RESEARCH ARTICLE

Clinical efficacy and influencing factors of ultrasound-guided microwave ablation for benign thyroid nodules

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Benign thyroid nodules are frequently detected in the population. Although traditional surgical removal is a commonly used treatment method, it has limitations such as leaving scars in the neck, potentially damaging the recurrent laryngeal nerve, and affecting thyroid function. Exploring more minimally invasive, safe, and aesthetically pleasing treatment options holds significant clinical significance. This research analyzed the safety and efficacy of ultrasound-guided microwave ablation in treating benign thyroid nodules and explored the influencing factors of its surgical effect. Patients who underwent ultrasound-guided microwave ablation of benign thyroid nodules in Changsha Central Hospital from February 2019 to April 2020 were selected with a total of 152 patients and 196 nodules. After the evaluation of no signs of malignancy, the nodules were identified as benign, and then microwave ablation was performed. Preoperative thyroid hormone levels were routinely checked, and postoperative follow-up was performed at 1, 3, 6, and 12 months to measure nodule size and assess complications, while scoring aesthetics and pain. The results showed that there were no statistically significant changes in thyroid function before and after microwave ablation. The mean volume of nodules before surgery was 2.14 ± 2.43 cm^3, while it was 0.64 ± 0.90 cm^3 one year after surgery (P < 0.05). No serious complications occurred. Compared with simultaneous resection, microwave ablation was superior in terms of incisional aesthetics and pain scores (P < 0.05). The results indicated that ultrasound-guided microwave ablation of benign thyroid nodules was effective and safe with fewer and mild complications and a greater reduction in nodule volume per unit of ablation energy.

Keywords: microwave ablation; ultrasound; thyroid; benign nodules.

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Introduction

Thyroid nodules are scattered lesions formed by abnormal proliferation of thyroid cells. Their occurrence is related to various factors such as genetics, iodine deficiency, and immune dysfunction. Epidemiological surveys show that the detection rate of thyroid nodules in the population is as high as 20% to 67%, and they are more common in people over 40 years old. Approximately 80% of them are benign nodules [1, 2].

In recent years, with the popularization of ultrasound technology and the improvement of health awareness, the detection rate of thyroid nodules has significantly increased, and their clinical management has received increasing attention. Currently, in addition to regular follow-up observation, surgical resection is the traditional main treatment method for benign thyroid nodules. However, surgery may leave a scar on the neck and carries the risk of damaging the recurrent laryngeal nerve, superior laryngeal nerve, and parathyroid glands. It may also affect thyroid function [3, 4]. Ultrasound-guided thermal ablation techniques including laser, radiofrequency, and microwave ablation have rapidly developed due to their advantages such as small trauma, quick recovery, and no scars. Microwave ablation shows unique value in treating thyroid nodules due to its fast-heating speed, controllable ablation range, and low susceptibility to the "thermal sink effect" of blood flow [5, 6]. Although preliminary studies have confirmed the effectiveness of microwave ablation, its clinical application still faces some challenges that need to be standardized and deepened such as precise indication grasping, standardized operation procedures, systematic management of complications, and long-term efficacy evaluation.

This study systematically explored the safety and short-term efficacy of ultrasound-guided microwave ablation for benign thyroid nodules and analyzed the factors affecting its ablation effect. This study employed a prospective cohort design, enrolling 152 patients with benign thyroid nodules who underwent ultrasound-guided microwave ablation at Changsha Central Hospital, Changsha, Hunan, China between February 2019 and April 2020, involving a total of 196 nodules. After preoperative assessment without malignant signs, microwave ablation was performed, and follow-up measurements of nodule size, thyroid function, complications, and cosmetic pain score were conducted at 1, 3, 6, and 12 months after surgery. The results of this study provided a more solid theoretical and practical basis for the standardized treatment of benign thyroid nodules with ultrasound-guided microwave ablation technology, thereby promoting the rational optimization and promotion of this minimally invasive technique in clinical practice.

