ISRCTN10524966 https://doi.org/10.1186/ISRCTN10524966

The dynamic changes and precise classification of parathyroid function within one year after thyroid cancer surgery

Submission date
18/09/2024

Recruitment status
No longer recruiting

Registration date
24/09/2024

Overall study status
Completed

Last Edited
23/09/2024

Condition category
Cancer

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Postoperative parathyroid dysfunction is a prevalent complication of thyroid surgery, however, there is no consensus on the trend of postoperative parathyroid function and standardized clinical intervention. This study systematically describes the dynamic changes in postoperative parathyroid hormone (PTH) levels after thyroid surgery and proposes corresponding clinical classifications and interventions.

Who can participate?
Patients diagnosed with thyroid carcinoma and undergoing surgical treatment at Sun Yat-Sen University Cancer Center (SYSUCC) from 2012 to 2022.

What does the study involve?
In this retrospective cohort study, participants were consecutively enrolled based on the inclusion and exclusion criteria. All patients included in the study had thyroid surgery performed by highly experienced surgeons, following clinical guidelines. The types of surgeries included thyroid lobectomy (TL), subtotal thyroidectomy (sub-TT), total thyroidectomy (TT), central neck dissection (CND), and lateral neck dissection (LND). If a parathyroid gland was accidentally removed during surgery, the surgeons would perform a parathyroid autotransplantation (PA) using standardized procedures. After surgery, the pathology results showed whether there was lymph node metastasis (cancer spread to lymph nodes) or if any parathyroid tissue was removed. A result of pN1 means there was lymph node metastasis, while pN0 means there was no lymph node involvement. "Parathyroid in specimen" indicates that parathyroid tissue was found in the pathology report. Before surgery, all patients underwent a thorough assessment, including blood tests, biochemical analyses, ultrasound exams of the neck and abdomen, CT scans of the neck and chest, and a physical examination. The preoperative blood tests measured levels of prePTH, calcium, phosphorus, and albumin. These tests were done two days before surgery at the SYSUCC Clinical Laboratory using standardized procedures. Basic clinical information such as gender, age, and BMI was also collected from the SYSUCC Information Center. After surgery, all patients had regular follow-up exams, including thyroid function tests, ultrasounds, and PTH tests. All PTH results within one year after surgery were included in this study.

What are the possible benefits and risks of participating?
Possible benefits of participation include access to screenings and effective treatments for those who continue to attend follow-up visits at our hospital. Additionally, there are no significant risks associated with participating in this study, as it is a retrospective study.

Where is the study run from?
Sun Yat-Sen University Cancer Center, China

When is the study starting and how long is it expected to run for?
March 2023 to December 2023

Who is funding the study?
1. The National Natural Science Foundation of China
2. The Guangdong Basic and Applied Basic Research Foundation
3. The Open Project Fund of the Sixth Affiliated Hospital of Guangzhou Medical University

Who is the main contact?
Kang Ning, MD, ningkang@sysucc.org.cn

Study website
http://english.sysucc.org.cn/

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Kang Ning

Contact details
Sun Yat-sen University Cancer Center, 651 Dongfeng Road East, Yuexiu District
Guangzhou
China
510060
+86 13540679678
ningkang@sysucc.org.cn

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

National Natural Science Foundation of China grant codes 82072981, 82272649 and 82303881, Guangdong Basic and Applied Basic Research Foundation grant code 2019A1515010150, 2023A1515010450, 2023A1515012903 and 2022A1515110033, Open Project Fund of the Sixth Affiliated Hospital of Guangzhou Medical University grant code 202011-201

Study information

Scientific Title
The impact of various clinical features on postoperative parathyroid function was analyzed in a cohort of 12,664 patients diagnosed with papillary thyroid cancer who underwent surgical treatment

Study objectives
Patients undergoing surgical treatment for papillary thyroid cancer exhibit varying patterns of postoperative parathyroid function based on their different clinical features

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/09/2023, Ethics Committee of Sun Yat-sen University Cancer Center (651 Dongfeng Road East, Yuexiu District, Guangzhou, 510060, China; +86 02087343009; llwyh@sysucc.org.cn), ref: B2023-455-01

Study design
Single-center observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Hospital, Medical and other records

Study type(s)
Screening

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Thyroid carcinoma

Interventions
In this retrospective cohort study, patients diagnosed with thyroid carcinoma and undergoing surgical treatment at Sun Yat-Sen University Cancer Center (SYSUCC) from 2012 to 2022 were consecutively enrolled.

