Clinical Study Protocol

Project Name: Long-term survival outcome based on primary non-ampulla duodenal adenocarcinoma

Solution version number/date: V1.0/2024.4.2

Group leader/Principal investigator: N/A

Group leader unit address: N/A

Research Department/Principal Investigator： General Surgery/Hao Liu

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Declaration of secrecy：

Summary of research scheme

Program name	Based on long-term survival outcomes of primary non-ampulla duodenal adenocarcinoma
Applicant	Nanfang Hospital of Southern Medical University
Principal investigator	Hao Liu
Study center and director	Southern Medical University Nanfang Hospital Hao Liu
Object of study	Duodenal adenocarcinoma (DA) patients
Objective	Main Objective: To determine whether radical DA resection is associated with an improvement in 5-year overall survival Secondary objectives: Adjuvant therapy, pancreatic invasion, and advanced tumor stage were identified as significant predictors of overall survival
Study group	Histologically confirmed non-ampulla DA (including all stages of disease at diagnosis)
Study design	Retrospective cohort study
Study duration	2024.04-2024.06
Sample size	400cases
Inclusion criteria	(1)At least 18 years old; (2)Voluntary signing of informed consent; (3)Non-ampulla DA patients were diagnosed according to the Chinese Medical Association's Clinical Diagnosis and Treatment Guidelines for Gastrointestinal Tumors (2022 edition), including patients at all stages of diagnosis; (4)Unless there is no other malignant tumor diagnosed in the ampulla DA.

Exclusion criteria	(1)Cancer of the ampulla or other forms of gastrointestinal cancer (2)Incomplete medical records (3)Missing diagnostic or therapeutic data (4)Follow-up was lost shortly after diagnosis
Efficiency analysis	Primary outcome measures for effectiveness analysis: median overall survival, 3 - and 5-year overall survival rates in the cohort Secondary outcome measures for effectiveness analysis: Overall survival with adjuvant therapy, pancreatic invasion, and advanced tumor
Statistic analysis	Statistical analysis Rigorous statistical methods were used to analyze the collected data. Survival outcomes, including OS and DFS, were calculated from the date of diagnosis until the date of death or last follow-up, and from the date of diagnosis until the date of disease recurrence or last follow-up of DFS. Kaplan-Meier survival curves were generated to illustrate survival trends over time, and log-rank tests were used to compare the distribution of survival among different patient subgroups[17]. Cox proportional hazard models were used to identify independent prognostic factors affecting survival. Variables considered in the model included demographic factors (age, sex), clinical features (BMI,jaundice,bleeding, anemia), preoperative laboratory values, treatment details (radical resection, adjuvant therapy),and pathological findings (AJCC stage, tumor differentiation and lymph node involvement rate). Hazard ratios (HRs) and 95% confidence intervals (CI) were calculated to estimate the strength of the association between each variable and survival outcomes[18].

Follow-up visit	The patients included in this study were from a hospital cohort that included cases diagnosed and treated in the Department of General Surgery at Nanfang Hospital of Southern Medical University. Inclusion criteria were histologically confirmed non-ampulla DA, including all stages of disease at diagnosis. Patients were excluded if they had ampulla cancer or other forms of gastrointestinal cancer, had incomplete medical records, or lost follow-up shortly after diagnosis.
Statistical approach	Statistical methods SPSS 25.0 and Prism 8.0.1 software were used for all statistical analyses.
Expected progress	Expected progress: From April 2024 to May 2024, data collection, sorting and analysis will be completed. From May 2024 to June 2024, monograph writing, submission and conclusion will be completed

1.Study background

Duodenal adenocarcinoma (DA) remains a relatively rare and mysterious entity among gastrointestinal malignancies, accounting for less than 1% of all gastrointestinal cancers, but more than 50% of small bowel cancers[1]. This scarcity has led to poor natural history descriptions of the disease and continued ambiguity around best management strategies. DA is often compared to colorectal cancer because they share a location in the gastrointestinal tract and exhibit similar molecular characteristics and potential pathways for tumor development[2]. However, left and right colon cancers have their unique genomic features and clinical manifestations, which stem from their specific location in the colon[3]. Therefore, tumor location and its genomic profile are considered to be important factors affecting the prognosis of colorectal cancer and small intestinal adenocarcinoma[4-5]. This underscores the need to treat the outcomes of each DA treatment modality as a distinct entity.