Materials and methods

General information on recruited patients

Patients diagnosed with benign thyroid nodules in Changsha Central Hospital (Changsha, Hunan, China) between February 2019 and April 2020, who also required microwave ablation (MWA) treatment with the aid of ultrasound guidance, were selected for this study. The inclusion criteria included that patients were diagnosed as benign thyroid nodules by ultrasound guided fine needle aspiration (US-FNA) prior to surgery, voluntarily refused surgical treatment, agreed about the treatment modalities of MWA, had no coagulation disorders, normal thyroid function prior to surgery, neck pain, discomfort or aesthetic disruption caused by high magnification. The exclusion criteria were that patients had more severe coagulation disorders, abnormal vocal cord function opposite the lesion, microwave ablation but not hydroalcoholic ablation, severe respiratory disease, confirmed malignancy, pregnancy and lactation. A total of 152 patients including 95 females (62.5%) and 57 males (37.5%), aged from 20 to 72 years old with an average of 49.43 ± 15.78 years old, were involved in this study. A total of 196 benign thyroid nodules were ablated including 40 in the left lobe, 47 in the right lobe, and 65 in both lobes. The ablation time ranged from 1.7 to 32.3 minutes with the average ablation time of 9.3 ± 7.5 minutes. All study procedures were approved by the Ethics Committee of Hunan Vocational College of Foreign Languages (Changsha, Hunan, China).

Treatment process

1. Pre-operative preparation

The puncture point was determined under ultrasound guidance by using either the GE LOGIQ E9 color doppler ultrasound diagnostic instrument (GE Medical Systems, Milwaukee, WI, USA) or the Siemens ACUSON S2000 color doppler ultrasound diagnostic instrument (Siemens Medical, Erlangen, Bavaria, Germany). According to the location of the nodule, the fluid isolation method was implemented. Briefly, when the nodule was close to the anterior side of

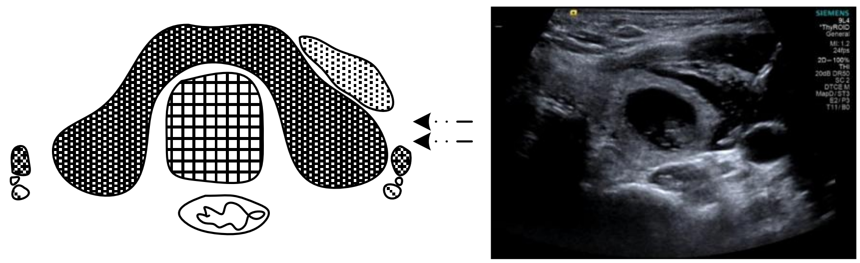

Figure 1. Injecting spacer outside thyroid capsule with puncture needle to protect surrounding tissues.

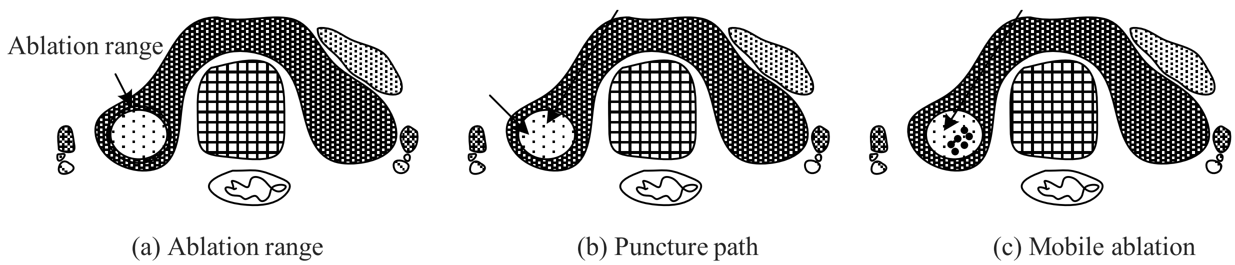

Figure 2. Schematic diagram of ablation range, puncture path and mobile ablation method.

the thyroid gland, a 0.5% lidocaine saline solution mixture was injected between the anterior cervical muscle group and the anterior capsule of the thyroid gland. When the nodule was on the dorsal side, it was injected between the trachea and the dorsal side of the thyroid gland. When the nodule was lateral, it was injected between the internal jugular vein, the common carotid artery, and the thyroid gland. The width of the isolation band was maintained at 3 - 5 mm to protect the surrounding important tissues (Figure 1).

