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RESEARCH ARTICLE

Retrospective Analysis of Thyroid Nodules after Microwave Ablation- A follow-up after Three and Six Months

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Abstract

The aim of this retrospective study was to evaluate the efficacy of single-treatment Microwave Ablation (MWA) in thyroid nodules.59 patients (36 women) with an average age of 59 years (age range: 33 - 84) with 68 cold, mainly solid or solid thyroid nodules were treated with cooled (16 nodules) or uncooled (52 nodules) microwave ablation. The pain was measured on a 10-point score during and after the treatment. Laboratory data was evaluated before, 24 h, three months and six months after MWA. Thyroid and nodule volumes were measured before, three months and six months after MWA. Blood flow, echogenity and elasticity of the nodules were measured before and after the treatment. Side effects either revealed by ultrasound or by patients' complaints were documented. A significant reduction of thyroid and nodule volume was observed in all cases. The reduction of the thyroid gland volume and the nodule volume after cooled MWA (cMWA) was slightly higher than after uncooled MWA (uMWA). The intensity of pain was higher in uMWA. Both uMWA and cMWA led to a significant decrease of nodule blood flow and echogenicity and to a significant increase of nodule elasticity (i.e. getting more solid). The thyroid function remained intact in all cases. No severe side-effects occurred except for a transient Horner's syndrome in one case. cMWA leads to a slightly higher but not significant reduction of the nodule and the thyroid volume than uMWA. Also, the patient's comfort during cMWA was higher than during uMWA. The risk of unintended side effects was less in cMWA. A single treatment provided sufficient results.

Introduction

With a prevalence of approximately 25%, goitres with growing nodules represent a wide spread medical condition discovered by palpation in 6% and by ultrasound in about 45% of the general population [1,2]. Surgery as common medical approach comes along with a vast number of perioperative complications such as injury of the recurrent laryngeal and vagus nerve, damage of the parathyroid glands, wound healing disorders, risk of infection, secondary haemorrhage, long hospitalization and anaesthetic risks. Therefore, an increasing number of non- and minimal invasive local ablative approaches have been attempted and have proven to be effective, controllable and safe for volume reduction in goitres and thyroid nodules in numerous international studies [3,4]. Ultrasound-guided (US-Guided) thermoablation provides such an effective and safe nonsurgical alternative treatment [5,6]. Monopolar and bipolar Radiofrequency Ablation (RFA) are well established methods for treating tumours in liver, osteoid osteomas and thyroid nodules [7,8]. RFA uses imaging guidance to place an electrode needle into the regarding tissue. High frequency electrical currents produced by a radio wave are passed through the electrode, creating heat that leads to coagulate necrosis [7,9]. High-Intensity Focused Ultrasound

(HIFU) offers a further safe, non-surgical, excellently tolerated, thermo-ablative alternative to treat nodular goitres effectively [2,10]. A large and growing number of studies describing the potential of Microwave Ablation (MWA) have been published in the recent years [11-14]. MWA is not only proven to be effective and predictable, but also advantageous when compared to other minimal invasive volume reducing techniques such as RFA or HIFU or combined with RIT. In MWA an electromagnetic field around the applicator antenna forces dipole ions to oscillate, through which tissue is heated to cytotoxic levels [11]. This procedure allows generating such high heat levels, that radiation through all biological tissues is possible. This may offer an advantage to other thermoablation methods [15]. This study is among the first to assess the efficacy of ultrasound-guided single-treatment cooled and uncooled MWA after a three and after a six months follow-up. In this study data were retrospectively analysed of cooled and uncooled single-treatment MWAs in 68thyroid nodules of 58 patients.

