



BMJ Open Infrapyloric (No. 206) and greater curvature (No. 204) lymph node metastasis in adenocarcinoma located in the right half of the transverse colon (InCLART Study): protocol for a multicentre prospective observational study

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ABSTRACT

Introduction In the case of right-sided transverse colon cancer (RTCC) and hepatic flexure colon cancer (HFCC), there is a potential connection of lymph drainage between mesentery and greater omentum. However, most previous reports have been limited case series with No. 206 and No. 204 lymph node (LN) dissection for RTCC and HFCC.

Methods and analysis The InCLART Study is a prospective observational study aiming to enrol 427 patients with RTCC and HFCC treated at 21 high-volume institutions in China. The prevalence of infrapyloric (No. 206) and greater curvature (No. 204) LN metastasis and short-term outcomes will be investigated in a consecutive series of patients with T2 or deeper invasion RTCC or HFCC, following the principle of complete mesocolic excision with central vascular ligation. Primary endpoints were performed to identify the prevalence of No. 206 and No. 204 LN metastasis. Secondary analyses will be used to estimate prognostic outcomes, intraoperative and postoperative complications, the consistency of preoperative evaluation and postoperative pathological results of LN metastasis.

Ethics and dissemination Ethical approval for the study has been granted by the Ruijin Hospital Ethics Committee (approval number: 2019-081) and has been or will be approved successively by each participating centre's Research Ethics Board. The findings will be disseminated in peer-reviewed publications.

Trial registration number ClinicalTrials.gov Registry (NCT03936530; <https://clinicaltrials.gov/ct2/show/NCT03936530>).

INTRODUCTION

For both sexes combined, colorectal cancer is estimated to be the third most commonly diagnosed cancer (10.2% of total cases) and

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ This study is a multicentre, highly standardised study with precise and routine dissection of No. 206 (infrapyloric) and No. 204 (greater curvature) lymph nodes (LNs).
- ⇒ This study was specifically designed to investigate right-sided transverse colon cancer and hepatic flexure colon cancer, which have potential high relevance with No. 206 and No. 204 LN metastasis.
- ⇒ This study will demonstrate the prevalence of No. 206 and No. 204 LN metastasis, and its risk factors.
- ⇒ The survival analysis could not determine the prognostic effect of No. 206 and No. 204 LN metastasis based on our trial, since it is an observational non-comparative study.

the second leading cause of cancer death (9.2% of total cancer deaths).¹

In the case of right-sided transverse colon cancer (RTCC) and hepatic flexure colon cancer (HFCC), there is a potential connection of lymph drainage between mesentery and greater omentum. Based on embryological theory, through a series of suspension, rotation and growth, the greater omentum and the transverse mesocolon overlay the frontal surface of the mesoduodenum during the period of 12–20 weeks of gestation.² The tissues are fused to form the confluent area, which is known as gastrocolic ligament (GCL). The infrapyloric (No. 206) and greater curvature (No. 204) lymph node (LN) are components of GCL. In RTCC and HFCC, the GCL connects the transverse colon to the stomach

and the pancreatic head, which allows the possibility of cancer cells to spread to No. 206 and No. 204 LNs via the confluent area.³⁻⁵

Right-sided colon cancer (RCC) has significant improvements in its management.⁶⁻⁷ However, the surgical resection of colon cancer continues to lack international standardisation.⁸ The extent of lymphadenectomy in RTCC and HFCC surgery remains controversial, and expanded lymphadenectomy has not been performed routinely in Japan and China.⁹⁻¹¹ They believe that in cancer located in the right half of the transverse colon (including hepatic flexure), the 'non-regional LN', which is in the infrapyloric area and along the gastroepiploic arcade, is classified as distant metastasis. However, expanded lymphadenectomy is a standard procedure in some Western countries.¹² Hohenberger *et al* recommended the dissection of the corresponding gastroepiploic arcade along the stomach for a distance of about 10 cm and of the infrapancreatic nodes in their study.¹³