2. Anesthesia and surgery

Local anesthesia was performed using 1% lidocaine. The mobile ablation technique was employed using a water-cooled tumor treatment instrument (Nanjing Yigao Medical Technology Co., Ltd., Nanjing, Jiangsu, China) with an output power ranging from 0 to 150 W, a frequency of 2,450 MHz ± 20 MHz, and the error of within ± 30%. The disposable ECO-100A cold-circulation microwave ablation needle (Nanjing Yigao Medical Technology Co., Ltd., Nanjing, Jiangsu, China) with the frequency of 2,450 MHz, power of 25 – 40 W was inserted into the farthest end of the nodule. The ablation was carried out layer by layer in an "from the lower pole to the upper pole, from the dorsal side to the ventral side" sequence, dynamically adjusting the needle path to ensure complete coverage (Figure 2). For cystic or cystic-solid nodules with a diameter > 2 cm, the cyst fluid was first drained, and then the cyst cavity was repeatedly rinsed with 0.9% sodium chloride solution before ablation. After the electronic ablation was completed, the blood supply to the ablation site and the extent of ablation were determined by ultrasound. The location and extent of ablation was also identified by ultrasonography. If a blood flow signal was found or not all ablations had taken place, another ablation was required. When contrast filling was not present, the procedure could be finally concluded.

3. Post-operative observation

After the ablation procedure, an ultrasound contrast imaging examination was conducted by using the injection type sulfur hexafluoride microbubbles (Bologna Company, Milan, Lombardy, Italy). If the ablation area was not filled with contrast agent, it was determined to be completely ablated. If there was residual blood supply, additional ablation would be performed until completion. If the nodule did not quickly absorb during the follow-up period after surgery, a coarse needle biopsy would be performed again in the ablation area.

Data collection

Patients' basic pre-surgery profile including thyroid hormone levels of FT3, FT4, TSH, gender, age, color doppler ultrasound of the thyroid as well as 2D ultrasound were collected to assess nodule grade. Postoperative follow-up was 12 months. The nodule size grouped by < 20 mm, 20 - 40 mm, > 40 mm and complications were assessed by the surgeon at 1, 3, 6, and 12 months, while patients' thyroid function was also checked at 1 year post operation. The effectiveness and safety of microwave ablation therapy was assessed, and factors that might have an impact on the postoperative outcome were analyzed. Thyroid function was checked by blood sampling before and 1 year after surgery. After surgery, the vertical orthogonal diameter and maximum diameter of the nodules were measured using ultrasound, while the nodule reduction rate and nodule volume rate were compared. Patients were observed for short-term and long-term complications after surgery. The nodule volume was calculated as follows.

$$V = \pi \times a \times b \times h / 6 \quad (1)$$

where *a* was the maximum transverse longitudinal diameter. *b* was the vertical diameter of the longitudinal diameter. *h* was the maximum transverse high diameter. *V* was the nodal volume. The nodule volume reduction rate (VRR) was then calculated below.

$$\text{VRR} = \frac{\text{Preoperative volume - Postoperative volume}}{\text{preoperative volume}} \times 100\% \quad (2)$$

Determination of relevant indicators

The study defined the effects of ablation as poor (VRR < 25%), improvement (25% ≤ VRR < 50%), significant (VRR ≥ 50%), and cure (VRR = 100%). The cosmetic outcome was assessed according to whether the mass could be palpated in the anterior neck with no mass being palpated as grade 1, a mass being palpated without cosmetic problems as grade 2, cosmetic problems with nodal convexity only during swallowing as grade 3, and a mass visible to the naked eye as grade 4. Pain was scored using the visual analogue scale (VAS) with 0 for no pain, 1 - 3 for mild pain, 4 - 6 for moderate pain, and 7 - 10 for significant pain that seriously interfered with normal life. The blood flow signal was scored using color doppler ultrasound with no color signal in the nodule as 0, a small amount of speckled color signal as 1, a color signal < 25% as 2, a color signal of 25 - 50% as 3, and a color signal > 50% as 4.

Statistical analysis

SPSS 24.0 software (IBM, Armonk, NY, USA) was employed for statistical analysis of this study. Mean ± standard deviation was used to express the measurement data. Paired t-test was used to compare parameters. Factors affecting postoperative VRR were screened by using one-way ANOVA. Parameters related to pre- and post- MWA volume, ablation energy per unit volume, nodal cystic composition, and blood flow grade were tested by one-way non-parametric tests for their effect on postoperative VRR. Spearman rank correlation analysis was used to evaluate the correlations between the postoperative volume reduction rate and power level, age, ablation time, blood flow grade, initial volume size, cystic-solidity grade, and unit volume ablation energy. *P* values less than 0.05 were defined as statistically significant.