Patients, Material and Methods

Patients

Data of 200 patients in the time between 2012 and 2017 were analysed. From these, fifty-nine patients (thirty-six females) with an average age of 59 (age range: 33 - 84) and a total of sixty-eight thyroid nodules matching the entry criteria were included in this study. The mean thyroid volume was 77.87 ml (volume range: 11.4 ml - 206 ml).The mean nodule volume was 54.09 ml (volume range: 0.5 ml - 206 ml). All patients underwent a single-treatment either cooled (thirteen patients with sixteen nodules) or uncooled (forty-six patients with fifty-two nodules) microwave ablation. Inclusion criteria for this study were either: symptomatic, cold, mainly solid or solid, benign thyroid nodules that made treatment inevitable (e.g. local compression syndromes or foreign body sensation), high operative risks, cosmetic concerns or refusal of surgery. Exclusion criteria for this study were either: thyroids with retrosternal growth, hot cystic or mainly cystic nodules, histological evidence for follicular proliferation malignancy, and abnormal calciton in measurement as evidence for medullary thyroid cancer or critical positions near vessels, nerves, oesophagus or trachea. All patients were treated by the same physician. To conduct this study an according application was accepted by the ethical commission.

Pre-ablative assessment

All patients underwent assessments before the therapy (T0), 24h post-ablation assessment (T1), three months follow-ups (T3) and six months follow-ups (T6). These assessments included B-mode ultrasound along with laboratory tests.

Laboratory evaluation

For every patient a complete thyroid hormone status including triiodothyronine (T3), thyroxine (T4), thyrotropin (TSH) and thyroglobulin (Tg) was analysed. Besides that, antibody detection tests against thyroid peroxidase(TPO-Ab), thyroglobulin (Tg-Ab) and thyrotropin receptor (TR-Ab) were also performed. These testswere determined with commercially available Immunoradiometric Assay (IRMA) or Radioimmunoassay (RIA) kits and had the following reference ranges:

T3: 1.0-3.3 nmol/L	Tg: 2-70 ng/ml	TPO-Ab: <50 IU/ml
T4: 55-170 nmol/L	Tg-Ab: <50 IU/ml	TR-Ab:<1.5IU/L
TSH: 0.3-4.0 mE/L		

Ultrasound evaluation

B-mode ultrasound images were used in this study to evaluate the size, volume, composition, and vascularisation of the thyroid and the nodules. The used ultrasound device was the “SonixTOUCH Ultrasound system®” (Ultrasonix Medical Corporation, Richmond, Canada). Blood flow, elasticity and echogenicity were categorized in three respectively four categories: blood flow was divided in a three-point scale (no perfusion=1; slight perfusion=2; high perfusion=3). The echogenicity was also graded on a three-point scale (hypo-echogenic = 1; iso-echogenic = 2; hyperechogenic = 3). A colour-coded ultrasound elasticity output was used to measure elasticity graded on a four-point scale (soft=ES 1, more soft than solid=ES 2, more solid than soft=ES 3, solid=ES4) according to the score of Ueno et al. [33].

Safety and tolerance evaluation

During the procedure the patients pain level was measured on a 10-point score ranging from “no pain” =0 to “the most imaginable pain” =10. Patients’ complaints about generated side effects and side effects seen in the ultrasound were documented.

Microwave ablation equipment

The cooled microwave ablations were performed with the HS Amica microwave ablation system (Hospital Services SpA, Aprilia, Italy). This system was able to generate maximum powers up to 100 W at a frequency of 2450 MHz. A water-cooled applicator of 14-16 G could be used depending on the target area.

The uncooled microwave ablations were performed with the Avecure MWG 881 (MedWaves, Inc.San Diego, USA) consisting of a microwave generator, a flexible low-loss coaxial cable and an antenna. It was able to generate an output power from 24-28 W at a frequency of 902-928MHz. Depending on the target area and the volume of the nodule different probes (14-16 G; small, medium or large), could be used to achieve the target temperature of 60-80°C (max. 140°C)with an ablation field of 1-4 cm [9,10,16]. In the treatments analysed in this study 16 G probes were used.

To optimize ablation safety, efficiency, predictability and energy transfer the frequency was automatically controlled with real-time temperature and reverse-power feedback during ablation.