Most previous reports have been limited case series with No. 206 and No. 204 LN dissection for RTCC and HFCC.¹²⁻¹⁶ Few studies have mentioned the metastasis rate of LN as well as its prognostic value and complications in these regions. Piozzi *et al* reported in their systematic review that No. 206 and No. 204 LN metastasis from RTCC and HFCC should be seriously taken into consideration.¹⁷ The rate of metastasis of these LNs is inconsistent, ranging from 2% to 13% in No. 206 LN and 4.1% to 9% in No. 204 LN. In 1995, Toyota *et al* reported five patients (2%) with No. 206 LN metastasis and a risk of gastrocolic LN (GCLN)+ of 12% for pathological (p)N (condition of regional nodes)+RCC close to the hepatic flexure and advocated the dissection of No. 206 LN whenever metastatic involvement was suspected.¹⁸ A previous study showed that in patients with carcinoma of the transverse colon (n=26), LN metastases were seen in both regions (No. 206 and No. 204) in one case, three cases in No. 206 and two cases in No. 204, respectively. In patients with carcinoma of the hepatic flexure (n=15), LN metastases in No. 206 and No. 204 were identified in one case, respectively.¹⁵ Feng *et al* found that among 18 cases with tumours located in the hepatic flexure that underwent No. 206 LN dissection, metastasis was found in three cases (17%), with one case (5.5%) of positive LNs observed in the greater omentum along the greater curvature.¹⁹ Bertelsen *et al* also reported GCLN metastases in 3 (5%) of 62 patients with tumours located in the proximity of the hepatic flexure or transverse colon. The risk of GCLN metastases was related to perineural invasion (p<0.001) and to N stage (p=0.01).¹² Moreover, Uematsu *et al* reported that metastases in the GCLN occurred in 9% of patients with T2 or deeper invasive colon cancer close to the hepatic flexure.¹⁴ Huang *et al* retrospectively analysed all 438 patients with RTCC or HFCC who underwent GCLN dissection from 2008 to 2018. The incidences of GCLN metastases in patients with pT1-2 (extent of primary tumour), pT3, and pT4 disease were 0, 5.2%, and 10.1%, respectively. The corresponding incidences

in patients with pN0, pN1, and pN2 were 0.4%, 6.3%, and 19.8%, respectively.²⁰ Liu *et al* retrospectively analysed 181 patients with colon cancer who received dissection of the No. 206 LN. The proportion of No. 206 LN metastases in the ileocecal group, ascending colon group, and hepatic flexure group was 3.4% (1 of 29), 1.6% (1 of 62), and 13.3% (12 of 90), respectively. No. 206 LN metastases are related to tumour location (p=0.019) and degree of differentiation (p<0.001).²¹

There are some limitations in previous studies. First, all studies were single-centre, retrospective studies with a limited sample size. Second, most of the studies did not specify the precise LN station. They often combined these two stations as GCLN because of the difficulty to recognise them separately in the specimens. Third, some studies were not specifically designed to investigate No. 206 and No. 204 LN metastasis. Fourth, some studies included patients with tumours located all along the right colon, which influenced the proportion of LN metastasis. Fifth, the procedure of the resection of No. 206 and No. 204 LNs in RTCC and HFCC has not yet been standardised. The extent of lymphadenectomy was heterogeneous among centres. Sixth, there is a lack of complete and long-term survival data of patients with involved No. 206 and No. 204 LNs. Seventh, some potential risk factors of LN metastasis were not analysed in some studies, such as carcinoembryonic antigen (CEA) level, N stage, differentiation, extramural venous invasion and perineural invasion.

To overcome these limitations, we designed this study with the nature of multicentre, highly standardised, with precise and routine dissection of No. 206 and No. 204 LNs, and with long-term observation. This study was specifically designed to investigate RTCC and HFCC, which have potential high relevance with No. 206 and No. 204 LN metastasis. We speculate that this study will demonstrate the prevalence of No. 206 and No. 204 LN metastasis, and its risk factors.