Results

General post operation conditions

All patients tolerated the ultrasound-guided microwave ablation surgery well. No hematoma or severe complications such as Horner's syndrome, tracheal injury or esophageal perforation occurred. Some minor complications occurred after operation including voice changes in 4 cases, hoarseness in 3 cases, pain in 7 cases, swelling in 2 cases, skin burns in 1 case, and hypothyroidism in 2 cases. The pain radiated to the shoulders, ears, and teeth, and resolved

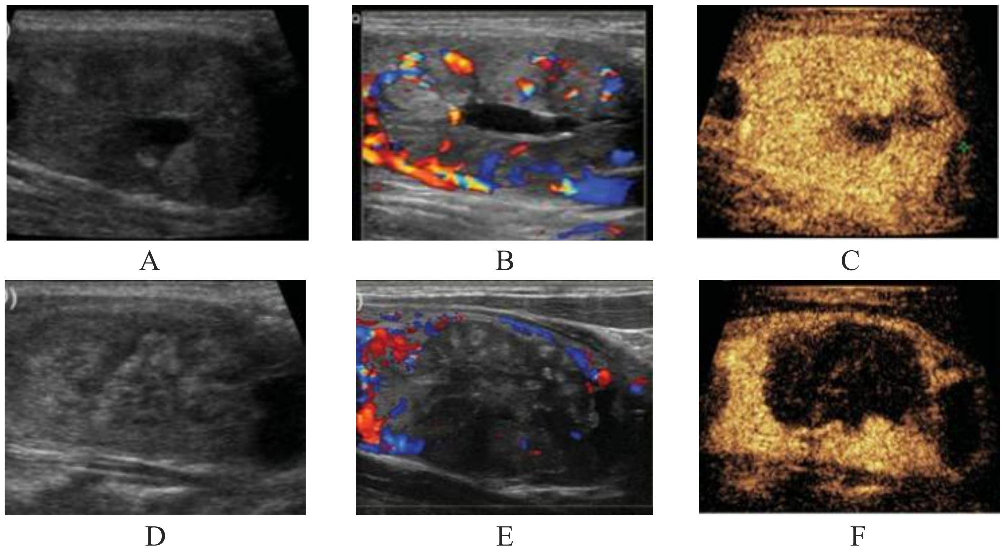

Figure 3. Results of ultrasound, color Doppler and contrast-enhanced ultrasound.

spontaneously within two days.

Ultrasound, color doppler and ultrasonographic performance

The ultrasound findings showed that pre-ablation images demonstrated a well-defined, regularly shaped nodule with uniform echogenicity and no lobulation or calcification, exhibiting moderate blood flow (20 - 55%) and strong contrast enhancement (Figure 3A-3C). Post-procedure images showed the ablation zone covered by a homogeneous hyperechoic area with no blood flow signal at all (Figure 3D-3F).

Thyroid function

The thyroid function tests of 152 patients before the operation and 1 year after microwave ablation remained within the normal range. Specifically, the FT3 level before the operation was 5.12 ± 0.62 pmol/L (normal range: 3.28 - 6.47 pmol/L), while 1 year after the operation, it was 5.24 ± 0.67 pmol/L. The FT4 level before the operation was 10.59 ± 1.28 pmol/L (normal range: 7.64 - 16.03 pmol/L), and 1 year after the operation, it was 10.88 ± 1.25 pmol/L. The TSH level before the operation was 1.28 ± 0.69 mmIU/L (normal range: 0.49 - 4.91 mmIU/L), and 1 year after the operation, it was 1.48 ± 0.53 mmIU/L. There were no statistically significant changes in these hormone levels before and after the operation ($P > 0.05$).

