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Comparison of health-related quality of life between radiofrequency ablation and surgery for unifocal T1N0M0 papillary thyroid carcinoma : follow-up study with up to 5 years of observation

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Abstract

Background:

Limited information is available on impact of radiofrequency ablation (RFA) and surgery resection (SR) on the quality of life (QoL) of patients with unifocal T1N0M0 PTC.

Purpose: This study is to compare the QoL of RFA and SR for unifocal T1N0M0 PTC.

Methods: This retrospective study was conducted in a single center. A retrospective data analysis was conducted on patients treated with RFA or SR for T1N0M0 PTC between March 2018 and March 2023. Propensity score matching (PSM) was employed to create comparable groups. The primary outcomes were the disease progression (pathologically confirmed local tumor progression, new tumors or LNM,

distant metastasis identified using CT, and PTC-related mortality) and QOL. The 36-item short form health survey (SF-36) and Thyroid Cancer-Specific Quality of Life Questionnaire (THYCA-QoL) were completed by patients to evaluate their QoL scores.

Results: A total of 265 patients underwent RFA, and 325 underwent surgery. After propensity score matching, 300 patients were ultimately included, with 150 in each group. The technical success rate was 100% for both groups. According to the SF-36 , PTC patients in Mainland China experienced impaired general QoL. In the two years following treatment, the QoL scores for the RFA and SR groups reached a level similar to that of the reference population. These improvements persisted 5 years post-operation. THYCA-QoL showed that the "problems with scarring" and "psychological" scale scores of patients in the RFA group were lower than in the SR group.

Conclusion: Our study suggests that RFA provides better cosmetic, and HRQoL outcomes for T1N0M0 PTC patients.

Keywords: Papillary thyroid carcinoma, radiofrequency ablation, surgery, quality of life

Introduction

Thyroid cancer ranked 9th in cancer incidence in 2020 worldwide[1]. Papillary thyroid carcinoma (PTC) is the most common subtype of thyroid carcinoma, accounting for 80–90% of all thyroid malignancies[2]. Among these, T1 tumors (≤2 cm in maximal diameter) without clinically apparent lymph node metastasis (LNM) or distant metastasis (T1N0M0) are commonly associated with indolent behavior and excellent prognosis[3]. T1 tumors are classified into T1a (largest diameter, ≤1.0 cm) and T1b (largest diameter, >1.0 cm and ≤2.0 cm)[4]. However, both groups exhibit similar disease progression and invasive management strategies[5]. Active surveillance (AS) is mentioned in the 2015 ATA guidelines for very low-risk PTC. However, the indications and contraindications are not very clear. Some people may develop anxiety during the active surveillance process[6; 7]. Current, surgical intervention is the

primary treatment for T1N0M0 PTC, with thyroid lobectomy rather than total thyroidectomy as the first-line surgical approach[5]. However, the risks associated with general anesthesia, surgical complications, neck scars, and the need for thyroid hormone supplementation may negatively impact a patient's quality of life (QoL)[8; 9; 10].

According to joint guidelines published in the European Thyroid Journal, thermal ablation may be considered for patients with low-risk PTC, particularly if they are at surgical risk, unwilling to undergo surgery or active surveillance[11]. Numerous studies have investigated the efficacy and safety of RFA in PTC, demonstrating its high feasibility, favorable tumor resolution rates, effective local disease management, and minimal complications[12; 13; 14; 15; 16; 17]. Furthermore, several meta-analyses have shown that thermal ablation, when compared to surgery, offers comparable QoL outcomes and non-inferior prognoses, all at a reduced cost[18; 19; 20; 21]. Despite these encouraging results, the comparison of QoL between thermal ablation and surgery remains controversial, because long-term follow-up data from a large cohort are unavailable. A recent prospective study showed RFA exhibited similar cancer control outcomes and superior Qol on par with surgery, however, the follow-up period was only 12 months[22].

Therefore, This study aimed to provide long-term data comparing the QoL between RFA and SR for T1N0M0 PTC, with follow-up extending up to five years.

Patients and Methods

Patients

We conducted a retrospective review of all patients with PTC who underwent RFA or SR between March 2018 and March 2023 at Gansu Provincial Hospital. The study was approved by the Ethics Committee of the Gansu Provincial Hospital(NO: 2024-373), and the subjects gave their informed consent for participation. All methods were performed in accordance with the relevant guidelines and regulations.

The control population for the SF-36 comparison was obtained from published normative data representing an age- and sex-matched general Chinese population. The

target population was patients who had undergone US-guided RFA or SR to manage T1N0M0 PTC at Gansu Provincial Hospital. Patients with PTC were recommended both SR and RFA, the definitive treatment modality was "self-selecting" after a full explanation of the differences between two procedures. Patients were incorporated into our study if they met the following criteria: (1) PTC confirmed by US-guided biopsy; (2) a solitary tumor with a maximum diameter of 2 cm or less; (3) no clinical or imaging evidence of extrathyroidal extension, lymph node metastasis(LNM), and distant metastases on the US, and neck and chest CT[23]; (4) surgical intervention typically involves thyroid lobectomy rather than total thyroidectomy; and (5) patients without any history of neck irradiation. Patients with multiple PTC or insufficient follow-up of less than 6 months were excluded. Further, patients with major comorbidities that suspected to have a substantial HRQoL impact (e.g. malignant tumors, chronic obstructive pulmonary disease(COPD), congestive heart failure) were also excluded. Patients agreed to complete QoL questionnaires electronically. Figure 1.

