

Outcomes of radiofrequency ablation and microwave ablation for T1N0M0 papillary thyroid carcinoma

Submission date 24/10/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 25/10/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 25/10/2023	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Ultrasound (US)-guided thermal ablation, including radiofrequency ablation (RFA), microwave ablation (MWA), laser ablation, and high-intensity focused ultrasound, are the local application of extreme temperatures to induce tumor apoptosis (cell death) and coagulative necrosis, and have been used for the treatment of tumors. In the last few years, these minimally invasive treatments have been considered potential alternatives for patients with T1N0M0 papillary thyroid carcinoma (PTC) who are at surgical risk or are unwilling to undergo surgery or active surveillance. RFA and MWA were the most frequently used and are differentiated by their methods of generating heat. This study aims to compare the clinical outcomes of patients with solitary T1N0M0 PTC who underwent RFA or MWA.

Who can participate?

Patients aged 18 to 80 years with T1N0M0 PTC

What does the study involve?

RFA or MWA was considered only in patients with T1N0M0 PTC unsuitable for surgery or rejected surgery/active surveillance clearly. The patients underwent RFA or MWA by US physicians with over 10 years of experience in interventional thyroid US-performed ablation. The RFA or MWA was selected according to the physician's experience and modality preference. After treatment, follow-ups were performed at 1, 3, 6, 12, and every 6-12 months thereafter. Ultrasound and contrast-enhanced ultrasound were performed at each follow-up evaluation. Chest CT was performed annually to monitor distant metastases. The study lasts 2 years in total.

What are the possible benefits and risks of participating?

Whether one of the two treatments (RFA, MWA) is superior to the other can be answered by the information obtained from this study. There are no expected risks of physical injury or harm.

Where is the study run from?

First Affiliated Hospital of Chinese PLA General Hospital (China)

When is the study starting and how long is it expected to run for?
July 2018 to September 2021

Who is funding the study?
First Affiliated Hospital of Chinese PLA General Hospital (China)

Who is the main contact?
Dr Lin Yan, gemma-y@163.com

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Protocol serial number

Nil known

Study information

Scientific Title

Comparative outcomes of radiofrequency ablation vs microwave ablation for patients with T1N0M0 papillary thyroid carcinoma

Study objectives

Radiofrequency ablation (RFA) and microwave ablation (MWA) had comparable clinical outcomes for the treatment for patients with T1N0M0 papillary thyroid carcinoma (PTC).

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 25/03/2021, Institutional Review Board of Chinese PLA General Hospital (No.28 Fuxing Road, Beijing, 100853, China; +86 (0)10-66937166; gemma-y@163.com), ref: S2019-211-02

Study design

Single-center retrospective cohort study

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

T1N0M0 papillary thyroid carcinoma

Interventions

A propensity score matching was used to evaluate the outcomes of radiofrequency ablation or microwave ablation for the treatment of T1N0M0 papillary thyroid carcinoma.

RFA or MWA was considered only in patients with T1N0M0 PTC unsuitable for surgery or rejected surgery/active surveillance clearly. The patients underwent RFA or MWA by US physicians with over 10 years of experience in interventional thyroid US-performed ablation. The RFA or MWA was selected according to the physician's experience and modality preference. After treatment, follow-ups were performed at 1, 3, 6, 12, and every 6-12 months thereafter. Ultrasound and contrast-enhanced ultrasound were performed at each follow-up evaluation. Chest CT was performed annually to monitor distant metastases. The study lasts 2 years in total.

Intervention Type

Procedure/Surgery

Primary outcome(s)

Disease progression, defined as follows:

1. Cervical lymph node metastases confirmed by biopsy
2. Recurrent tumor confirmed by biopsy
3. Persistent tumor (residual tumor at the site of the ablated tumor) confirmed malignant by biopsy
4. Distant metastases confirmed by chest CT

Recurrence-free survival was calculated from treatment initiation to disease progression or the last follow-up visit

Key secondary outcome(s)

1. Volume reduction = $([\text{initial volume} - \text{final volume}] \times 100) / \text{initial volume}$ measured using ultrasound at 1, 3, 6, 12 months, and every 6-12 months thereafter
2. Tumor complete disappearance (complete disappearance of the ablated tumor on ultrasound and contrast-enhanced ultrasound) at 1, 3, 6, 12 months, and every 6-12 months thereafter
3. Complications, recorded by the standard for image-guided thyroid ablation after RFA or MWA treatment

Completion date

30/09/2021

Eligibility

Key inclusion criteria

1. Solitary papillary thyroid carcinoma confirmed by core-needle biopsy or fine-needle aspiration
2. Tumors with a maximum diameter ≤ 20 mm
3. No clinical or imaging evidence of extrathyroidal extension, lymph node metastases and distant metastases on ultrasound, and neck and chest CT
4. No history of neck irradiation
5. Follow-up period ≥ 24 months

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

80 years

Sex

All

Total final enrolment

1111

Key exclusion criteria

1. Convincing evidence of aggressive type on biopsy
2. Multiple tumors
3. Incomplete data or lost to follow-up

Date of first enrolment

01/07/2018

Date of final enrolment

30/09/2021

Locations

Countries of recruitment

China

Study participating centre
Chinese PLA General Hospital
No.28 Fuxing Road
Beijing
China
100853

Sponsor information

Organisation

First Affiliated Hospital of Chinese PLA General Hospital

ROR

<https://ror.org/039713658>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

General Hospital of People's Liberation Army

Alternative Name(s)

PLA General Hospital

Funding Body Type

Government organisation

Funding Body Subtype

Local government

Location

China

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analyses during the current study will be available upon request from Dr Lin Yan (gemma-y@163.com).

The type of data that will be shared: anonymized data

Dates of availability: 31/12/2025

Whether consent from participants was required and obtained: consent has been obtained.
Comments on data anonymization: all data have been anonymized.

IPD sharing plan summary

Available on request