Change in total nodule volume

The nodule volume changes following microwave ablation demonstrated that the mean pretreatment volume was 2.14 ± 2.43 cm^3. At all follow-up time points of 1, 3, 6, and 12 months after the surgery, a significant reduction in volume was observed, which decreased to 1.19 ± 1.28, 0.90 ± 1.37, 0.69 ± 1.15, and 0.54 ± 0.88 cm^3, respectively ($P < 0.05$). The corresponding volume reduction rates were 42.26 ± 20.59%, 53.41 ± 19.85%, 75.66 ± 28.03%, and 69.11 ± 31.58%, respectively. The mean volume decreased for all nodule types including cystic, mixed, and solid during follow-up showed that cystic nodules demonstrated the most pronounced early volume reduction with a significantly higher reduction rate than solid and mixed nodules at the 1st and 3rd months of follow-ups ($P < 0.05$). Mixed nodules showed significant volume reduction at 1 month, while solid nodules exhibited a significant decrease by the 1-year follow-up ($P < 0.05$). The volume reduction rates among the three nodule types were not significantly different at the 6- and 12-month time points ($P > 0.05$) (Figure 4).

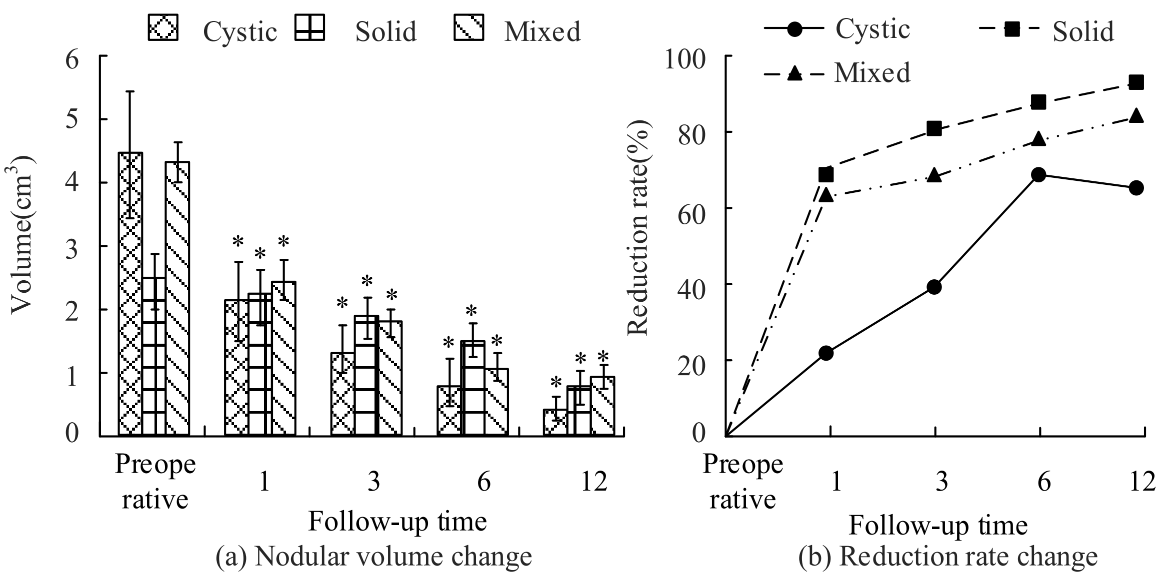

Figure 4. The change of average nodule volume of different types of nodules at each stage of preoperative and follow-up. *: a significant difference from preoperative nodules.

