×										
Adverse event		×	×									
Chemotherapy			×									
Tumor assessment			×	×	×	×	×	×	×	×	×	×
Follow-up information				×	×	×	×	×	×	×	×	×

Figure 2

The items of enrolment, interventions and assessments in the flowchart. The symbol of × represent that the program needs to be collected. −1, 2 weeks before operation; 0, Perioperation; 1, postoperative adjuvant chemotherapy time; follow-up 2~10 refers to time points that listed in the following: 2, 1 months after surgery; 3, 3 months after surgery; 4, 6 months after surgery; 5, 9 months after surgery; 6, 12 months after surgery; 7, 18 months after surgery; 8, 24 months after surgery; 9, 30 months after surgery; 10, 36 months after surgery.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SPIRITFillablechecklist.doc