US-guided RFA procedure

US-guided RFA was performed using a LOGIQ E9 system (GE HealthCare, Chicago, IL, USA) with a 6 to 15-MHz linear array probe. A 17-gauge RFA electrode with a 0.5- or 0.7-cm active tip (Cooltip Radiofrequency Ablation System, Covidien, Dublin, Ireland) was used for RFA. RFA procedure was performed by the same sonographer (Z Zhou.) with >12 years of experience in thermal ablation treatment of thyroid nodules.

Before RFA, the needle-tract route was determined using US or CEUS and two different needle-tract routes. Prior to RFA, the relationship between the tumour and critical cervical structures was carefully evaluated to locate the most appropriate puncture site. After that, local anaesthesia with 1% lidocaine was administered. Sterilized water was continuously injected between the peripheral nodule area and surrounding critical structure during the ablation to ensure a safe distance of at least 5 mm that could prevent thermal injury of adjacent structures. Ablation was performed layer by layer, following the "from far to near" or "from deep to shallow" principle

[24]. The power was set from 30 W to 70 W depending on the size of the active tip. Ablation was terminated after the hyperechoic zone covered the entire tumor and extended at least 2 mm beyond the original margin. Contrast-enhanced ultrasound (CEUS) was performed immediately after ablation to evaluate its effectiveness. If any residual enhancement areas were detected or the safety margin was inadequate, complementary ablation was immediately performed to ensure comprehensive treatment.

Surgery Procedure

For SR patients, all the operations were carried out by general surgeons with 10 years' clinical experience under general anesthesia, and the surgical strategies followed the American Thyroid Association Management guidelines[5] .

HRQoL Questionnaires

For HRQoL assessment generic QoL questionnaire RAND SF-36 were used [25; 26]. The tool consists of 36 questions, concerning two main components: Physical Component Summary (PCS), which reflects, in its turn, the mean score of four domains—physical functioning (PF), role physical functioning (RPF), bodily pain (BP) and general health (GH), and Mental Component Summary (MCS), which is compiled from the mean score of other four domains—vitality (VT), social functioning (SF), role emotional functioning (REF) and mental health (MH). After the transforming of the raw data into scaling QoL scores, the results are ranged from 0 to 100 scores for each of the eight scales. The higher the SF-36 questionnaire score, the better the HRQoL.

Thyroid Cancer-Specific Quality of Life Questionnaire (THYCA-QoL) was used to assess the thyroid-specific symptoms resulting from the thyroid cancer itself or its treatment[27; 28]. The questionnaire consists of 24 items, with a time frame of the previous week and each item is scored on a four-point response scale ranging from 1, 'not at all' to 4, 'very much'. The THYCA-QoL consists of seven symptom scales (neuromuscular, voice, concentration, sympathetic, throat/mouth, psychological and sensory problems) and six single items (problems with scar, felt chilly, tingling

hands/feet, gained weight, headaches, interest in sex) Scores were linear transformed to a 0–100 scale. A higher score on this scale means worse HRQoL.

Outcome measurements

This study defined technical success as complete non-enhancement on CEUS and hyperechogenicity on grayscale US of the target tumor immediately after ablation according to the planned procedure[29]. The primary outcomes were the disease progression (pathologically confirmed local tumor progression, new tumors or LNM, distant metastasis identified using CT, and PTC-related mortality) and QOL. Local tumor progression was defined as the appearance of a PTC lesion at the edge of the ablation zone, and a new tumor was defined as a PTC lesion emerging in a previously uninvolved thyroid region and not due to lymph node metastasis. Secondary outcomes included changes in ablation zone size, and complication rates. Complications were defined according to the criteria of the Society of Interventional Radiology[30; 31]. Permanent RLN injury was characterized by hoarseness lasting for over 6 months post-ablation and confirmed vocal cord paralysis on laryngoscopy.

Patients filled out the questionnaires including Thyroid Cancer–Specific Quality of Life Questionnaire (THYCA-QoL)[27; 28] and Short Form-36 Health Survey (SF-36) [25; 26] several times – upon admission to the hospital. At the admission to the hospital patients filled out paper versions of the questionnaires. During the follow-up questionnaires were completed electronically– the research staff contacted patients by WeChat or email in accordance with study time-points.

Statistical Analysis

To reduce the probability of selection bias, propensity score matching (PSM) was performed. Propensity scores were estimated using a logistic regression model that included age, sex, marriage, education, employment status, place to live, family history and T classification. Patients in the RFA group were matched to those in the SR group (1:1), with the nearest neighbor estimated propensity score within a range of 0.02 standard deviation. After PSM, there was no statistically significant difference in baseline QoL between the two groups (all $P<0.001$).