Resection of No. 206 and No. 204 LNs does not simply mean removing certain nodes but the whole area, including the fat tissue, LNs and lymphatic vessels. Manipulation and improper handling of a metastatic node during surgery may increase the risk of cancer cell dissemination after curative surgery. Free cancer cells can be released from lymphovascular pedicles opened during lymphadenectomy.²² However, there are vascular connections between both the hepatic flexure and greater omentum and the uncinate process of the pancreas, which demonstrate that these two areas directly face the pancreas and small vessels, whose injury results in troublesome postoperative complications such as pancreatitis, haemorrhage, peripancreatic abscess and pancreatic fistula.²⁻²³ Moreover, Deng *et al* have shown that delayed gastric emptying is more likely to develop in patients who undergo GCLN dissection (p=0.001).²⁴ Bertelsen *et al* mentioned that the additional dissection of these LNs confers no survival benefit but potential damage.²⁵ Thus, the safety and feasibility

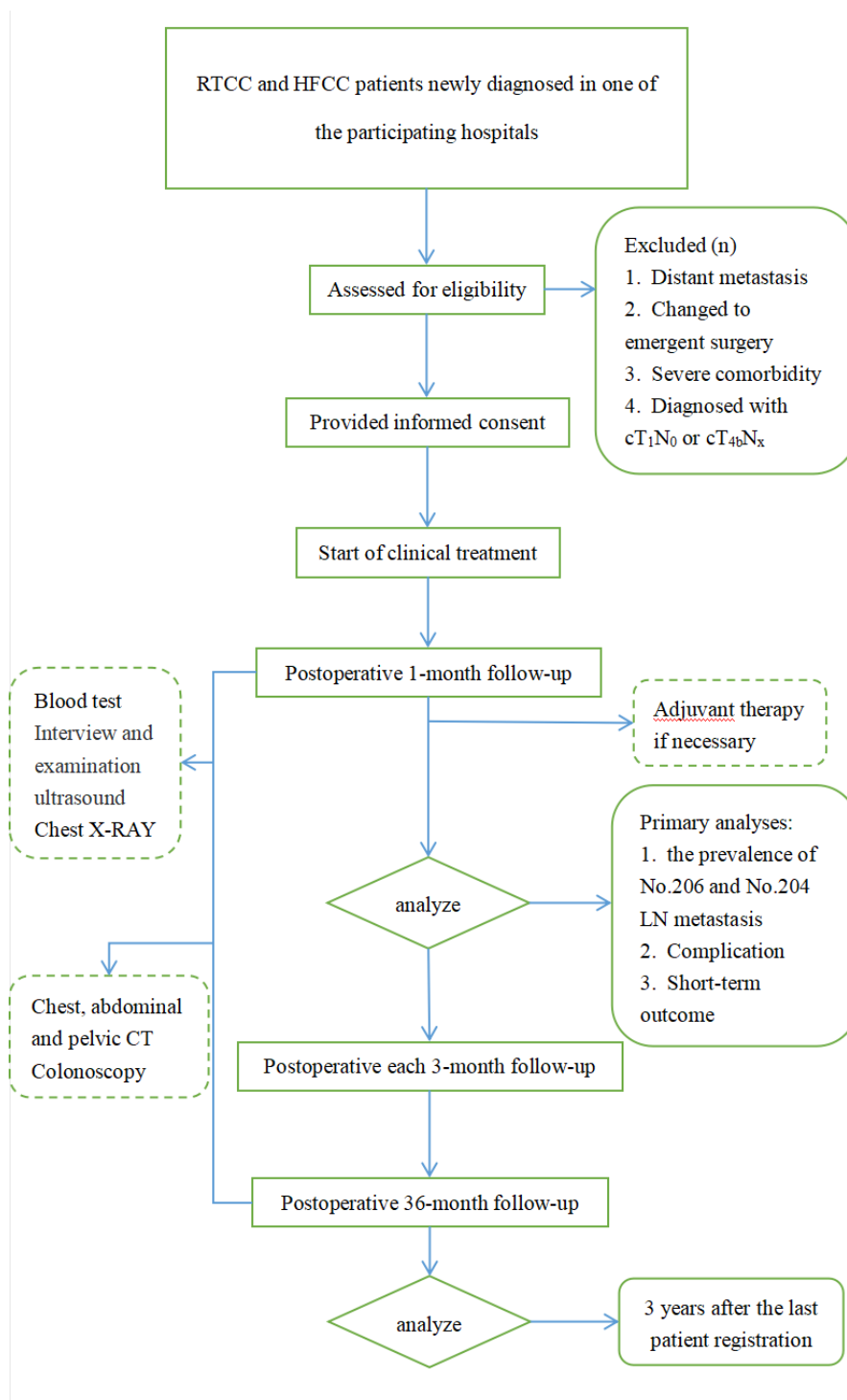


Figure 1 Cohort chart. No. 204, greater curvature LN; No. 206, infrapyloric LN; HFCC, hepatic flexure colon cancer; LN, lymph node; RTCC, right-sided transverse colon cancer.

of lymphadenectomy of this area is one of the secondary endpoints of our study.

Thus, the InCLART Study aims to clarify the prevalence of No. 206 and No. 204 LN metastasis in RTCC and HFCC. This study will also investigate the risk factors of LN metastasis and perioperative outcomes. This study is expected to lay the foundation for further high-quality multicentre randomised controlled trial (RCT) research in right hemicolectomy.

METHODS AND ANALYSIS

Study design

The InCLART Study is a multicentre, observational, prospective study that collects clinical and pathological data to assess the prevalence of No. 206 and No. 204 LN metastasis and identify the risk factors of metastasis. This study is expected to lay the foundation for further high-quality multicentre RCT research. The study will enrol a total of 427 consecutive patients with RTCC and HFCC