Procedure

To provide the best possible access to the thyroid, the patient was placed in a supine position with a hyperextended neck. First, the nodule was revaluated by B-mode ultrasound. After finding the nodule an injection site was determined and local anaesthesia (Mepivacain hydrochloride 1 %) and analgesics (Novalgin® i.v.) were applied. A small skin incision (1-2 mm) was conducted with a trans-isthmic access as it provides a good visualization of the probe and therefore prevents damage to vital structures e.g. as the recurrental laryngeal nerve, trachea or the oesophagus. After the small skin incision, the ablation antenna was under sonographic monitoring placed into an exact position. When energy was supplied intra-nodular ion movement around the dipole (mainly water molecules) lead to a temperature raise of the tissue to 60-110°C, resulting in an irreversible coagulation necrosis. This could be seen by an echo transformation of the nodule. Energy transfer was kept up until the entire nodule appeared hyper-echogenic and was coated with microbubbles showing the heat created during MWA. Throughout and after the ablation, the integrity of the laryngeal nerve was verified by talking to the patient to exclude possible phonation anomalies. The complete procedure was performed under sterile conditions.

Statistical analysis

Prism 6 for Mac OS X Version 6.0 f (GraphPad Software, La Jolla, California, USA) was used to perform statistical analysis. Wilcoxon matched-pairs signed rank tests were performed to compare the sonographic scores mentioned above, before and after treatment. Statistical significance was indicated with p-values < 0.05 ($p < 0.05$).

Results

Assessment of patients´ tolerance and safety

The mean pain score during the uncooled microwave ablation was five. The mean pain score during the cooled microwave ablation was two. None of the patients suffered severe superficial hematoma. All patients suffered light skin burns after the MWA. No severe side effects e.g. nerve injury, tissue necrosis, abscess, nodule rupture or voice changes occurred in our study except for a reversible Horner's syndrome in one case. All occurred side effects (i.e. skin burns, light hematoma, pain, transient Horner's syndrome) disappeared after a few weeks.

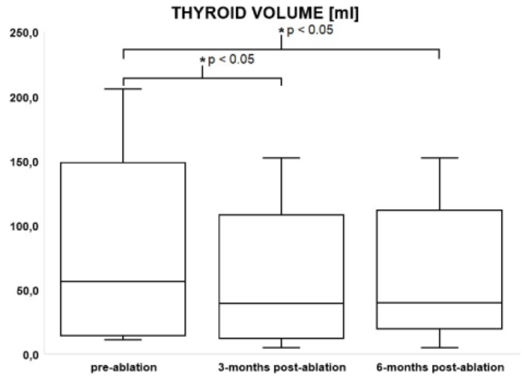

Figure 1: Comparison of thyroid volumes pre-ablation, 3- and 6-months post-ablation.

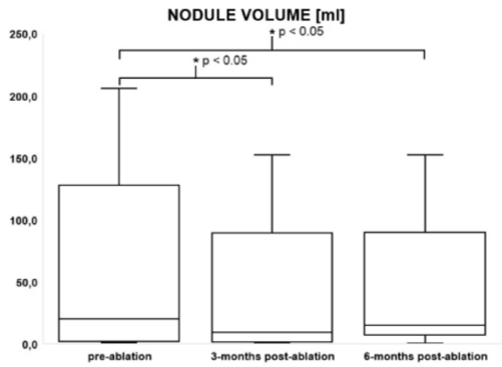

Figure 2: Comparison of nodule volumes pre-ablation, 3- and 6-months post-ablation.

Assessment of the efficacy

Microwave ablation resulted in significant ($p < 0.05$) decrease of thyroid gland and thyroid nodule volume after six months (T6) (Figure1 & Figure 2). Most of the patients did not follow the planned follow-up check-ups. This leads to the lack of patient data on one hand and to the assumption on the other hand that most of the absent patient did not have any complaints leading to not keeping the appointments of the follow-ups.

