Microwave ablation as an efficient therapy for primary hyperparathyroidism: Efficacy and predictors of treatment success

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Abstract

Background:Microwave ablation has a great potential to treat primary hyperparathyroidism; but its predictors and the therapeutic efficiency are not clear enough and so the more investigations are required. Aim:The purpose of this study was to explore safety and predictors of the MWA efficacy in patients with primary hyperparathyroidism (PHPT) induced by parathyroid adenoma. Methods: Patients with PHPT treated with MWA were included in this study. Depending on the treatment efficacy, patients divided into two groups as response and no response group. Possible predictors as age, gender, Parathyroid adenoma volume, baseline levels of calcium (Ca), phosphorous (P), alkaline phosphate (ALP), vitamin D and location of parathyroid adenoma and the instrumental parameters which are microwave ablation time and power were compared between two groups. The resulting possible predictors the MWA efficacy exhibiting statistically significant difference was investigated by using logistic regression. Results: Thirty-two patients participated into predictor analysis for MWA efficacy. Comparison of the values of response and no response groups in terms possible predictors revealed only the baseline Ca level as the potential predictor of the efficacy of MWA ($P < 0.05$). Further logistic regression results showed the baseline Ca level as insignificant to construct a mathematical model to predict the efficacy of MWA ($P = 0.071$). Furthermore, a significant difference in time differences was observed after 1 day of the MWA treatments in the levels of Ca, P, and PHT except than ALP, those of which was 30 days later ($P < 0.001$). Later on, the difference stayed steady until the end of follow up. Conclusions:MWA is an effective and safe therapy for in patients with PHPT caused by parathyroid adenoma. Baseline Ca level has been found as potential but detailed investigations revealed none of the explored factors as predictive for the assessed patients. Keywords:Primary hyperparathyroidism, microwave ablation, predictor, efficacy

Microwave ablation as an efficient therapy for primary hyperparathyroidism: Efficacy and predictors of treatment success

Short title: Microwave ablation for primary hyperparathyroidism

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Abstract

Background: Microwave ablation has a great potential to treat primary hyperparathyroidism; but its predictors and the therapeutic efficiency are not clear enough and so the more investigations are required.

Aim: The purpose of this study was to explore safety and predictors of the MWA efficacy in patients with primary hyperparathyroidism (PHPT) induced by parathyroid adenoma.

Methods: Patients with PHPT treated with MWA were included in this study. Depending on the treatment efficacy, patients divided into two groups as response and no response group. Possible predictors as age, gender, Parathyroid adenoma volume, baseline levels of calcium (Ca), phosphorous (P), alkaline phosphate (ALP), vitamin D and location of parathyroid adenoma and the instrumental parameters which are microwave ablation time and power were compared between two groups. The resulting possible predictors the MWA efficacy exhibiting statistically significant difference was investigated by using logistic regression.

Results: Thirty-two patients participated into predictor analysis for MWA efficacy. Comparison of the values of response and no response groups in terms possible predictors revealed only the baseline Ca level as the potential predictor of the efficacy of MWA ($P<0.05$). Further logistic regression results showed the baseline Ca level as insignificant to construct a mathematical model to predict the efficacy of MWA ($P = 0.071$). Furthermore, a significant difference in time differences was observed after 1 day of the MWA

treatments in the levels of Ca, P, and PHT except than ALP, those of which was 30 days later (P <0.001). Later on, the difference stayed steady until the end of follow up.

Conclusions: MWA is an effective and safe therapy for in patients with PHPT caused by parathyroid adenoma. Baseline Ca level has been found as potential but detailed investigations revealed none of the explored factors as predictive for the assessed patients.

Keywords: Primary hyperparathyroidism, microwave ablation, predictor, efficacy.

What's already known about this topic?

Although MWA therapy has been applied in several studies for the treatment of benign thyroid nodules and mostly used in secondary hyperparathyroidism, a little attention; however, has been paid to the patients with primary hyperparathyroidism (PHPT). In this point, the purpose of this study was to explore safety and predictors of the MWA efficacy in patients with primary hyperparathyroidism (PHPT) induced by parathyroid adenoma.

What does this article add?

* Only the baseline Ca level was observed as the potential predictor of the efficacy of MWA (P <0.05).

* Ca level as insignificant to construct a mathematical model to predict the efficacy of MWA (P = 0.071).