Box 1 Collaborating institutions

Ruijin Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai.

1. The First Affiliated Hospital of Jilin University, Changchun.
2. Zhangzhou Affiliated Hospital of Fujian Medical University, Zhangzhou.
3. The Second Affiliated Hospital of Fujian Medical University, Fuzhou.
4. Peking Union Medical College Hospital, Beijing.
5. Renji Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai.
6. Fujian Provincial Cancer Hospital, Fuzhou.
7. Meizhou People's Hospital and Meizhou Academy of Medical Sciences, Meizhou.
8. The First Affiliated Hospital of Xiamen University, Xiamen.
9. Affiliated Hospital of Qinghai University, Xining.
10. The First Affiliated Hospital of Xi'an Jiao Tong University, Xi'an.
11. Chinese PLA General Hospital, Beijing.
12. Guangdong General Hospital and Guangdong Academy of Medical Sciences, Guangzhou.
13. Shandong Provincial Hospital Affiliated to Shandong First Medical University, Ji'nan.
14. The First Hospital of China Medical University, Dalian.
15. Affiliated Hangzhou First People's Hospital, Zhejiang University School of Medicine, Hangzhou.
16. Beijing Friendship Hospital, Capital Medical University and National Clinical Research Center for Digestive Diseases, Beijing.
17. Key Laboratory of Carcinogenesis and Translational Research, Ministry of Education, Gastrointestinal Cancer Center, Peking University Cancer Hospital and Institute, Beijing.
18. The First Affiliated Hospital of Naval Medical University, Shanghai.
19. Beijing Chao-Yang Hospital, Capital Medical University, Beijing.
20. Zhongshan Hospital, Fudan University, Shanghai.

undergoing right hemicolectomy with complete mesocolic excision (CME) at baseline with a follow-up of 3 years (figure 1). This study is scheduled to enrol consecutive patients in 21 high-volume medical centres in China (box 1). Ethical approval for the study was granted by the Ruijin Hospital Ethics Committee (approval number: 2019-081) and registered at ClinicalTrials.gov (trial number: NCT03936530). The estimated enrolment time will be basically completed in June 2023.