For those patients that did keep the appointments of the follow-ups (22 patients with uMWA and 5 patients with cMWA) the mean reduction of the thyroid gland volume was 24.92 ml (32.01%) after three months and 32.96 ml (42.32%) six months months post-ablation (Figure 1). The mean reduction of the thyroid volume of the patients with cMWA was 39.46 ml (37.68%) after three months and 46.52 ml (44.42%) after six months. The mean reduction of the thyroid volume of the patients with uMWA was 21.26 ml (30.12%) after three months and 29.87 ml (41.62%) after six months. The mean reduction of the nodule volume after MWA was

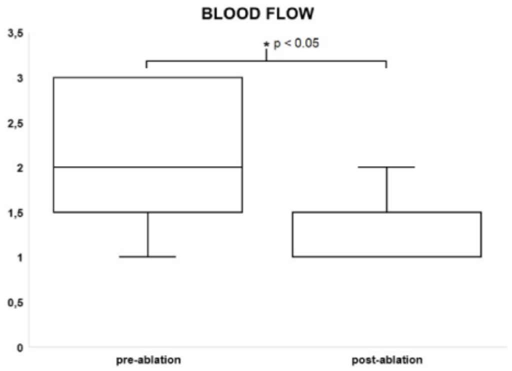

Figure 3: Comparison of nodule blood flow pre- and 24h post-ablation.

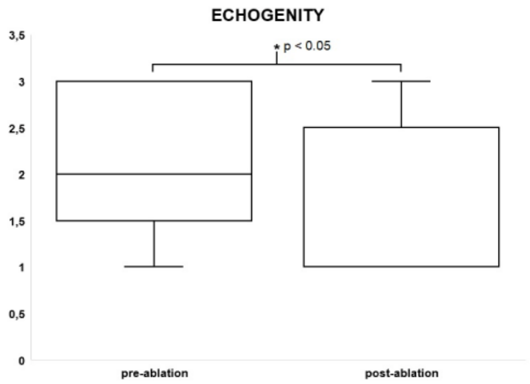

Figure 4: Comparison of nodule echogenity pre- and 24h post-ablation.

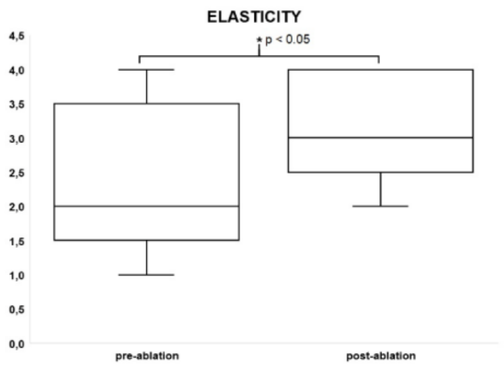

Figure 5: Comparison of nodule elasticity pre- and 24h post-ablation.

22.06 ml (40.78%) after three months and 25 ml (46.21%) after six months (Figure 2). The mean reduction of the nodule volume of the patients with cMWA was 33.91 ml (41.14%) after three months and 36.02 ml (43.73%) after six months. The mean reduction of the nodule volume of the patients with uMWA was 19.37 ml (40.64%) after three months and 22.49 ml (47.20%) after six months. MWA had a significant decrease in blood circulation ($p < 0.05$) (Figure 3) and echogenicity ($p < 0.05$) (Figure 4) and a significant increase in elasticity-score ($p < 0.05$) (Fig. 5) and Tg ($p < 0.05$). Tg-concentration three- and six-months post ablation showed no significant differences to baseline Tg concentration. No significant ($p > 0.05$) changes of TR-Ab level could be observed in the follow-up. No loss of thyroid function was noted.