The treatment of DA faces several challenges, including the lack of established guidelines based on worldwide scientific evidence, the difficulty of early detection due to the rarity of the disease and the lack of specific screening markers, and the limited evidence supporting various treatment modalities[6-7]. Surgical resection is the only possible treatment for DA. The complexity of surgery, which often includes pancreaticoduodenectomy, has evolved over the years, and advances in perioperative care and surgical techniques have helped reduce morbidity and mortality, but there has been no uniform improvement in long-term survival outcomes[8-10]. Adjuvant therapy, including chemotherapy and radiotherapy, has been explored as a means of improving survival, especially in cases with adverse pathological features, such as lymph node involvement or the advanced stage of diagnosis[11].

Despite these reasons, the efficacy of adjuvant therapy for DA remains controversial. There have been no randomized controlled trials comparing the efficacy of single surgery with perioperative adjuvant treatment for DA. All of the studies were retrospective comparisons of the outcomes of surgery alone and combined surgery, so there may be selection bias in patients[12-14]. Numerous meta-analyses and systematic reviews have investigated the treatment of DA in depth, but most studies have been retrospective, single-center, and small-sample size series, especially in China[15-16]. To address this knowledge gap, we conducted a hospital-based cohort study designed to investigate long-

term outcomes in patients with DA and to disaggregate the effects of tumor characteristics, surgery, and adjuvant therapy on survival outcomes.

2.Study purpose

2.1 Main Objectives: Whether radical DA resection is associated with improvement in 5-year overall survival

2.2 Secondary objectives: Adjuvant therapy, pancreatic invasion, and advanced tumor stage were identified as significant predictors of overall survival

3.Study endpoint

3.1 Primary endpoints: Median overall survival, 3 - and 5-year overall survival rates for the cohort

3.2 Secondary endpoints: overall survival with adjuvant therapy, pancreatic invasion, and advanced tumor

4.Study design

This retrospective analysis was designed to clarify long-term survival outcomes in patients diagnosed with non-ampulla DA. The study spans a 15-year period, from 2009 to 2023, capturing a comprehensive dataset that reflects advancements in diagnostic and treatment strategies over time. This cohort of 400 patients was carefully selected to provide a robust data set for analyzing survival outcomes and identifying prognostic factors affecting overall survival (OS) and disease-free survival (DFS).

No randomized or any protocol-driven treatment will be administered or provided to the subjects during the study. If clinically applicable, treatment decisions and treatment options are made at the discretion of the treating physician.

5.Study population

The patients included in this study were diagnosed and treated in the Department of General Surgery of Nanfang Hospital, Southern Medical University. Inclusion criteria are histologically confirmed non-ampulla DA includes all stages of disease at diagnosis.

5.1 Diagnostic criteria:

Non-ampulla DA patients were diagnosed according to the Chinese Medical Association Clinical Diagnosis and Treatment Guidelines for Gastrointestinal Tumors (2022 edition).

5.2 Inclusion criteria:

(1) At least 18 years of age;

(2) Voluntarily sign informed consent;

(3) Non-ampulla DA patients were diagnosed according to the Guidelines for Clinical Diagnosis and Treatment of Gastrointestinal Tumors of the Chinese Medical Association (2022 edition), including patients at all stages of diagnosis;

(4) Unless there are no other malignant tumors in the ampulla other than DA.

5.3 Exclusion criteria:

(1) Cancer of the ampulla or other forms of gastrointestinal cancer Medical records are incomplete

(2) Diagnostic or therapeutic data is missing

(3) Follow-up was lost shortly after diagnosis

(4) The non-ampulla DA patients were judged by the investigators to be unsuitable for participating in this study

5.4 Case withdrawal and exfoliation

(1) All enrolled subjects have the right to withdraw from the study at any time. Reasons for case withdrawal:

(2) The subjects asked to withdraw and did not want to continue to participate in the study;

(3) Subjects lost follow-up;

(4) Participants were deemed unfit to continue in the study for other reasons;

(5) The subjects were also participating in other studies.

Subjects who dropped out of the study were considered as shedding cases. When the patient falls off, the patient should be contacted as far as possible, evaluate the project and fill out the research summary page.

6.Study methods and procedures

Because this is an observational retrospective study, no additional visits or laboratory analyses or assessments beyond those required by routine clinical practice are required. Patients must sign the latest Ethic-

approved informed form before performing data collection consent form (ICF), after obtaining the patient's knowledge, the study will collect the patient's clinical routine treatment information.

6.1 Informed consent and inclusion

Informed consent (i.e. informed consent signed and dated) is provided. Subjects who meet all other inclusion/exclusion criteria, Were considered to be enrolled in this study.

6.2 Subject identification number

Each subject is given a unique identification number, subject numbering rules are sample type number + sequence number, sequence number.The value starts from 001 and increases in sequence, for example, NFC001. All study documents (such as case reports, clinical records, etc.) will adopt this identification number

6.3 Data source/Data collection process

Data for this study were obtained by extracting routine clinical records of enrolled subjects. The investigator was asked to stay throughout the monitoring period enter information from the original medical record into the study record sheet.