Endpoints

The primary endpoint of this study is the prevalence of No. 206 and No. 204 LN metastasis. Secondary endpoints include short-term prognostic outcomes, intraoperative and postoperative complications rate, recurrent site, the risk factors of No. 206 and No. 204 LN metastasis, and the consistency of preoperative evaluation and postoperative pathological results of No. 204 and No. 206 LN metastasis.

Parameters collected

All clinicopathological information is stored in an Electronic Data Capture System online (available at <http://crs.clinbrain.cn>). The data include patient characteristics, perioperative factors, postoperative complications, pathological information and adjuvant chemotherapy information. Prognostic information will be collected up to 3 years after surgery (box 2).

Box 2 Clinical and pathological data collected from the study

Patient characteristics

- ⇒ Age and sex.
- ⇒ BMI.
- ⇒ ASA.
- ⇒ Tumour location.

Surgery-related factors

- ⇒ Year and month of surgery.
- ⇒ Operation type (open/laparoscopic).
- ⇒ Anastomotic type (side-to-side/others).
- ⇒ Intraoperative complications.
- ⇒ Operation time and estimated blood loss.
- ⇒ Postoperative outcomes including time of liquid diet intake, postoperative hospital stays.
- ⇒ Morbidity (Clavien-Dindo grade) and 30-day mortality.

Postoperative complications

- ⇒ Anastomotic leakage, bleeding, pancreatic fistula, chylous fistula, ileus, wound infection, etc.

Pathological information

- ⇒ Length of resected bowel.
- ⇒ pT stage.
- ⇒ Tumour grade.
- ⇒ Residual tumour (R0/R1).
- ⇒ Margin (proximal/distal to the tumour).
- ⇒ Extramural venous invasion and perineural invasion.
- ⇒ Number of lymph nodes retrieved and involved.
 - ⇒ Pericolic lymph nodes.
 - ⇒ Intermediate lymph nodes (around first feeding artery/around other feeding arteries).
 - ⇒ Main lymph nodes: No. 203, No. 213 and No. 223 lymph nodes (at the root of ileocolonic artery, right colon artery and middle colon artery).
 - ⇒ No. 206 lymph nodes.
 - ⇒ No. 204 lymph nodes.

Postoperative treatment

- ⇒ Adjuvant chemotherapy.
- ⇒ Prognostic outcomes.
- ⇒ Year and month of final follow-up.
- ⇒ Prognostic outcomes and cause of death.
- ⇒ Year and month of recurrence.
- ⇒ Recurrence site.

(Remnant mesenteric lymph nodes/anastomosis/liver/lung/peritoneum/non-mesenteric lymph nodes/other.)

Other.

Photographs of resected specimen.

ASA, American Society of Anesthesiologists; BMI, body mass index; p, pathological; T, extent of primary tumour.

Source: American Joint Committee on Cancer tumour, node, metastases staging, eighth edition.

Sample size

The sample size was calculated using the primary endpoint. According to previous studies,^{12 14–16 18 19 21 26 27} our hypothesis is that the metastasis rate of No. 206 and No. 204 LNs was set as 10% ($p=10\%$). Class I error= 0.05 ($Z\alpha=1.96$), and the allowable error was D ($D=0.3\times P$). According to the formula, $N=Z\alpha^2\times P\times(1-P)/D^2$, with

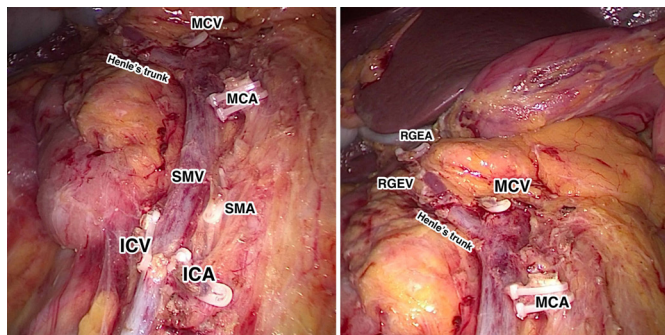


Figure 2 Exposing the vessel, then lymph nodes at the origin of the supplying arteries are dissected. ICA, ileocolic artery; ICV, ileocolic vein; MCA, middle colic artery; MCV, middle colic vein; RGEA, right gastroepiploic artery; RGEV, right gastroepiploic vein; SMA, superior mesenteric artery; SMV, superior mesenteric vein.

a drop-out rate of 10%, the target sample size of the InCLART Study is 427.