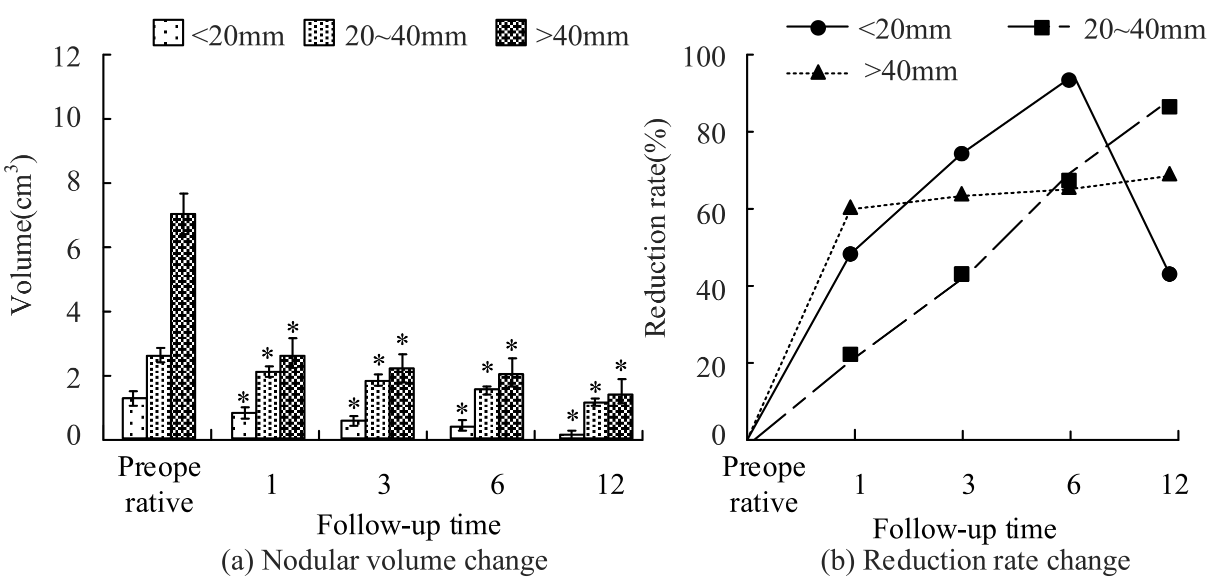

Figure 5. The changes of nodule volume of different initial diameters at various follow-up stages. *: a significant difference from preoperative nodules.

Comparison of results of changes in nodule volumes of different diameters

All nodule size groups demonstrated significant volume reduction by the 1-year follow-up. Nodules < 20 mm showed the most significant volume decrease at 6 months ($P < 0.05$). At the 1 month follow-up, nodules of 20 - 40 mm exhibited a statistically greater reduction than that of the other groups ($P < 0.05$). While all groups showed significant volume loss at 1 month ($P < 0.05$), the reduction rates were not significantly different between groups at the 3rd and 12th month time points. Nodules > 40 mm also demonstrated significant early reduction at 1 month with a gradual decrease in speed over the course of a year (Figure 5).

Table 1. Correlation analysis of postoperative VRR and different factors.

	1 month	3 months	6 months	12 months
Power level	0.798	0.569	0.392	0.598
Age	0.036	0.215	0.346	0.493
Ablation time	0.268	0.231	0.208	0.287
Blood flow grade	0.004	0.003	0.002	0.005
Volume size	0.000	0.002	0.005	0.019
Cystic and solid grade	0.002	0.001	0.003	0.007
Ablation energy per unit volume	0.000	0.002	0.003	0.021

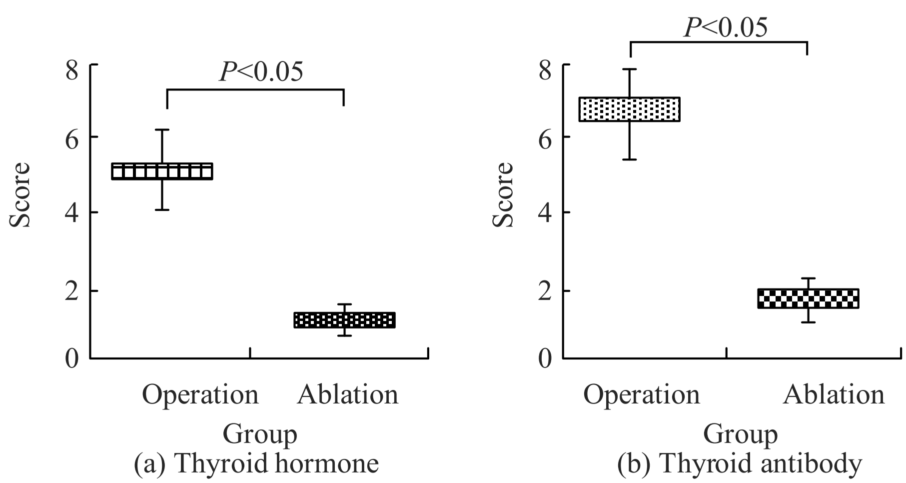

Figure 6. Comparison of incision aesthetic score and VAS pain score between patients in operation group and patients in ablation group.

Correlation of VRR with different influencing factors

The correlation analysis between postoperative VSR and different factors showed that 1 month after surgery, the patient's nodal blood flow profile, nodal cystic solidity grade, ablation energy per unit volume, and initial nodal size were all significantly correlated with VSR ($P < 0.05$) (Table 1).

