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Original research

EFFICACY AND SAFETY OF SINGLE-SESSION RADIOFREQUENCY ABLATION FOR BENIGN PREDOMINANTLY CYSTIC THYROID NODULES: A 12-MONTH FOLLOW-UP STUDY

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ABSTRACT

Objective: *To evaluate the efficacy and safety of single-session RFA for PCTNs in a Vietnamese cohort over a 12-month follow-up period.*

Methods: *This prospective study included 28 patients with PCTNs (50 - 90% cystic component) treated at the Family Hospital in Da Nang, Vietnam, from June 2023 to April 2025. Primary outcomes included volume reduction rate (VRR) and therapeutic success (VRR > 50%), assessed at 1, 6, and 12 months post-RFA. Thyroid function stability and complication rates were also evaluated.*

Results: *RFA demonstrated significant volume reduction, with mean VRR improving from 61.5% at 1 month to 81.8% at 12 months (p = 0.006). The therapeutic success rate increased from 75% at 1 month to 94.7% at 6 months, maintaining 84.6% at 12 months (p = 0.002). No major complications were reported, and thyroid function remained stable throughout the follow-up.*

Conclusion: *Single-session RFA is a safe and effective minimally invasive treatment for PCTNs, providing substantial volume reduction without major complications. This approach is particularly suitable for patients who decline surgery or have contraindications to surgical intervention. However, longer-term studies are required to assess durability and recurrence rates.*

Keywords: *Radiofrequency ablation, Predominantly cystic thyroid nodules, thyroid nodules.*

I. INTRODUCTION

Thyroid nodules are the second most common endocrine disorder after diabetes, representing a significant clinical concern. Among these, partially cystic thyroid nodules (PCTNs) account for a substantial proportion, making up about 53.5% of all thyroid nodules, with approximately 13.7% being predominantly cystic, characterized by more than 75% cystic content. Although generally benign, PCTNs can lead to considerable symptoms, including local compression, aesthetic issues, and psychological discomfort, emphasizing the need for effective and minimally invasive management [1, 2]. While simple aspiration or ethanol ablation (EA) have been conventional approaches for purely cystic thyroid nodules, these techniques often result in high recurrence rates due to incomplete ablation of the solid components that contribute to regrowth [3, 4]. In contrast, radiofrequency ablation (RFA) has emerged as a promising alternative, offering high long-term volume reduction rates (VRR) and lower recurrence risk as well as complications [5, 6].

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Several studies have reported encouraging outcomes for RFA in the treatment of PCTNs. For instance, a randomized clinical trial in Korea demonstrated that RFA achieved a volume reduction rate of approximately 87.5% at 6 months, comparable to the 82.4% achieved with EA, but with significantly lower recurrence rates over extended follow-up periods [7]. Retrospective analyses further support the efficacy of RFA, reporting average VRRs of 80-90%, with significantly reduced recurrence rates (approximately 5-6%) compared to EA (26-33%) [8]. This suggests that RFA may offer a more durable therapeutic benefit, particularly for nodules with a significant solid component. Additionally, nodules with a higher initial solid proportion or increased vascularity have been shown to require higher energy delivery during RFA to achieve optimal outcomes. This is because solid tissue conducts heat more readily, and increased vascularity can act as a "heat sink," dispersing the heat generated by RFA [9, 10].

Despite these promising results, the clinical application of RFA in Southeast Asia, including Vietnam, remains limited due to factors such as cost, access to technology, and physician expertise. Furthermore, few studies have specifically examined the outcomes of RFA for PCTNs in this region, where the disease burden and patient demographics may differ significantly from those in developed countries [11]. This study aims to address this gap by evaluating the short-term (1 month), mid-term (6 months), and long-term (12 months) outcomes of single-session RFA for PCTNs in a Vietnamese cohort, providing critical insights into its efficacy, safety, and practical feasibility in a resource-limited healthcare setting.

II. METHODS AND MATERIALS

2.1. Study design and patient's selection

This prospective study was designed and carried out in compliance with the ethical principles outlined in the Declaration of Helsinki. Approval was obtained from the Ethics Committee of the Institutional Review Board at the University of Medicine and Pharmacy, Hue University, Vietnam (Approval Number: H2023/050). Informed written consent was secured from all participants before their enrollment in the study.