All statistical analyses were performed using the Statistical Package for the Social Sciences software for Windows 22.0 (SPSS Inc., Chicago, Illinois). Continuous data are presented as means ± SDs if the data fit a normal distribution or as medians with 25%–75% IQRs if the data did not fit a normal distribution. Categorical variables are presented as frequencies (percentages). Continuous variables were compared by using the independent t-test or Wilcoxon rank-sum test between the two groups. Qualitative variables were analyzed using Chi-square test or Fisher's exact test. Comparisons between preoperative and postoperative values and between PTC patients and the general China population (SF-36 scores) were performed using the one sample t-test. All tests were two sided, with $P < 0.05$ considered to indicate a statistically significant difference.

Results

Patient characteristics

A total of 265 patients underwent RFA, and 325 underwent SR. After propensity score matching, 300 patients were ultimately included, with 150 in each group. Their ages RFA group ranged from 23 years to 74 years (mean, 41.2 ± 12.4 years) and 85.3% were females. SR group ranged from 28 years to 71 years (mean, 44.1 ± 11.5 years) and 77.3% were females. The median follow-up for the RFA group was 38 (28–60) months and for the SR group 39(30–61) months. In total, 95% of patients reached the 2-year follow-up, and 65% reached 5 years. The follow-up duration was comparable between the RFA and surgery groups ($P = 0.85$). The detailed clinical features of the patients are shown in Table 1.

Disease progression

Complete ablation was achieved in 150 patients in a single session. In the SR group, all 150 patients with PTCs underwent successful unilateral SR during a single procedure. The technical success rate was 100% for both groups. There was a significant reduction in the maximum diameter from the third month post-RFA, compared with pre-RFA measurements. The cumulative complete disappearance rates at 1, 3, and 5 years were 20.8.0%, 90.2%, and 97.5%, respectively. No major

complications occurred in the RFA groups; however, three complications were reported in the surgery group (hoarse voice: n=1; hematoma: n=1; surgical site infection: n=1). All patient recovered 4 month after surgery. In the SR group, the rate of thyroid hormone replacement therapy after SR was 22.7% (34 of 150 patients) ; however, none of the patients in the RFA group required thyroid hormone replacement therapy.

At the end of the follow-up period, this study documented five instances of disease progression: four cases of new tumor occurrence three years post-operation (two in the RFA group and two in the SR group) and one case of local tumor progression 10 months post-RFA. No distant metastasis or LNM and disease-related fatalities were observed in all patients. All cases were validated using FNA and subsequently treated with additional RFA. Notably, no further disease progression was noted up to the final follow-ups at 50 months after the initial treatment.

SF-36 Questionnaire Scores

Figure 2 describes the QoL before 2, and 5 years after postoperation for patients with T1N0M0 PTC in comparison with an age-matched and sex-matched general China population. Before surgery, patients with T1N0M0 PTC had impaired HRQoL in comparison with the reference population as shown by a significantly lower mean each dimension score. Meanwhile, we also found that younger women (<40 years) had a lower QoL than older patients (P= 0.022).

2 years after the operation, physical functioning, role physical functioning, general health, and mental health in patients became comparable to those of the general Chinese population, with no significant differences observed. However, other dimension scores remained significantly lower. Notable, the only notable difference between the RFA and SR groups was in role emotional functioning. These improvements persisted 5 years post-operation, at which point vitality was also no longer significantly different.

THYCA-Qol Questionnaire Scores

In the following 5 years, THYCA-QoL score comparison between patients in the

RFA group and SR group were presented in Figures 3. There were significant differences in problems with scarring (P= 0.026), psychological (P= 0.029) between the groups. The “problems with scarring” and “psychological” scale scores of patients in the RFA group were lower than in the SR group, indicating a lower level of complaint relating to symptom in the RFA group.

Discussion

The standard treatment for unifocal T1N0M0 PTC is surgery, usually unilateral lobectomy[5]. However, due to the indolent nature of this tumor, AS has been advocated for very low-risk PTC in the 2015 ATA guidelines[5]. The main drawback of AS is the anxiety caused by indwelling tumor[32]. A meta-analysis reported that 32%–69% patients underwent delayed surgery during AS because of anxiety other than disease progression[33]. Conversely, in our study, none of the patients underwent delayed surgery because of anxiety. This aligns with a meta-analysis on low-risk PTC treated with thermal ablation, which found no cases of patients opting for delayed surgery due to anxiety[34].

Due to the relatively slow clinical progression of PTC, long-term follow-up is warranted for evaluating both the effectiveness and safety of the treatment. In our 5-year follow-up study, there was no obvious difference in tumor progression and recurrence-free survival rates between the two groups, which aligns with a previous systematic review and meta-analysis[35]. Given the increasing incidence of thyroid cancer, ablation may become a viable option for indolent PTC. Some researchers found that local ablation might release immune-associated antigens and therefore enhance host adaptive immune responses, thus inhibiting the growth of primary lesions and metastasis[36; 37].

QoL is an important measure for tumours with such good prognosis. To our knowledge, this study represents one of a few studies that have assessed general and disease-specific quality of life using a thyroid cancer-specific quality of life questionnaire in patients with PTC in Mainland China. The present study indicated that PTC patients in Mainland China experienced impaired general QoL compared to

the reference population, especially young adults, which was in accordance with results reported in previous studies[38; 39; 40]. Although PTC has a low disease-specific mortality rate, there remains a small but significant risk of short- and long-term complications associated with surgery, radioiodine therapy, and medical treatment. Additionally, all survivors require lifelong surveillance for disease recurrence. In the short term, QoL may decline even further after surgery compared to preoperative levels[41]. Emotional and psychological concerns, particularly among young adults, are largely unmet. These issues likely contribute to the increased reports of psychological distress and anxiety[40], aligning with findings from other cancer patient surveys that highlight negative emotions related to body image, perceived stigma, and the emotional challenges of the cancer experience [42].

