ISRCTN85501259 https://doi.org/10.1186/ISRCTN85501259

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

Submission date
24/10/2023

Recruitment status
No longer recruiting

Registration date
25/10/2023

Overall study status
Completed

Last Edited
25/10/2023

Condition category
Cancer

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
Prof Yukun Luo

ORCID ID
https://orcid.org/0000-0002-5944-8198

Contact details
No.28 Fuxing Road
Beijing
China
100853
+86 (0)1066937394
lyk301@yeah.net

Additional identifiers

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

Primary study design
Observational

Study design
Single-center retrospective cohort study

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 = ([initial volume-final volume] × 100)/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