This study enrolled patients with predominantly cystic thyroid nodules (PCTNs - proportion of cystic component ranging from 50% to under 90% of the nodule volume) who underwent radiofrequency ablation (RFA) at the Centre of Endocrinology and Diabetes, Danang Family Hospital, between June 2023 and April 2025. The patient recruitment period spanned from June 1st, 2023, to March 1st, 2025.

Inclusion criteria for this study were as follows: (1) diagnosis of a predominantly cystic thyroid nodule with the cystic component constituting 50% to under 90% of the total nodule volume; (2) presence of clinical symptoms or cosmetic concerns; (3) documented thyroid function, including serum free thyroxine (FT4) and thyroid-stimulating hormone (TSH) levels; (4) cytology-confirmed benign thyroid nodules through one or two ultrasound-guided fine-needle aspiration (FNA) procedures; (5) refusal of surgical treatment; and (6) ability to adhere to a follow-up schedule of at least one month, six months, and twelve months post-ablation.

Prior to the RFA procedure, all patients received a comprehensive explanation of the technique, encompassing its potential benefits and risks, to ensure fully informed consent

2.2. Pre-ablation assessment

All participants in this study underwent standardized ultrasound examinations performed by a single, experienced radiologist within the same medical institution. Ultrasound-guided fine-needle aspiration (FNA) was consistently conducted by an endocrinologist (Nguyen Van Bang), a certified professional with over five years of expertise in thyroid interventions. A real-time ultrasound system (Acuson NX2 or NX3, Siemens Medical Solutions, California, USA) equipped with an 8-12 MHz linear transducer was utilized for all cases.

The ultrasound evaluation encompassed the measurement of nodule dimensions and the assessment of internal fluid composition. For each thyroid nodule, three orthogonal diameters were meticulously recorded, and the volume was subsequently calculated using the ellipsoid volume formula: $V=\pi abc/6$, where V denotes the volume and a, b, and crepresent the three measured orthogonal diameters. Thyroid function was evaluated through laboratory tests obtained prior to the intervention and at 1, 6, and 12 months post-treatment

2.3. Procedure

The RFA procedure was performed on an outpatient basis with patients positioned supine and their necks slightly hyperextended to optimize access. A single, certified endocrinologist with over five years of experience in this specific ablation technique executed the entire procedure under continuous ultrasound guidance. Following meticulous skin antisepsis and the administration of local anesthesia (2% lidocaine) at the needle entry point and within the perithyroidal tissues, an 18-gauge needle was introduced to access the PCTNs under real-time ultrasound visualization via an isthmic approach. The internal cystic fluid was aspirated to the maximal extent feasible using either a 20 ml or 50 ml syringe. In instances where the cyst contained highly viscous colloid, a larger 16-gauge needle was utilized for aspiration, followed by the pump of sterile saline to facilitate the subsequent evacuation of the colloid material prior to the ablation phase [12].

Prior to the ablation of the thyroid nodule and its associated vasculature, complete aspiration of the cystic fluid was performed. Subsequently, a cooled, internally irrigated monopolar electrode (with a 5 mm or 7 mm active tip) connected to a radiofrequency generator (CoATherm AK-F200, APRO KOREA Inc., Gyeonggi-do, Korea) was introduced into the nodule under real-time ultrasound guidance utilizing the isthmic approach. The moving-shot technique was employed to systematically ablate the nodule in a unit-by-unit manner. Furthermore, Doppler ultrasonography was utilized to identify and specifically target vascular structures both within and surrounding the nodule to ensure comprehensive ablation. Successful and complete ablation of the nodule was confirmed intraprocedurally by the visualization of a transient hyperechoic zone on ultrasound imaging, indicative of effective thermal coagulation [12-14].