Our study evaluated the HRQoL of patients with PTC under different treatment strategies. In the two years following treatment, the QoL scores for the RFA and SR groups reached a level similar to that of the reference population, and most of the QoL parameters were comparable between the RFA and SR groups. This finding is consistent with previous studies indicating that the postoperative QoL of patients with differentiated thyroid cancer can be comparable to that of the general population after a long-term follow-up[43; 44].

Although this study did not utilize a specific distress screening tool, the domains assessed by the THYCA-QoL closely align with recognized distress domains. Distress has been referred to as the sixth vital sign in cancer patients, with growing evidence suggesting that elevated distress levels can negatively affect treatment outcomes, follow-up adherence, and overall QoL[45]. A Korean study using the same distress assessment tool, along with their version of the Mini-Mental Scale, found that anxiety and helplessness were the primary contributors to distress in PTC survivors. These findings correspond to the anxiety and psychological domains identified in the present cohort [46].

In the present study, the mean THYCA-Total score lower than that reported by Chen et al[39]. indicating that patients in this study may have better thyroid

cancer-specific QoL than those who were included in the study by Chen et al. Differences in the participants might be one possible explanation. In our study, all patients had undergone lobectomy, while the proportion in Chan et al.'s study was 52.5%.

In the THYCA-QoL questionnaire, PTC patients had a short-term decrease in QoL at three months after the procedure, the decline may be due to temporary damage to the recurrent laryngeal nerve and hoarseness after ablation,which was in accordance with results reported in previous studies [39; 47; 48; 49]. In the continuous observation process in this study, most of the QoL parameters for the RFA and SR groups showed considerable improvements. Lubitz et al[50] also showed a temporary decrease of QoL after initial therapy, but after six months QoL was comparable to baseline. However, their study did not have data on QoL before surgery. Cancer patients usually perceive improved HRQoL after months or years of recovery. This suggested that the effects of surgery on patients' QoL can be recovered in a very short time. And in the long term, RFA and SR can improve patients' QoL.

We also observed that patients treated with minimally invasive surgery reported better disease-specific QoL compared to those treated with conventional surgery. The THYCA-QoL questionnaire results showed worse results in problems with scarring and psychological in the SR group. The higher psychological problem scores of the SR group may be related to the long-term thyroid hormone replacement therapy or that patients seriously anxious about their disease tend more to adopt SR. RFA damages thyroid function less and does not require life-long hormone replacement, which may improve the patient's survival experience. However, further preoperative psychological evaluation is needed.

The study has limitation, because this was a retrospective study, although propensity score matching was used to minimize selection bias, the possibility of residual confounding cannot be completely excluded. The number of variables included in the matching model was selected to balance adjustment adequacy with the available number of outcome events to avoid overfitting. Future prospective registry studies with predefined inclusion criteria are warranted to further validate these

findings. Besides, the manuscript lacks sufficient data regarding how active surveillance might compare in terms of QOL, which is a notable limitation. Future prospective studies incorporating active surveillance cohorts are warranted to better elucidate the comparative impact of different management strategies on patients' quality

Conclusions

The present study indicated that PTC patients in Mainland China experienced impaired general and thyroid cancer-specific QoL. RFA provides better cosmetic, and HRQoL outcomes for T1N0M0 PTC patients, so RFA is a better option for T1N0M0 PTC patients who have esthetic needs.

Data availability

The datasets generated and/or analysed during the current study are not publicly available due to protect study participant privacy, but are available from the corresponding author on reasonable request.

Author contributions Z.Z, Y.X and J.X researched the conception and design of the study. Y.Y and D.Y analyzed and interpreted the data. Z.Z and Y.X wrote the manuscript. L.L, D.Y and Y.L contributed to the discussion and reviewed the manuscript. All authors read and approved the final manuscript.

Compliance with ethical standards

Conflict of interest The authors declare no competing interests

Ethics approval The study was performed according to the guidelines of the Helsinki Declaration and was approved by the Ethics Committee of the Gansu Provincial Hospital(NO: 2024-373). The subjects gave their informed consent for participation.