6.4 Data Collection Procedure

(1) Record demographic data: date of birth, gender, initials;

(2) Medical history and physical examination (including vital signs, height, weight, BMI, physical examination of all systems; HCC history Present history, etiology)

(3) Clinical presentation (symptoms, tumor location, stage of diagnosis), treatment modalities (surgical intervention, adjuvant therapy) and survival outcome (survival time, recurrence), details of surgical procedure (resection extent, lymph node dissection);

(4) Record laboratory test results: including preoperative laboratory values (such as CEA, CA19-9 levels) and available genetic markers Markers (KRAS mutation, dMMR/MSI-H);

(5) Pathological findings (tumor differentiation, lymphatic vascular infiltration, perineural infiltration) were recorded.

7.Study termination/suspension criteria

7.1 The Sponsor has the right to terminate/suspend the study. Before terminating/suspending a clinical study, the sponsor shall notify the investigator,ethics committee and relevant regulatory authorities, and state the reasons. After early termination/suspension of the study, restart of the study must be obtained the Ethics Committee reviewed and agreed.

7.2 Termination/suspension requested by the Ethics Committee.

8.Rules to end clinical studies

The collection ended when 400 non-ampulla DA patients were enrolled.

9. Data management

9.1 Data Management

(1) The researcher must ensure that the data is true, complete and accurate;

(2) When any correction is made in the research record, the revised data should only be underlined, the reasons should be explained, and the researcher should sign and note clear date, shall not erase, cover the original record;

(3) Complete laboratory inspection items.

9.2. Data recording and file saving

Subject data on the case report form shall be recorded in subject code and subject may only use subject code or their initials are identified.

In this study, independent data management software will be used for data management and management will be set according to different division of labor of different personnel and viewing rights; The principal investigator has the right to view and manage the whole project data and process; Research assistants are personally responsible only data entry and check permission of the subject.

10. Statistical analysis

All statistical analyses were performed using SPSS 25.0 and Prism 8.0.1 software. Frequency and percentage tables were used for disaggregated data

Chi-square test (or Fisher exact test) was used to compare the differences between groups. The mean is used for continuous data conforming to a normal distribution the t test was used to compare the differences between groups, and the median and quartile were used for continuous data that did not conform to the normal distribution the spacing (P25-P75) indicates that the difference between groups is non-parametric. All tests were two-tailed tests, and $P<0.05$ was considered consistent the significance of planning.

10.1 Sample size determination

This retrospective analysis was designed to clarify long-term survival outcomes in patients diagnosed with non-ampulla DA. The study spans 15 years the annual period, from 2009 to 2023, captures a comprehensive dataset that reflects diagnosis over time and advances in treatment strategies. The cohort consisted of 400 patients, carefully selected for analyzing survival outcomes and determining the impact on total life prognostic factors for duration of survival (OS) and disease-free survival (DFS) provide a robust data set.

10.2 Statistical Methods

All statistical analyses were performed using SPSS 25.0 and Prism 8.0.1 software.

10.3 Statistical Software and General Requirements:

All statistical analyses were performed using SPSS 25.0 and Prism 8.0.1 software. All tests were two-tailed tests ($P<0.05$) it was considered statistically significant.

11. Research management

11.1 Comply with relevant laws and regulations

(1) Investigators should adopt standard operating procedures to implement quality control and quality assurance systems for clinical studies;

(2) The original data must meet the requirements of relevant laws and regulations;

(3) Laboratory test results must be accurate and reliable;

(4) The observations and findings used should be verified to ensure the reliability of the data;

(5) Establish a complete research organization and clarify the responsibilities of personnel at all levels;

(6) The main researcher shall be responsible for the overall quality control and carry out the responsibilities of personnel at all levels;

(7) The principal investigator shall be responsible for the design of the study plan and informed consent, and the principal investigator shall write the study after the study is completed summary report;

(8) The designated researcher shall be responsible for developing the study implementation rules and SOP for use in the study;

(9) Before the study, the research team shall organize a learning program for all participants, and all participants shall undergo GCP training;

(10) The doctors and nurses participating in the study should strictly abide by the program regulations, follow the procedure, and not change at will;

(11) Designated statisticians are responsible for the overall statistical processing of the data.

11.2 Protect subjects' privacy

All data of the subjects during the study period will be recorded into a computer and stored confidentially and analyzed, and may be verified by the relevant institution if necessary records are reviewed to verify the authenticity, accuracy and completeness of the data, and the data obtained may also be published in academic journals.However, the subject's name will not be released and the subject's privacy will be kept confidential.

extra precautions are taken to ensure confidentiality of documents and to prevent identification of subjects through genetic data. However,In exceptional circumstances, someone may see a subject's genetic data and personal identification number. For example, in the emergence of medical

In the case of emergency, the sponsor, its representative physician or investigator is aware of the subject identification number and has the subject's genetic data the right to access. In addition, the relevant regulatory authorities requested access to the relevant documents.