2.4. Follow-up

Post-procedural follow-up evaluations, encompassing ultrasound imaging, thyroid function assays, and clinical assessments, were performed at one month, six months, and 12 months. These follow-up assessments employed identical evaluation methodologies to those utilized at baseline, prior to the radiofrequency ablation (RFA) intervention. The primary endpoint, treatment efficacy, was determined by calculating the volume reduction rate (VRR), with therapeutic success defined as a VRR exceeding 50%. Secondary endpoints, focusing on safety outcomes, were evaluated in accordance with the guidelines established by the international consensus working group on image-guided tumor ablation. Major complications were defined as events resulting in significant morbidity or disability, necessitating escalated medical intervention, hospital admission, or blood transfusion due to severe hemorrhage, as well as instances of permanent vocal cord dysfunction. Minor complications included transient adverse effects such as localized pain or temporary voice alterations [15].

$$\text{VRR (\%)} = \frac{(\text{Baseline volume} - \text{1 month posttreatment volume})}{\text{Baseline volume}} \times 100\%$$

2.5. Statistical analysis

Statistical analyses were performed utilizing SPSS version 20.0 for Windows. Safety outcomes were reported as the frequency of events and their corresponding percentages. To assess RFA efficacy, the mean and standard deviation (SD) of the volume reduction ratio (VRR) were calculated at the 1-month, 6-month, and 12-month post-ablation follow-up intervals. Changes in nodule volume, maximum diameter, free thyroxine (FT4), and thyroid-stimulating hormone (TSH) levels from baseline to the 1-month, 6-month, and 12-month post-treatment assessments were evaluated using repeated measures ANOVA or the Friedman test, contingent upon the data distribution. To compare volume reduction rates and therapeutic success rates across the 1-month, 6-month, and 12-month follow-up points, the Friedman test or Wilcoxon signed-rank test was applied when the data did not meet the assumptions of normality, serving as a non-parametric alternative to paired t-tests. Multiple linear regression analysis was employed to identify independent predictors of efficacy, specifically the VRR at 6 months. Statistical significance was established at a p-value of less than 0.05.

III. RESULTS

From June 2023 to April 2025, a total of 30 patients diagnosed with PCTNs were deemed eligible for inclusion through the Ehealth program, but 2 patients declined RFA treatment, resulting in 28 patients receiving the intervention. Specifically, 26 patients completed the 1-month follow-up, 19 continued to the 6-month follow-up, and 13 remained under observation at the 12-month mark at the end April 2025 (Figure 1). The study was conducted without any complications, either major or minor.