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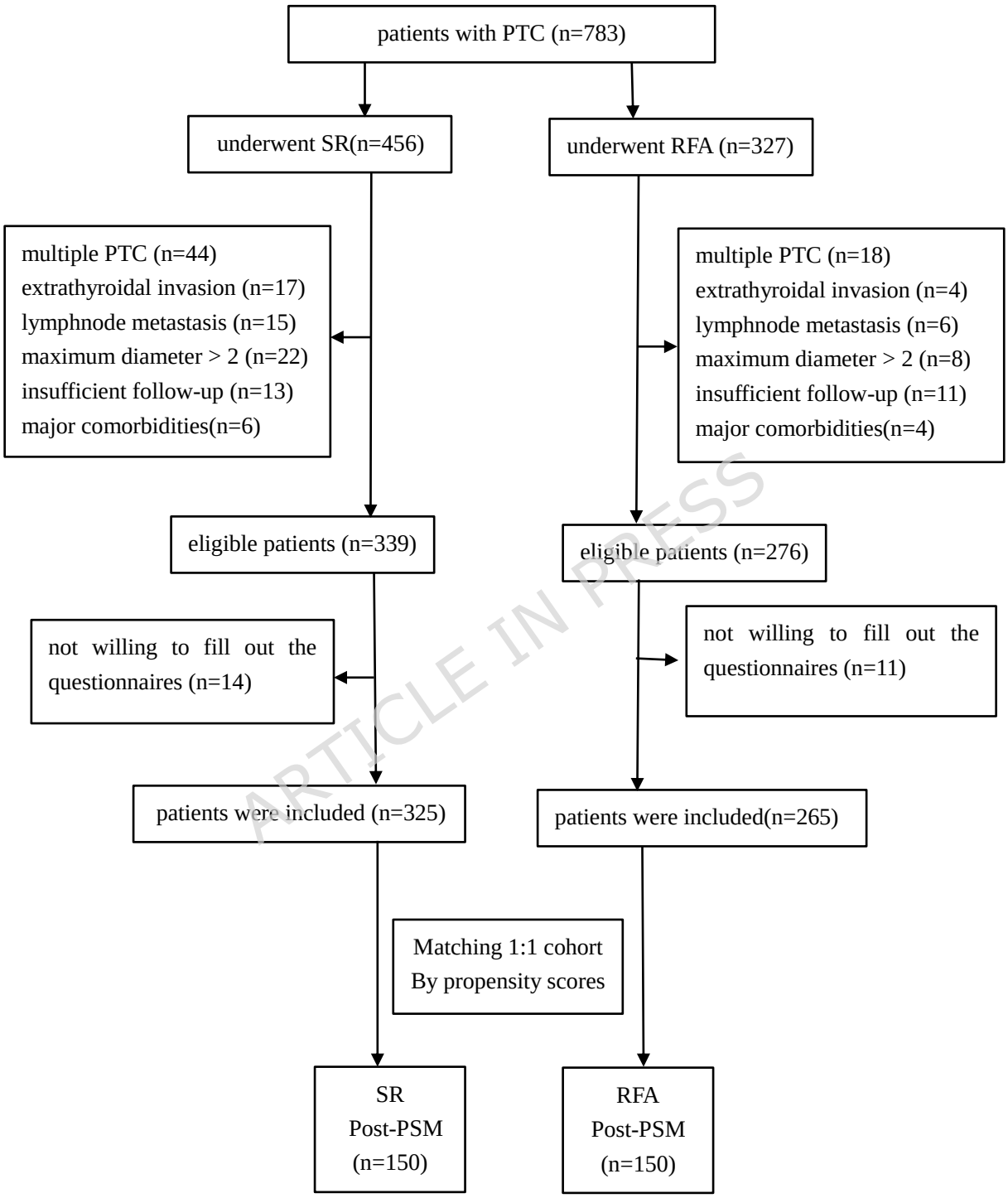
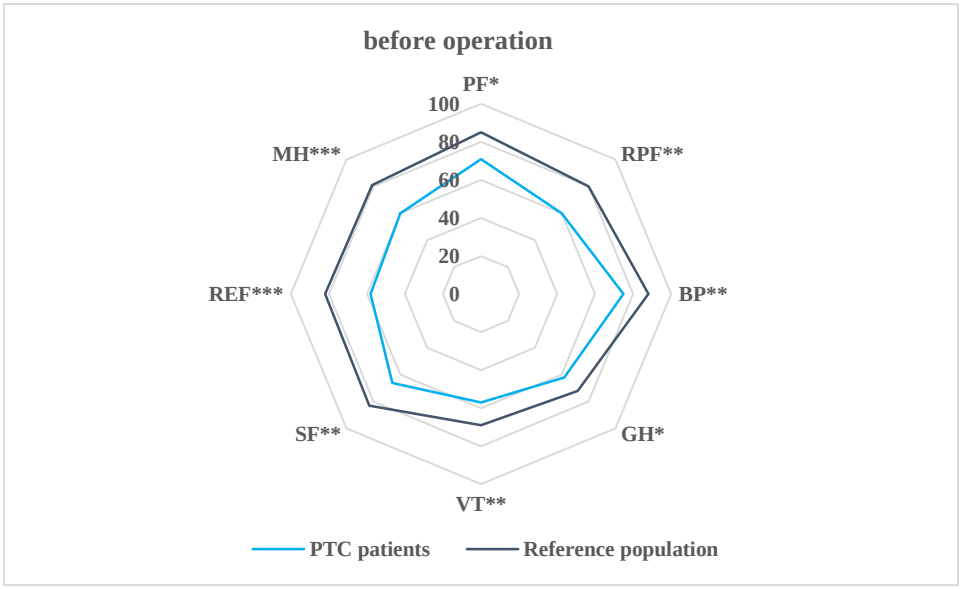
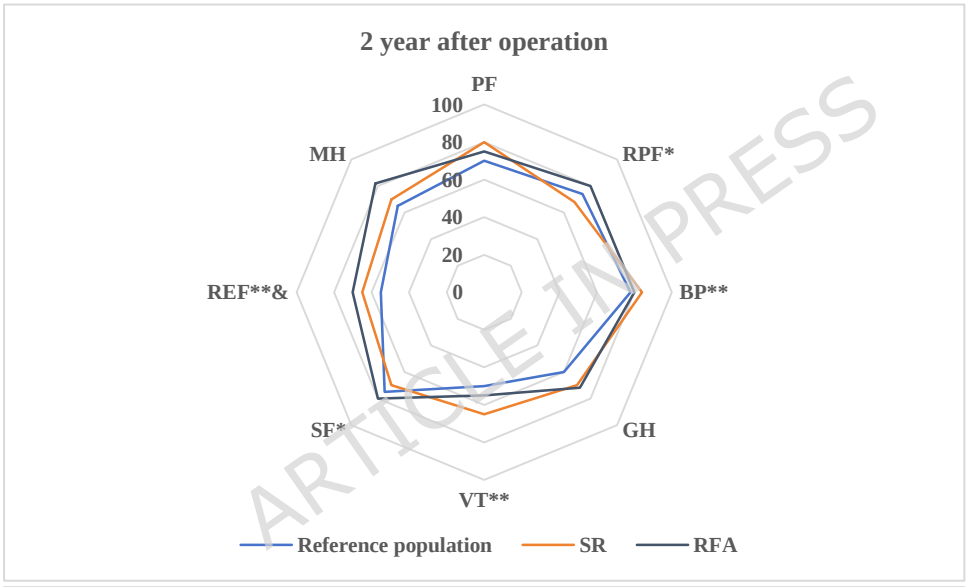