11.3 Problems occurred in the study and their treatment measures

(1) Revision of the Plan: After the plan is approved by the Ethics Committee, if the plan is to be revised, a "Plan Revision Note" shall be formulated, and signed by the principal investigator. The scheme can only be revised with the consent of the researcher and the applicant for drug registration through consultation;

(2) The revised plan shall be submitted to the Ethics Committee for review and approval before implementation;

(3) No participant in the study shall violate the protocol.

11.4 Quality control and quality assurance

11.4.1 Quality assurance:

Sponsor, partner units entrusted by Sponsor with all or part of the responsibilities and tasks related to this study (including CRO, SMO, statistical unit, clinical center, etc.) shall establish their own quality assurance system to fulfill their respective responsibilities, and strictly follow the clinical research program and adopt the corresponding standard operating procedures to ensure the quality control and quality assurance of clinical research implementation of the system.

11.4.2 Quality assurance of clinical research process

Prior to the initiation of a clinical study, the investigator should receive training in the study protocol, so that the investigator is aware of the clinical study protocol and its respective aspects the specific connotation of indicators is fully understood and recognized. Quality control personnel should check the basic conditions of clinical research to ensure clinical research

Conditions can meet the requirements of the scheme. During the study, researchers should carefully perform clinical exercises according to institutional SOP and study protocol requirements do such work, and record in a true, timely, complete and standardized manner. Quality control personnel on the research process and the corresponding original records and other quality checks. After the end of the study, the research unit collates the corresponding project documents, which are checked by the quality control personnel file preservation. The quality assurance department of the clinical research unit shall conduct an implementability audit of the research conducted. When a non-match is found, promptly notify the researcher and the person in charge of the unit to correct, and track the correction.

11.4.3 Expected progress and completion date of the clinical study

From April 2024 to May 2024, data collection, sorting and analysis will be completed.

From May 2024 to June 2024, I completed the writing, submission and conclusion of the monograph.

11.5 Responsibilities and other related work undertaken by each party

(1) Sponsor's duties

The sponsor is responsible for initiating, applying for and organizing this clinical study and providing research funds.

(2) Responsibilities of researchers

Researchers will design programmes and regulations in accordance with the moral, ethical and scientific principles set out in the Declaration of Helsinki and relevant regulations this clinical study will be carried out. Researchers should be aware of the procedures and requirements for reporting SAE, and record and report these as required event. The researcher shall accurately, completely, timely and legally load the data into the eCRF, and accept the sponsor or CRO company's submission To ensure the quality of clinical studies, the inspection or inspection of dispatched inspectors or inspectors and the inspection and inspection of drug regulatory authorities.

(3) Sponsor research methods for data publication

The sponsor has exclusive rights to this research data. Unless agreed in writing by the sponsor or reflected in the cooperation agreement, the final the report should not be published on an individual basis until it is completed. The Sponsor has the final say in respect of the manuscript and publication.

12. Research relevant ethics

12.1 Ethics Committee

Before the start of the study, the researcher should submit the researcher handbook, research protocol, informed consent and other materials to the Ethics Committee for review
Batch. Any amendments to the study protocol must be approved by the Ethics Committee.

12.2 Informed Consent

Qualified researchers must explain the nature, purpose, and process of the study in detail to each subject in the informed consent sequence, expected timing, potential risks and benefits, and any discomfort that may arise. Each subject is required to know which the study is voluntary and he/she may withdraw from the study at any time as well as withdraw informed consent without affecting him/her subsequently treatment or relationship with the treating physician.

Informed consent should be given in a standard writing format and in non-professional language as far as possible. Each informed consent form is required,include all of the above and include a voluntary declaration. Informed consent must be submitted to the Ethics Committee for approval.

13. References

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Clinical study protocol confirmation signature page

Long-term survival outcome based on primary non-ampulla duodenal adenocarcinoma

Consent from the principal investigator regarding the protocol:

I have read this protocol carefully, I agree with all the information included in the protocol that is necessary to conduct the research, and I agree to carry out as described in the protocol. I understand that the study should not be initiated without the approval of the Ethics Committee, and that the relevant regulations of the organization should be fully complied with.

Informed consent and corresponding documentation for all participants are required. After the informed consent is signed, the clinical study will be conducted in accordance with the requirements of the Helsinki Eason and the relevant laws and regulations for the clinical application of the research technology.

Principal Investigator Signature: 

Date:2024.04.02