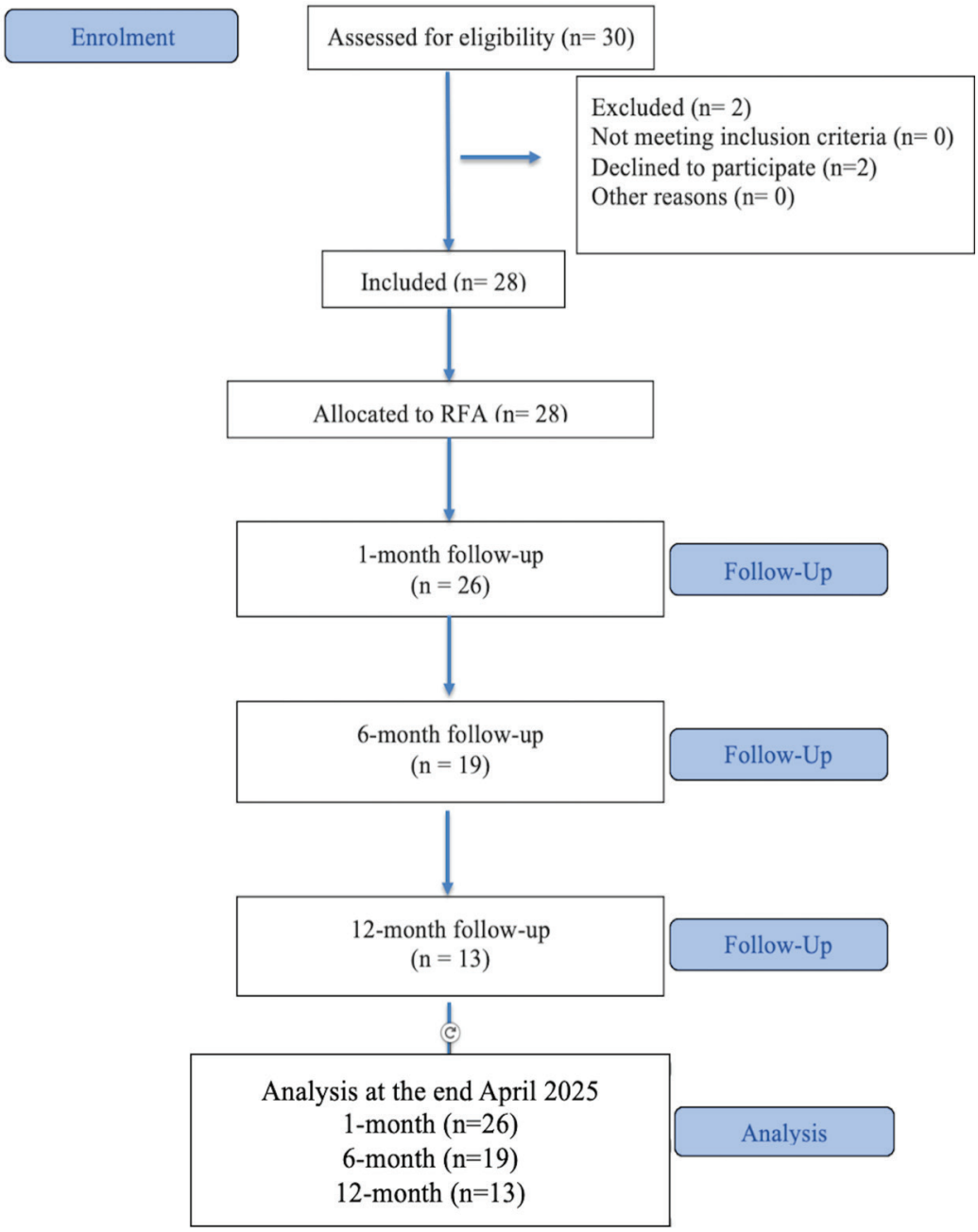

Figure 1: Consort flow diagram of patient enrollment and follow-up

Table 1 presents the baseline demographics and clinical characteristics of the 28 patients enrolled in this study. The cohort comprised 2 males (7.1%) and 26 females (92.9%), with a mean age of 38.6 ± 14.1 years (range: 14-64 years). The mean baseline nodule diameter was 31.4 ± 8.2 mm and volume 9.3 ± 8.9 mL.

Thyroid function was normal, with mean TSH 1.47 ± 0.96 µIU/mL and FT4 1.25 ± 0.19 ng/dL. The average aspirated fluid volume was 4.72 ± 5.2 mL. Nodules were located in the right lobe (53.6%), isthmus (3.6%), and left lobe (42.8%). Baseline cosmetic and symptom scores were 3.04 ± 1.01 and 4.5 ± 4.3, respectively. The mean procedure time was 14.5 ± 10.06 minutes with 8.57 ± 3.95 mL of lidocaine used. RFA delivered 20.04 ± 18.32 kJ of energy, with minimum and maximum RF powers of 23.39 ± 4.5 W and 46.07 ± 11.96 W, respectively.

Table 1: Baseline characteristics of 28 patients and PCTNs

Characteristic	Summary statistics (N = 28)
Gender (n, %)	
Male	2 (7.1)
Female	26 (92.9)
Age (year), (mean ± SD)	38.6 ± 14.1 (14 - 64)
Largest diameter (mm), (mean ± SD)	31.4 ± 8.2 (20 - 48.6)
Nodule volume (mL), (mean ± SD)	9.3 ± 8.9 (1.41 - 36.96)
TSH (microUI/ml), (mean ± SD)	1.47 ± 0.96 (0.11 - 4.17)
FT4 (ng/dl), (mean ± SD)	1.25 ± 0.19 (0.76 - 1.52)
Volume of fluid aspirated (ml)	4.72 ± 5.2 (1 - 25)
Location (n,%)	
Right lobe	15 (53.6)
Ismuth	1 (3.6)
Left lobe	12 (42.8)
Cosmetic score	3.04 ± 1.01 (1 - 4)
Symptom score	4.5 ± 4.3 (0 - 10)
Time of procedure	14.5 ± 10.06 (5 - 42)
Vlidocain	8.57 ± 3.95 (4 - 20)
Energy	20.04 ± 18.32 (4.61 - 70)
Power min	23.39 ± 4.5 (20 - 30)
Power max	46.07 ± 11.96 (30 - 70)