Figure1 Patient flowchart. PTC, Papillary thyroid carcinoma; RFA, radiofrequency ablation; SR, surgical resection





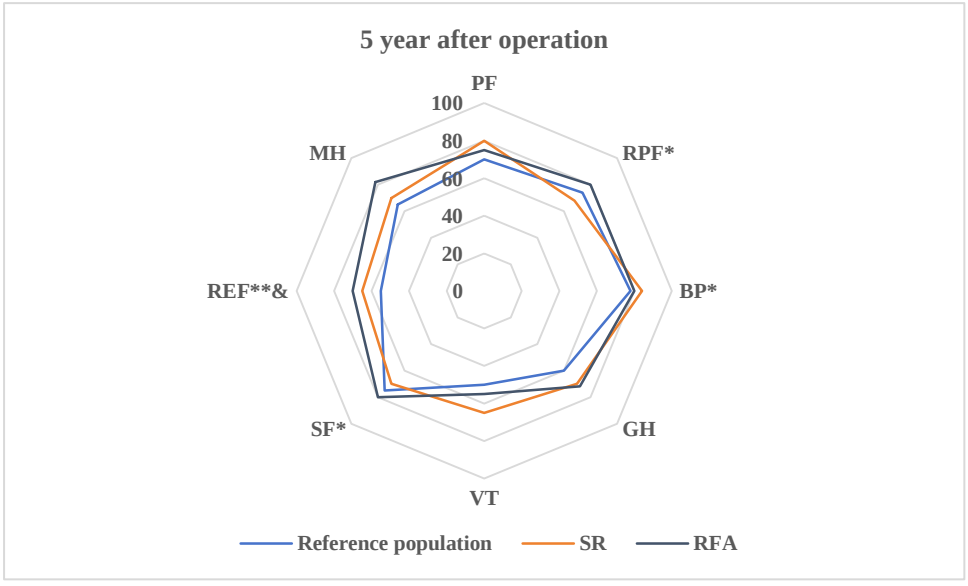
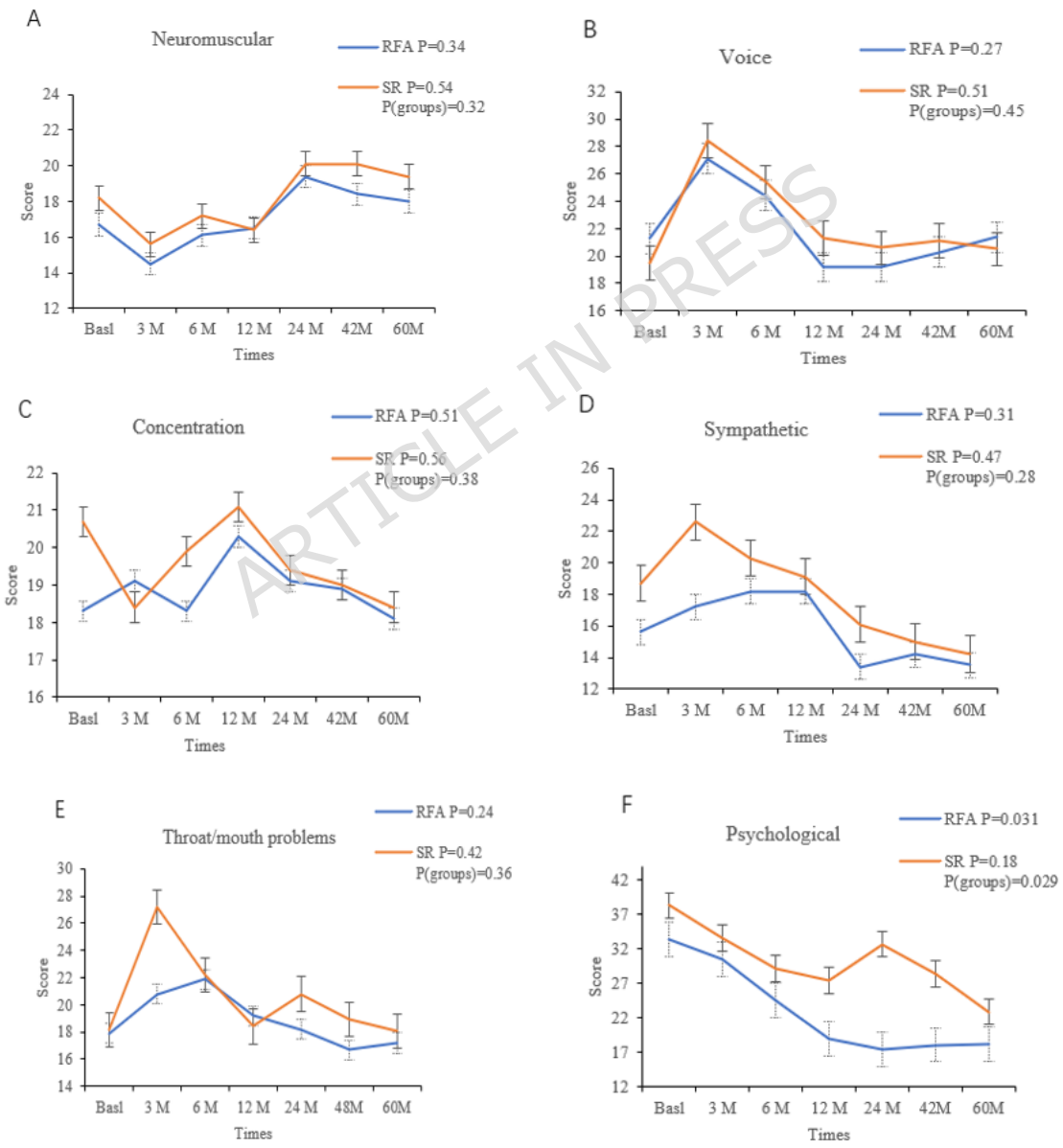