* A significant difference in time differences was observed after 1 day of the MWA treatments in the levels of Ca, P, and PHT except than ALP, those of which was 30 days later (P <0.001). Later on, the difference stayed steady until the end of follow up.

* MW ablation was found safe and effective treatment method in the treatment of PHPT, and it can reduce Ca and PTH levels and nodule size when the treatment success considered.

Introduction

Over-activation of the parathyroid glands and excessive secretion of parathyroid hormone (PTH) can cause primary hyperparathyroidism (PHPT), which is characterized by hypercalcaemia with high or inappropriately normal PTH concentrations. PHPT might present high normal or even normal calcium (Ca) levels (normocalcemic hyperparathyroidism)[1]. Approximately 80% of patients with single benign parathyroid adenoma are considered to be the most common cause of PHPT, while 15-20% of PHPT has the multiglandular disease[2]. The majority of PHPT patients, nearly 70-80%, are asymptomatic and diagnosed in routine blood tests. On the other hand, symptomatic patients display osteoporosis or neuromuscular changes (weakness, cognitive changes, and fatigue), and nephrolithiasis[3]. According to the guidelines in the 4th International Workshop, the definitive treatment for PHPT is still the surgical method [4]. In recent years, thermal ablation methods involving laser, radiofrequency, and particularly microwave ablation (MWA) have been offering a good alternative for the treatment of patients with hyperparathyroidism, having surgical treatment risk or refusing the surgery. The main purpose of these techniques is thermal necrotizing of the parathyroid adenoma[5–7]. Compared to surgery, these procedures have some advantages such as being less invasive, repeatable, and having a fast recovery time [8]. Indeed, MWA is a commonly used thermal ablation method and exhibited promising clinical results. Previous studies have shown that the applicability of MWA is a safe and an effective in treating hyperparathyroidism [5,9,10]. The MWA procedure is mostly used in secondary hyperparathyroidism; however, a little attention has been paid to the patients with PHPT[11–15]. The present paper investigates the safety and efficacy of MWA in patients with PHPT caused by parathyroid adenoma.

2. Materials and Methods

2.1. Ethics statement

This study was approved by University of Health Sciences Antalya Training and Research Hospital Ethics Committee and written informed consent was obtained all patients before procedure

2.2. Study design and the patients

Thirty-two patients with PHPT from February 2017 to August 2020 who are eligible to study protocol were included. The adenoma of all patients enrolled in the study were thought to be benign. In case of malignancy findings, surgical resection was recommended instead of fine needle aspiration biopsy [16]. The inclusion criteria, based on the guidelines [4] were as follows: patients with symptomatic PHPT; patients with asymptomatic PHPT, whose serum Ca concentration is at least 0.25 mmol/L higher than the upper limit of normal range; who have skeletal involvement as a decrease in bone mineral density patients with renal involvement as creatinine clearance less than 60 ml/min, nephrolithiasis or nephrocalcinosis, patients who have hypercalciuria (>10 mmol per day) or patients younger than 50 years old. Preablation data of the study group was summarized in Table 1.

For the prediction assay, age, gender, parathyroid adenoma volume, microwave ablation time (sec) and power (Watt), baseline level of Ca, phosphorous (P), alkane phosphate (ALP) and PTH, vitamin D level, location of parathyroid adenoma were recorded. Afterwards, depending on the treatment efficacy, which has the criteria of treatment success if the six-month follow-up of PTH has lesser than 88.0 ng/L and Ca is at the normal range, patients divided into response and no response groups. Then, the predictive abilities of the potential factors were investigated by logistic regression to evaluate its role in the MWA efficacy.

2.3. Laboratory assessment

Ca, P, ALP, PTH, and Vitamin D levels were measured before the MWA procedure and 1 day, 1 month, and 6 months after MWA therapy. Ca, P and ALP were measured using AU5800 Series Chemistry Analyzers (Beckman Coulter Inc., Brea, CA, USA). PTH and vitamin D levels were measured with Dx1 800 DxI 800 Access Immunoassay System (Beckman Coulter Inc., Brea, CA, USA). The normal ranges were as follows: Ca, 2.2-2.65 mmol/L; P, 0.81-1.45 mmol/L, PTH, 12-88 ng/L; ALP, 30-120 u/L and vitamin D, 74.8-249.6 nmol/L. The volume and the location of parathyroid adenomas were localized by ultrasound and 99mTc sestamibi (MIBI). Parathyroid wash out was only performed when the lesion could not be clearly localized with these imaging methods.