Subjective efficacy evaluation

The subjective outcome evaluation of all patients after the procedure mainly included the aesthetic incision and pain scores recorded after the procedure. The results showed that there were significant differences in the aesthetic incision scores and VAS pain scores between patients in the surgical group and those in the ablation group ($P < 0.05$) (Figure 6).

Discussion

With the spread of health education among the population, ultrasound is widely used in most hospitals, detecting about 67% of thyroid nodules and diagnosing 90 - 95% of these as benign [7-9]. The current screening for thyroid nodules shows a significant gender difference with a higher prevalence in women than men. Several researchers have found that surgery is not recommended for asymptomatic benign thyroid nodules, and that regular follow-up is sufficient to achieve effective disease control [10-12]. However, most patients experience varying degrees of worry and anxiety about their thyroid nodules, resulting in a high psychological need for nodule treatment and driving clinical exploration of treatment options. When treating thyroid nodules, permanent surgical scars are difficult to avoid and greatly affect the aesthetics of the neck. It may also damage tissues such as the superior and recurrent laryngeal nerves, as well as recurrence after surgery [13-15]. These complications can have a serious psychological impact on the patient's condition. Therefore, patients with benign thyroid nodules are interested in minimally invasive treatment options, and most patients are more willing to accept this treatment. Previous studies have investigated different treatment options for benign thyroid nodules such as lasers, radiofrequency, and microwave ablation, demonstrating the effective results of ultrasound-guided microwave ablation [16-18]. This study explored microwave ablation of benign thyroid nodules under ultrasound guidance to analyze its clinical efficacy and safety, and to explore the factors that affected surgical outcomes. The nodules of this study showed varying degrees of reduction in size as the follow-up time progressed. At 1 month post-operative follow-up, the mean nodule volume decreased significantly from the preoperative volume, while at the one year post-operative follow-up stage, the mean volume of the nodules reduced even more significantly, confirming treatment effect. The benign thyroid nodules were divided into three groups according to their different diameters and microwave ablation was performed separately. The results showed that the most significant reduction in size occurred in nodules less than 20 mm at 6 months post-operatively and in nodules between 20 mm and 40 mm at 1 month post-operatively compared to that in the other two groups. Nodules larger than 40 mm in diameter decreased significantly in size at this time and remained stable. The nodules < 20 mm in the first 6 months had a significant reduction in size, which was because the blood supply around the thyroid gland was more abundant at this stage, and the necrotic tissue had the strongest absorption capacity at 6 months after surgery. The rate at which the nodule reached full resorption after microwave ablation was completely related to its nature, size, and surrounding blood supply. The diameter of the nodule was inversely correlated with the absorption rate. Solid nodules were absorbed more slowly than cystic nodules, and the size of the blood supply was positively correlated with the absorption rate [19-21]. The nodules > 40 mm were significantly smaller at the first follow-up in this study, probably because they were more mixed in nature and their volume decreased substantially after completing cystic fluid aspiration. The smaller size of cystic and solid nodules would shrink the most after microwave ablation, while the larger size of solid nodules would shrink relatively slowly, a phenomenon determined by their composition. Furthermore, the comprehensive assessment of thyroid function in this study revealed that, at the 1-year follow-up after ablation, the levels of FT4, FT3, and TSH in the patients were all normal, indicating that, although microwave ablation might cause certain damage to some normal thyroid tissues, it had no significant impact on overall thyroid function. During microwave ablation, most patients experienced mild fever or pain in the ablation area, which was usually resolved on its own. The ablation only stopped when the pain was unbearable. Postoperative pain scores and incision cosmetic scores were used to evaluate subjective efficacy. Patients in the microwave ablation group achieved both therapeutic effects and scar-free necks. Postoperatively, they used less pain medication and had significantly shorter hospital stays. Ultrasound-guided microwave ablation for benign thyroid nodules is an effective minimally invasive technique that can significantly reduce the size of nodules, has a low complication rate, causes less trauma, and improves symptoms and aesthetic appearance. The cystic and solid nature of thyroid nodules, blood flow conditions, the amount of energy required for ablation per unit volume, and the initial volume size are all closely related to the volume reduction rate. However, this study does not compare this technique with other thermal ablation techniques such as radiofrequency ablation, which requires further refinement and improvement in future research.

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