Following the initial RFA session, a significant and sustained reduction in both nodule diameter and volume was observed over 12 months ($p < 0.0001$ for both). The mean diameter decreased from 31.4 mm at baseline to 23.2 mm at 1 month, 17.0 mm at 6 months, and 16.5 mm at 12 months. Similarly, nodule volume dropped from 9.3 mL to 3.2 mL, 1.6 mL, and 2.1 mL, respectively. Thyroid function remained stable, with no significant changes in TSH ($p = 0.6$) or FT4 ($p = 0.63$) throughout the follow-up period. These findings confirm that RFA effectively induces long-term volume reduction without affecting thyroid function (Table 2).

Table 2: Treatment Outcomes of Initial Radiofrequency Ablation Session

Characteristic	Treatment outcomes				p
	Initial (N=28)	1 month (N=26)	6 months (N =19)	12 months (N=13)	
Largest diameter (mm), (mean ± SD)	31.39 ± 8.19	23.17 ± 6.92	16.99 ± 8.36	16.49 ± 9.71	0.0001
Nodule volume (mL), (mean ± SD)	9.33 ± 8.86	3.24 ± 2.95	1.59 ± 2.03	2.07 ± 4.22	0.0001
TSH (microUI/ml), (mean ± SD)	1.47 ± 0.96	1.28 ± 0.84	1.47 ± 0.93	1.36 ± 1.02	0.6
FT4 (ng/dl), (mean ± SD)	1.25 ± 0.19	1.29 ± 0.21	1.21 ± 0.16	1.26 ± 0.22	0.63

(*), p-value for both the Ethanol Ablation and Radiofrequency Ablation Groups

Table 3 summarizes the outcomes of radiofrequency ablation (RFA) for PCTN treatment at 1-month, 6-month, and 12-month follow-up intervals. The volume reduction rate (VRR) following RFA demonstrated a statistically significant increase over the 12-month follow-up period ($p = 0.006$). Specifically, the mean VRR for PCTNs was 61.50 ± 22.59% at 1 month, which significantly improved to 81.64 ± 18.19% at 6 months, and was maintained at 81.82 ± 24.68% at 12 months. The therapeutic success rate, defined as VRR > 50%, also showed a statistically significant improvement over time ($p < 0.002$). At 1 month post-RFA, the therapeutic success rate was 75.0% (21 out of 26 nodules), increasing to 94.7% (18 out of 19 nodules) at 6 months, and remaining high at 84.6% (11 out of 13 nodules) at the 12-month assessment.

Table 3: Follow-Up Outcomes of Radiofrequency Ablation for PCTNs at 1, 6, and 12 Months

Outcome	Treatment outcomes			p
	1 month (N=26)	6 months (N=19)	12 months (N=13)	
VRR (%)	61.50 ± 22.59	81.64 ± 18.19	81.82 ± 24.68	0.006
Therapeutic success rate (n,%)	21/36 (75.0)	18/19 (94.7)	11/13 (84.6)	0.002

According to the multiple linear regression analysis, no significant correlations were observed between the volume reduction ratio (VRR) at one and six months after ablation and any of the evaluated clinical or ultrasonographic parameters, including demographic data, thyroid function indicators, procedural details, and specific nodule features

IV. DISCUSSION

In recent years, RFA has emerged as a minimally invasive alternative for the management of various benign thyroid pathologies, encompassing solid and cystic non-functioning benign nodules, as well as autonomously functioning thyroid nodules. Furthermore, its application has been explored in the treatment of low-risk papillary thyroid carcinoma and recurrent thyroid cancers [16-23].

Our prospective study conducted from June 2023 to April 2025 evaluated the efficacy and safety of single-session RFA for treating benign PCTNs. Our findings indicate that RFA is a safe and effective minimally invasive treatment, achieving significant volume reduction rates (VRRs) without major complications or impact on thyroid function.