Discussion

This study is among the first to assess the efficacy of ultrasound-guided single-treatment MWA. Our results underline the thesis that a single-treatment session is sufficient to achieve significant results of MWA treatment in thyroid nodules comparable to multiple treatment sessions. Further advantages of a single-treatment session compared to multiple treatment sessions and also to surgical approaches are the high cost effectiveness and the reduction of the risk of infection [14,29]. Expenses can also be saved when it comes to the post-treatment part. While patients are bound to the intake of thyroid medicine after a thyroidectomy e.g. thyroxine, patients generally do not need any thyroid medicine after MWA.

Multiple studies deal with volume reduction after thermal ablation of thyroid nodules. Largely, these studies offer results that are comparable to the outcome of this study: Feng et al. reported from a mean nodule volume reduction ratio of 46% after 12 months [12] while Yue et. al. observed a volume reduction ratio greater than 50% in 82% (209of 254) of measured nodules in a six months follow-up [14]. These results match the result of our study with a nodule volume reduction of 46%six months after the ablation. The MWA instrument used in their study has an internally cooled shaft antenna and a generator that can produce1-1,000 W of power at 2,450 MHz. Internally-cooled MWA allows higher power levels and thus larger ablation zones [17], which most likely explains Yue et. al.'s higher average volume reduction of 65% in their study by only cooled MWA compared to 46% in this study by both cooled and uncooled MWA together. A further reason for the differences concerning volume reduction might be the composition of the ablated nodules. The authors of the studies mentioned above classified the treated nodules into either solid, mainly solid, mainly cystic, or cystic nodules whereas all nodules treated in our study were defined as mainly solid or solid. Several studies have proven that cystic nodules show larger volume reduction than complex or solid ones. This can most likely be related to the extraction of the cystic component after draining the nodule during the ablation procedure [12,14]. In addition to these reasons one major reason for the outcome in this study and especially the outcome for cMWA is the high loss of patients in the follow-ups due to missing the appointments.

Table 1: Thyroid gland and nodule volume; pre and post-ablation.

	Before ablation		3 months after ablation		6 months after ablation	
	Thyroid gland volume [ml]	Nodule volume [ml]	Thyroid gland volume [ml]	Nodule volume [ml]	Thyroid gland volume [ml]	Nodule volume [ml]
All patients	77.87	54.09	52,95	32,03	44,91	29,09
Patients with cMWA	104.72	82.42	65,26	48,51	58,20	46,40
Patients with uMWA	71.77	47.65	50,15	28,28	41,90	25,16

Table 2: Reduction of the thyroid gland and nodule volumes.

	3 months after ablation		6 months after ablation	
	Thyroid gland volume reduction [%]	Nodule volume reduction [%]	Thyroid gland volume reduction [%]	Nodule volume reduction [%]
All patients	32,01	40,78	42,32	46,21
Patients with cMWA	37,68	41,14	44,42	43,70
Patients with uMWA	30,12	40,64	41,62	47,20

A significant ($p < 0.05$) difference between the thyroid nodule volume reduction of the 3-monthand 6-month follow-up can be observed. Yue et al. reported similar results [14]. However, the volume decrease between three months and six months post ablation is far smaller than the reduction measured between the initial nodular volume and the 3-month follow-up. Up to now, no study has focused on the issue that the highest decrease in nodule volume is detected in the first three months after treatment. Studies dealing on the temporal evolvement of nodule reduction could constitute enrichment to the treatment of thyroid nodules.

The generator used in the current study is only capable of producing 24-28 W at a frequency of928 MHz, which may be an additional reason for the smaller volume reduction achieved. Generally, the two frequencies that are used in clinical treatment are 2,45 GHz on one hand and 902-928 MHz on the other hand. Only a few studies have investigated the most advantageous frequency in a microwave ablation device. Sun et al. compared two systems: one working with 915 MHz and another one working with 2,45GHz. Both systems had a cooled-shaft antenna. The results of their study showed that a 915 MHz cooled-shaft antenna generates a significantly larger ablation zone than a 2,450 MHz cooled shaft antenna [18]. However, further studies will be necessary to sufficiently determine the best possible frequency of MWA.