Eligibility criteria

The inclusion criteria were as follows: (1) adults aged ≥ 18 years and ≤ 75 years; (2) American Society of Anesthesiologists I–III; (3) individuals pathologically diagnosed with adenocarcinoma or high-grade intraepithelial neoplasia through endoscopic biopsy; (4) tumours located in hepatic flexure or the right half of the transverse colon; (5) extended right hemicolectomy with CME; (6) patients with clinical (c)T2–4aN_{any}M0; (7) individuals who agreed to receive standard adjuvant therapy; and (8) individuals willing to participate and sign informed consent.

The exclusion criteria were as follows: (1) patients with multiple colon cancers; (2) patients with cT1N0 or cT4bN_{any}; (3) distant metastasis; (4) emergency surgery for bleeding, obstruction and perforation; (5) female patients who were pregnant and (6) refusal to participate in the study.

CT scan and colonoscopy will be performed to every single participant before the operation, and the CT images will be uploaded to the database. We set up an imaging reading committee composed of three radiologists with extensive experience. They will decide whether the participants meet the inclusion criteria of tumour

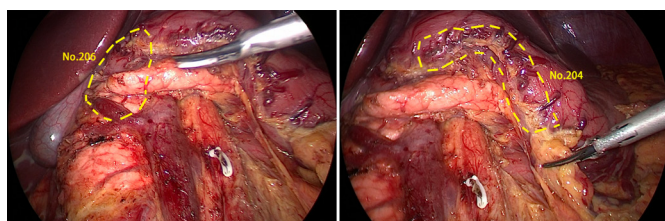


Figure 3 No. 206 lymph nodes are dissected up to the first branch and down to the junction of the right gastroepiploic vein and the anterior pancreaticoduodenal vein; No. 204 lymph nodes are dissected along the greater curvature of the stomach at the distal end of the first branch of the right gastroepiploic artery. No. 204, greater curvature lymph node; No. 206, infrapyloric lymph node.

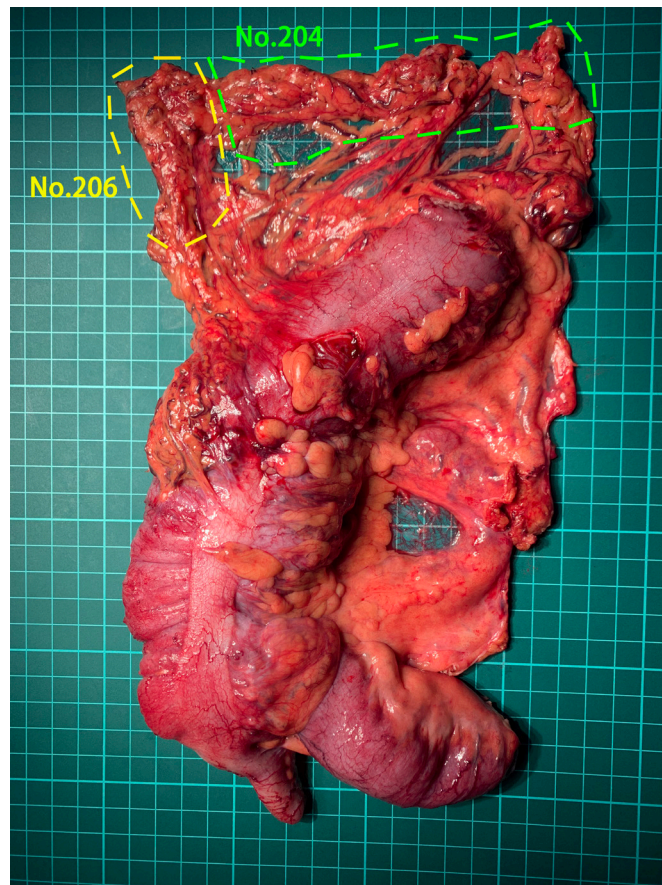


Figure 4 Photography for specimen 1. No. 204, greater curvature lymph node; No. 206, infrapyloric lymph node.