The outcomes of our study align with existing literature on the application of RFA for benign

thyroid nodules. Notably, a randomized controlled trial conducted by Ha et al. (2015) comparing RFA and ethanol ablation (EA) in the treatment of PCTNs reported no statistically significant difference in volume reduction rate (VRR) at 6 months (RFA: 87.5% ± 11.5% vs. EA: 82.4% ± 28.6%, p = 0.710). However, our investigation revealed a higher VRR for RFA at 1 month (61.5%) compared to historical data on EA (53.09%), suggesting a potential for more rapid volume reduction with RFA, particularly in purely cystic nodules. This early advantage may be attributed to the capacity of RFA to target vascular structures and more effectively ablate solid components, a process facilitated by the moving-shot technique and Doppler ultrasonography employed in our study [24].

Recurrence poses a notable challenge following ethanol ablation (EA). Specifically, Sung et al. (2015) documented a recurrence rate of 38.3% after EA for predominantly cystic thyroid nodules (PCTNs), identifying an initial nodule volume exceeding 20 mL and high vascularity (grade > 1) as independent prognostic factors for recurrence. In contrast, our study observed no instances of recurrence within the 12-month follow-up period; however, extended longitudinal data are warranted to corroborate this finding. The absence of recurrence in our cohort may be attributable to the targeted ablation of vascular structures facilitated by Doppler ultrasonography and the moving-shot technique, which potentially enhances the precision and long-term efficacy of RFA [25].

Lee et al. (2010) suggested radiofrequency ablation (RFA) as a complementary therapeutic modality for thyroid nodules exhibiting incomplete resolution following ethanol ablation (EA), particularly those retaining residual solid components.This observation holds specific relevance for predominantly cystic thyroid nodules (PCTNs), where solid portions may persist post-EA, potentially contributing to recurrence. The favorable outcomes achieved in our study with PCTNs,despite demonstrating lower volume reduction rates (VRRs) compared to purely cystic nodules, lend support to the utility of RFA in the management of these more complex nodular entities (2010) [26].

While RFA demonstrates high efficacy in purely cystic nodules through complete fluid removal and wall ablation, the treatment of predominantly cystic thyroid nodules (PCTNs) presents greater challenges due to the presence of solid components. This may account for the lower volume reduction rates (VRRs) observed in PCTNs compared to purely cystic nodules, necessitating a more meticulous ablation technique. The utilization of the moving-shot technique and Doppler ultrasound plays a crucial role in optimizing RFA efficacy in PCTNs by targeting vascularity, thereby minimizing the risk of recurrence

In comparison to ethanol ablation (EA), the capacity of radiofrequency ablation (RFA) to ablate both cystic and solid constituents renders it a more versatile therapeutic modality, particularly for thyroid nodules exhibiting a higher proportion of solid tissue or those with an elevated risk of recurrence. Nevertheless, the procedural simplicity and lower economic burden associated with EA make it a more readily accessible option in settings with limited resources. Consequently, the selection between RFA and EA should be guided by a comprehensive evaluation of nodule characteristics, patient preferences, and economic considerations.

Clinical implications: RFA offers a safe and effective minimally invasive alternative to surgery for patients with benign PCTNs, particularly those who refuse surgery or have contraindications. The high VRRs and absence of major complications make RFA an attractive option for PCTNs.

Several limitations should be acknowledged in interpreting the findings of this study. Firstly, the 12-month follow-up period, while appropriate for assessing short-term therapeutic efficacy, may be insufficient for capturing long-term outcomes such as recurrence rates and durability of treatment effects. Secondly, the relatively small sample size of 28 patients restricts the broader applicability of the results, potentially limiting the statistical power to detect smaller effect sizes. Thirdly, the study design includes certain retrospective elements, introducing the potential for selection bias, which may affect the validity of the observed outcomes. Additionally, the absence of complete medical records for some patients resulted in missing data on vascularity,

cosmetic outcomes, and symptom improvement, thereby preventing a more comprehensive evaluation of treatment efficacy beyond volumetric reduction rates (VRR). Lastly, the lack of a parallel control group receiving ethanol ablation (EA) within the same study cohort constrains the ability to draw definitive conclusions regarding the comparative effectiveness of RFA.

V. CONCLUSION

In conclusion, single-session RFA is a safe and effective treatment for benign PCTNs. Further research is needed to refine treatment algorithms and enhance patient outcomes in the management of benign PCTNs.

Declarations

Ethics approval and consent to participate: Written informed consent form was given to patients. This report is a part of PhD thesis.

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