Laboratory data of all patients was evaluated pre-therapy, 24h post-ablation, three-months follow up (T3) and six-months follow up (T6).The ablation procedure led to a significant increase of Tg-concentration ($p < 0.05$) 24h after treatment (ø 4.1 µg/ml) but decreased to its original level at T3 ($p > 0.05$). The fact that Tg-concentration changed drastically after MWA procedure is most likely referable to the destruction of nodule tissue. Valcavi et. al reported that significant changes of serum Thyreoglobulin after ablation procedure are induced by a high distribution of Tg due to thyroid injury. Still Thyreoglobulin is a nonspecific parameter as it reflects thyroid injury but simultaneously also the change of thyroid mass [4]. Yet, no significant ($p> 0.05$) difference could be detected between Tg concentration measured at T3 and T6.

No significant changes between the laboratory test of T3 and T6 were measured. This can also be observed in other studies [19]. As it can be seen in other studies our results support the thesis that thyroid gland function remains intact after MWA procedure [12,19]. To evaluate the treatment success after uncooled microwave ablation, nodule elasticity, echogenicity, and Doppler blood-flow were compared pre- and post-ablational via B-mode ultrasonography. Ultrasonography provides a fast and cost-effective method to diagnose and evaluate thyroid nodules [20]. Significant decrease of echogenicity ($p < 0.05$) and Doppler blood flow ($p < 0.05$) and significant increase of elasticity pointed out ablation success. Feng et. al also reported a significant decrease in nodule vascularization after MWA [12]. Unfortunately, the results of B-mode ultrasonography and colour-coded Doppler ultrasound are limited because artefacts can easily occur although ultrasound is an easily realizable method to measure nodular changes after MWA [23].

Despite its proven effectiveness and large number of advantages, MWA treatment has like any other local ablative approach also its own limitations and side effects. Feng et. al. reported nerve injury in their study, which could not be observed in the current study. All patients suffered light skin burns after ablation. This could most likely be referred to the heat transfer through the antenna shaft. Liang. et. al. reported from many skin-burns which occurred when non-cooled-shaft antenna was used. Only few cases of skin burns were encountered when cooled-shaft antenna was applied. Based on the results of Liang et. al. the high number of light skin burns observed in this study is most likely referable to the use of uncooled-shaft antenna [24]. The mean pain intensity of the patients treated with an uncooled antenna in the current study was five. Korkusuz et. al. reported a mean pain level of three (intensities reaching from 1-7) during radiofrequency ablation and similar to this study a mean pain level of two (intensities reaching from 1-10) during cooled microwave ablation [8,25]. The pain during treatment procedure is most likely to be traced back on the shaft heating. To prevent serious skin burns and pain comparatively low-power ablation cycles were utilized.

None of the patients in the current study suffered from severe hematoma, which most likely is due to the heat created on the antennas shaft. Through the increasing heat among the antenna's shaft during the ablation procedure, vessels around the antenna are destroyed leading to a lack of hematoma.

Most of the side effects in the current study were an outgrowth of ablation with an uncooled MWA system. When using uncooled-shaft antennas for MWA, an elevation of applied energy leads to a rapid increase of antenna temperature (up to 90°C), which results in unintended tissue coagulation. This leads to higher patient pain level and may lead to severe damages as voice changes and nerve palsy as reported in multiple studies [14,26,27]. A reduction of side effects and an increase in patients' comfort during ablation procedure could be and was achieved by using cooled-shaft antenna MWA [28,29].

Conclusion

Our results underline the efficacy of single-treatment MWA of benign thyroid nodules. It is an easily performed and cost-efficient treatment alternative with a low risk of severe side effects. The outcome of a single-treatment with cMWA is slightly better than the outcome of the uMWA treatment although not significant.

Still further studies need to be performed to improve safety, efficiency and increase experiences. The single-treatment session performed in the current study showed results comparable to studies evaluating success after multiple-treatment session treatments.

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