Figure 2 SF-36 questionnaire results in patients with T1N0M0 PTC before, 2, and 5 years after postoperation, compared with the age-matched and sex-matched general China population. Scores between PTC patients and age-matched and sex-matched China reference population were compared using Student's t tests; *P<0.05, **P<0.01, and ***P<0.001. &P<0.05 (RFA group compared to SR group). PTC, papillary thyroid carcinoma; PF, physical functioning , RPF, role physical functioning , BP, bodily pain, GH, general health, VT, vitality, SF, social functioning, REF, role emotional functioning, MH, mental health.



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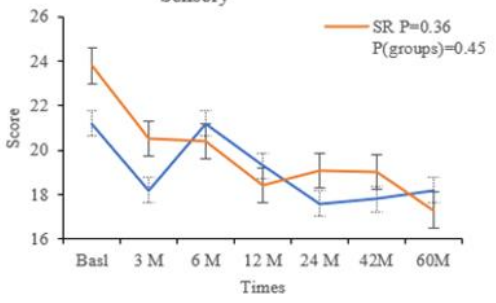

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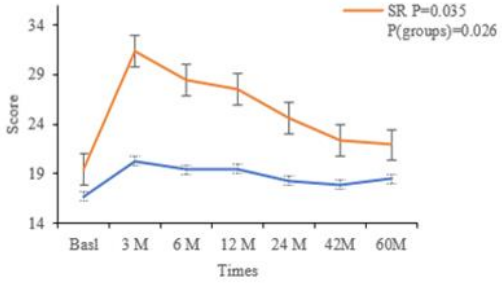

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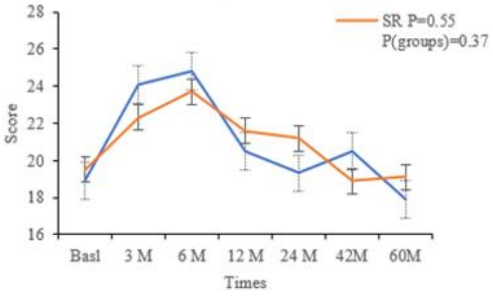

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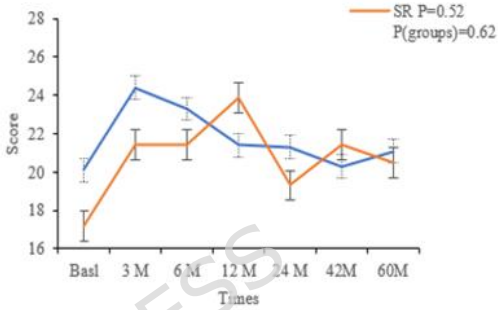

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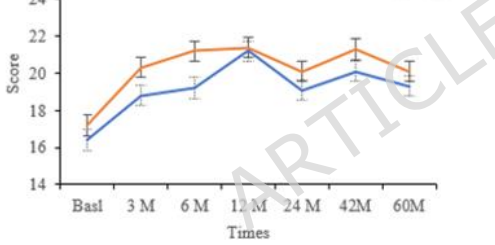