All included patients underwent thyroid surgery performed by a surgeon with senior professional titles according to clinical guideline requirements, including thyroid lobectomy (TL), subtotal thyroidectomy (sub-TT), total thyroidectomy (TT), central neck dissection (CND), and lateral neck dissection (LND). In case of inadvertent parathyroidectomy, surgeons will perform parathyroid autotransplantation (PA) according to standardized procedures. Postoperative pathological results reflect the status of lymph node metastasis and parathyroidectomy. pN1 indicates lymph node metastasis, while pN0 signifies the absence of lymph node involvement. "Parathyroid in specimen" indicates the identification of parathyroid tissue in the postoperative pathology.

Before surgery, all patients will undergo a comprehensive assessment, including routine blood tests, biochemical analyses, cervical and abdominal ultrasound examination, neck and chest CT scans, and a physical examination. The preoperative serum parameters included preoperative PTH (prePTH), calcium, phosphorus, and albumin in this study. These preoperative serum indicators were analyzed by the SYSUCC Clinical Laboratory using standardized procedures, conducted two days before the surgery. In addition, basic clinical information such as gender, age, and BMI was directly exported from the SYSUCC Information Center. All patients are required to undergo regular follow-up examinations after surgery, including thyroid function tests, ultrasound, and PTH. All PTH results within one year postoperatively were included in this study.

Intervention Type
Procedure/Surgery

Primary outcome measure
Postoperative parathyroid hormone values measured using data collected from medical records following standard laboratory testing methods within 30 days postoperatively

Secondary outcome measures
Postoperative parathyroid hormone values measured using data collected from medical records following standard laboratory testing methods from 30 days to 365 days postoperatively.

Overall study start date
02/03/2023

Completion date
30/12/2023

Eligibility

Key inclusion criteria
1. Confirmed pathological diagnosis of papillary thyroid carcinoma
2. Patients who underwent initial thyroid surgery as primary treatment
3. Normal preoperative parathyroid function (normal PTH and serum calcium level)
4. At least one preoperative and postoperative PTH measurement was conducted

Participant type(s)
Patient

Age group

Adult

Sex
Both

Target number of participants
30000

Total final enrolment
12664

Key exclusion criteria
1. A history of previous thyroid or parathyroid surgery
2. Concurrent parathyroid adenoma diagnosis
3. Other types of thyroid surgeries such as minimally invasive or combined surgeries
4. Lack of complete medical records of patients

Date of first enrolment
09/09/2023

Date of final enrolment
28/11/2023

Locations

Countries of recruitment
China

Study participating centre
Sun Yat-Sen University Cancer Center
651 Dongfeng Road East, Yuexiu District
Guangzhou
China
510060

Sponsor information

Organisation
Sun Yat-sen University Cancer Center

Sponsor details
651 Dongfeng Road East, Yuexiu District
Guangzhou
China
510060

+86 02087343227
llwyh@sysucc.org.cn

Sponsor type
Hospital/treatment centre

Website
http://english.sysucc.org.cn/

ROR
https://ror.org/0400g8r85

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Funder Name
Basic and Applied Basic Research Foundation of Guangdong Province

Alternative Name(s)
Guangdong Basic and Applied Basic Research Foundation, Guangdong Basic and Applied Basic Research Fund Regional Joint Youth Fund,

Funding Body Type
Government organisation

Funding Body Subtype

Local government

Location
China

Funder Name
Open Project Fund of the Sixth Affiliated Hospital of Guangzhou Medical University

Results and Publications

Publication and dissemination plan
Planned publication in the peer-reviewed International Journal of Surgery

Intention to publish date
15/03/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be available upon request from Kang Ning, ningkang@sysucc.org.cn

IPD sharing plan summary
Available on request