stage before the enrolment. Besides, we set up a quality control committee composed of three experts, each of whom has extensive experience (at least 500 cases) of right hemicolectomy with CME. The photographs of resected specimens and lymphadenectomy will be taken and uploaded to the database. The quality control committee will evaluate the completeness of CME based on these photographs, and the cases that are not qualified will be excluded from the trial.

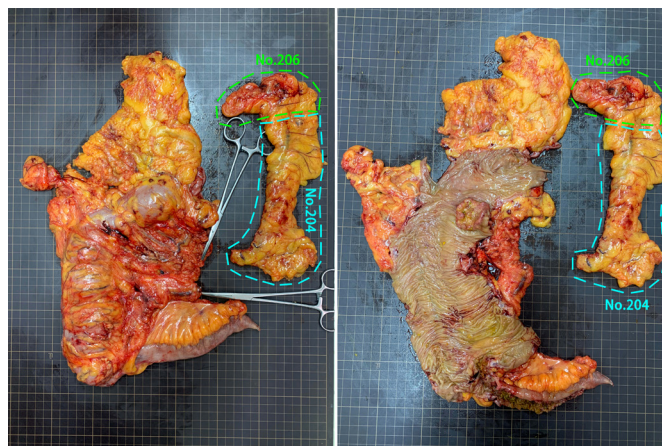


Figure 5 Photography for specimen 2. No. 204, greater curvature lymph node; No. 206, infrapyloric lymph node.

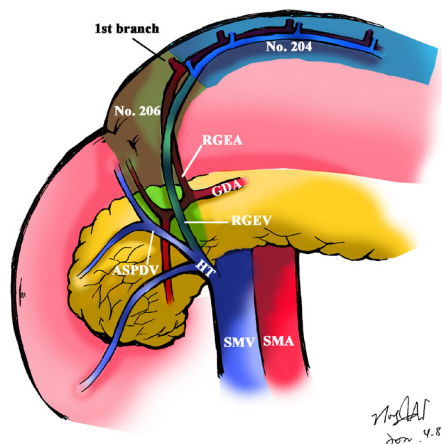


Figure 6 Extent of No. 206 and No. 204 lymph node dissection. No. 204, greater curvature lymph node; No. 206, infrapyloric lymph node; ASPDV, anterior superior pancreaticoduodenal vein; GDA, gastroduodenal artery; HT, Henle's trunk; RGEA, right gastroepiploic artery; RGEV, right gastroepiploic vein; SMA, superior mesenteric artery; SMV, superior mesenteric vein.

Study procedures

Surgical approach

The primary tumour, intact mesocolon and regional LNs were removed in accordance with the principles of CME surgery. D3 LN dissection with central vascular ligation was performed in all patients. The dissection included LNs (No. 203, No. 213 and No. 223) at the root of the colon artery (ileocolonic artery, right colon artery or middle colon artery) related to tumour blood supply from the superior mesenteric artery. Furthermore, No. 204 LN and No. 206 LN were also removed along the greater curvature of the stomach approximately 10–15 cm from the gastroepiploic arcade opposite to the tumour site (figures 2 and 3).

Specific notes

- Photographs of resected specimens should be taken and uploaded to the database (figures 4 and 5).

- LNs No. 203, No. 213, No. 223, No. 206 and No. 204 should be separately submitted for pathological examination. Retrieved LNs are grouped as follows:
 No. 203: LNs at the origin of the ileocolic artery.
 No. 213: LNs at the origin of the right colic artery.
 No. 223: LNs at the origin of the middle colic artery.
 No. 206: LNs in the area around the origin of the right gastroepiploic artery (up to the first branch of the right gastroepiploic artery and down to the junction of the right gastroepiploic vein and the anterior pancreaticoduodenal vein) (figure 6).
 No. 204: LNs distributed along the greater curvature of the stomach (10 cm at the distal of the first branch of the right gastroepiploic artery) (figure 6).