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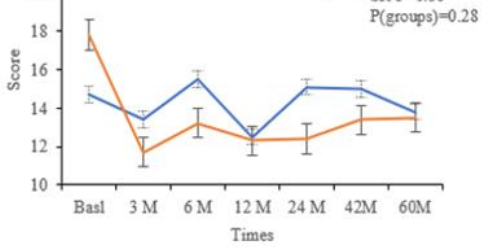

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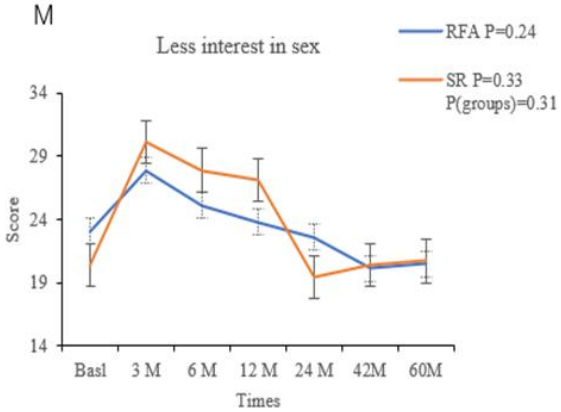

Fig 3 Comparison of HRQoL in patients who underwent RFA and SR by using THYCA-QoL at 1, 3, 6, 12, 24,42 and 60 months postsurgery.

Parameters: A. Neuromuscular; B. Voice; C. Concentration; D. Sympathetic; E. Throat/mouth; F. Psychological; G. Sensory; H. Problems with scar; I. Felt chilly; J. Tingling hands/feet; K. Gained weight; L. Headache; M. Interested in sex. Note: P denotes p value for longitudinal changes within each group; P (groups) denotes the p value for longitudinal changes between groups.

Table 1 Clinical characteristics of papillary thyroid carcinoma patients in RFA group and SR group.

Characteristic	Before PSM			After PSM		
	RFA group (n=265)	SR group (n=325)	*P*	RFA group (n=150)	SR group (n=150)	*P*
Age (years)			0.043			0.295
≤55	108（40.4%）	159（48.9%）		89 (59.3%)	80 (53.3%)	
>55	158（59.6%）	166（51.1%）		61(40.7%)	70 (46.7%)	
Sex			0.012			0.075
Male	75（28.3%）	124（38.2%）		22 (14.7%)	34 (22.7%)	
Female	190（71.7%）	201（61.8%）		128 (85.3%)	116 (77.3%)	
BMI (kg/m2)			0.219			0.497
≤27.9	154（58.1%）	205（63.1%）		132 (88%)	128 (85.3%)	
>27.9	111（41.9%）	120（36.9%）		18 (12%)	22 (14.7%)	
Marriage			0.000			0.123
Married	201（75.8%）	298（91.7%）		123(82.0%)	112 (74.7%)	
Unmarried	64（24.2%）	27（8.3%）		27 18(%)	38 (25.3%)	

Education						0.512
College degree or higher	111 (41.9%)	87 (26.8%)	0.000	42(28%)	37 (24.7%)	
Others	154 (58.1%)	238 (73.2%)		108 (72%)	113 (75.3%)	
Employment status			0.036			0.327
Employed	167 (63.0%)	177 (54.5%)		54(36%)	46 (30.7%)	
Unemployed	98 (37%)	148 (45.5%)		96(64%)	104 (69.3%)	
Place to live			0.005			0.971
Urban	155 (58.5%)	152 (46.8%)		70 (46.7%)	75(50.0%)	
Rural areas	110 (41.5%)	173 (53.2%)		80 (53.3%)	75 (50.0%)	
Family history			0.072			0.777
Yes	31 (11.7%)	42 (12.9%)		6 (4.0%)	7 (4.7%)	
No	234 (88.3%)	283 (87.1%)		144 (96.0%)	143 (95.3%)	
T classification			0.000			0.199
T1a	160 (68.1%)	140 (43.1%)		92 (74.7%)	81 (54%)	
T1b	75 (31.9%)	185 (56.9%)		58 (25.3%)	69 (46%)	
Smoker			0.603			0.215
Yes	115 (43.3%)	148 (%)		21 (14.0%)	29 (19.3%)	
No	150 (56.6%)	177 (%)		129 (86.0%)	121 (80.7%)	
Tpo-Ab (< 4.11 IU/ml)			0.292			0.208
Negative	224 (84.5%)	264 (81.2%)		130 (86.7%)	122 (81.3%)	
Positive	41 (15.5%)	61 (18.8%)		20 (13.3%)	28 (18.7%)	
Tg-Ab (< 5.61 IU/ml)			0.250			0.097

Negative	230 (86.8%)	271 (83.4%)	138 (92.0%)	129 (86%)
Positive	35 (13.2%)	54 (16.6%)	12 (8.0%)	21 (14%)

T1a indicates a tumor smaller than 1cm, T1b indicates a tumor larger than 1 cm but smaller than 2 cm. RFA, radiofrequency ablation; SR, surgical resection; BMI, body mass index; Tpo-Ab, Thyroid peroxidase antibodies; Tg-Ab, anti thyroglobulin antibodies; PSM, propensity score matching.