Postoperative adjuvant therapy

According to the National Comprehensive Cancer Network guidelines for colon cancer, surveillance is recommended for pT1–2N0M0 patients who do not receive postoperative adjuvant therapy.²⁸ For patients with pT3–4N0M0, the expected benefits and risks of chemotherapy should be evaluated to select an appropriate regimen. For pT_{any}N1–2M0 patients, adjuvant chemotherapy with FOLFOX/CapeOX is recommended after surgery. If there is no disease progression, standard adjuvant chemotherapy will be performed for 6 months after surgery. If disease progression occurs, follow-up treatment will be determined according to the disease condition.

Surveillance after surgery

In principle, the duration of surveillance is 3 years after surgery. Schedule of follow-up programmes is shown in figure 7.

1. Surveillance schedule: 1 month after surgery, once every 3 months for up to 1 year after surgery and once every 6 months for 2–3 years after surgery.
2. Content: interview and examination, blood test (including tumour marker), abdominal ultrasound, chest X-ray, CT and colonoscopy.

Content	years/months after surgery												
	1m	3	6	1year			2years			3years			
				9	12	3	6	9	12	3	6	9	12
Interview and examination	√	√	√	√	√	√	√	√	√	√	√	√	√
Blood test	√	√	√	√	√	√	√	√	√	√	√	√	√
Abdominal ultrasound	√	√	√	√	√	√	√	√	√	√	√	√	√
Chest X-RAY			√		√		√		√		√		√
Chest, abdominal and pelvic CT					√				√				√
Colonoscopy					√				√				√

Figure 7 Schedule of follow-up programmes.

Statistical analysis

Continuous variables with a normal distribution are described as the mean \pm SD and will be compared using Student's t-test, whereas the other continuous variables are presented as medians with IQR and will be compared using the Mann-Whitney U test. Categorical variables are described as percentages and frequencies. The χ^2 test and Fisher's exact test will be used to compare the categorical variables.

The clinical and pathological characteristics of the patients will be subjected to univariate analysis, including age, gender, pT stage, pN stage, pathologically confirmed central LN involvement, neural invasion, lymphovascular invasion, carcinoembryonic antigen (CEA) and carbohydrate antigen 199 (CA-199). The statistical analysis will be performed using the SPSS software package V.23.0. A p value of ≤ 0.05 is considered statistically significant.

Patient and public involvement

None.

Ethics and dissemination

Ethical approval for the study was granted by the Ruijin Hospital Ethics Committee (approval number: 2019-081) and registered at ClinicalTrials.gov (trial number: NCT03936530).

All patients will understand and agree to the aims and process of the trial, possible results and risks. Researchers explain the process of the trial and answer questions from the participants. Participants enable to discuss it with family members or guardians before agreeing to participate. The investigators must inform the participants that study participation is voluntary and that he/she may withdraw from the study at any time. The rights and welfare of participants will be protected, and it is emphasised that the quality of their medical care will not be affected by their refusal to participate in the study.

Any changes in the protocol will be reported to the Medical Ethical Committee.

Informed verbal and written consent will be obtained for all participants at enrolment in the InCLART Study. An original copy will be for the investigator's safekeeping.

The results will be submitted for publication to an international, peer-reviewed journal, regardless of whether the results are positive or negative in relation to the study hypothesis.

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Contributors AY and ZC contributed equally to this work. AY and LZ have made substantial contributions to the conception and design of the study, AY, ZC, H-JH, KD, SL, WK, JM, BF, AL, MZ and LZ have been involved in drafting the manuscript or revising it critically for important intellectual content and have given final approval of the version to be published. AY, ZC, MZ and LZ have made contributions to the design of the study and gave substantial contributions to the organisation of this trial. All authors have given final approval of the version to be published, including the local investigators at the participating centres.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not required.

Provenance and peer review Not commissioned; externally peer reviewed.

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