2.4. Microwave ablation procedure

Three orthogonal diameters of the parathyroid adenoma were measured before ablation and follow-up with a real-time ultrasound system with a 5-14 MHz linear probe. The volume of the nodule was calculated automatically through the software program of the Aplio 500, Toshiba Medical Systems, Tokyo, Japan. Microwave ablation system (ECO-100AI3), consisting of a microwave generator producing 30-40 W of power at 2450 MHz either continuously or in a pulse; a flexible cable, and internally-cooled 16-gauge thyroid antenna with 10 cm shaft length with a 3 mm active tip was used. Parathyroid adenoma ablation was performed on an outpatient basis under local anesthesia without sedation. The patient was placed in a supine position with the neck mildly hyperextended. After determining the appropriate puncture side, a mixture of 30/70% lidocaine (Osel Pharmaceuticals, Istanbul, Turkey) and saline was applied along the puncture path from the skin to the thyroid capsule after then infused into the surrounding thyroid capsule to protect vital recurrent laryngeal nerves, esophagus and trachea adjacent to the parathyroid adenoma. Internally cooled thyroid microwave ablation antenna was positioned under ultrasound guidance via trans-isthmic approach or lateral cervical approach. A moving shot technique was used to ablate the parathyroid adenoma throughout the procedure.

Therapy was completed when the entire nodule was covered with hyperechoic microbubbles, which is used indicative of ablation. Heart rate and oxygen saturation were continuously monitored during the procedure. After the procedure, all patients were followed by cold compression to prevent neck hematoma. The patients who were informed about the symptoms of hypocalcemia were discharged after 4 hours of follow-up.

2.5. Statistical analysis

The analysis of data was conducted by SPSS® 20.0 (Statistical Packages for Social Sciences; SPSS Inc, Chicago, Illinois, USA). The normality of the data was assessed with Shapiro-Wilk test of normality (P >0.05). All the normally distributed continues variables were presented as mean ± standard deviations whereas the rest and the categorical variables were reports as median (interquartile ranges) and percentages. Due to the non-normal distribution in Ca, P, ALP and PTH values, Friedman and Wilcoxon' signed rank tests was used in their comparison with time difference. Mann-Whitney U test was used for the comparison of the values in two non-normal distributed groups. Fischer exact test was also used to compare categorical variables between response and no response groups. The significance level was based on a P value of less than 0.05.

Age, gender, Parathyroid adenoma volume, baseline levels of Ca, P, ALP, vitamin D, location of parathyroid adenoma, microwave ablation time and power were compared and identified as possible predictive factors between response and no response group. The no response group was considered as the control group. The differences between the control group and the response group were evaluated by using Mann-Whitney U and χ^2 test. The detailed further investigations of the possible factors were explored by using logistic regression.

3. Results

3.1. Possible predictors of the efficacy of MWA

Investigation of the possible predictors was conducted on 32 patients. The response group had 28 patients while no response groups had the 4 patients. Only statistically significant difference was observed at the baseline serum Ca levels of the two groups (P <0.05). No statistically significant any other differences were observed between the two groups for the rest of the other characteristics which are summarized in Table 2.

3.2. Investigation of the efficacy of predictors for MWA efficacy

Baseline levels of Ca were analyzed by using logistic regression in order to show the predictive role of it as MWA efficacy on PHPT patients. However, the results of univariate logistic regression analysis revealed no statistically significant difference, and a predictive model has not been constructed to show the predictive role of baseline Ca level on the response for the PHPT patients (P =0.071).

3.3. Treatment outcomes and effect

Figure 1 presents the results of the six-month follow up median values for Ca, ALP, P, and PTH values. Investigation of Figure 3 demonstrates that changes in the followed parameters were statistically significant compared to baseline (P <0.001) (Figure 1) in different times. An obvious statistically significant decrease was observed for the median values of Ca (2.9 mmol/L) and PTH (99.50 ng/L) while that of P (0.9 mmol/L) was decreased in 1 day after MWA therapy. On the other hand, no significant change was observed in ALP (82.00 u/L) at 1 day after MWA. A statically significant difference was obtained after one month later in the ALP levels (P <0.001). The detailed results were also summarized in Table 3.

3.4. Side effect of complications

Most patients experienced a slight tingling and pain sensation in the neck, but this was well tolerated without causing interruption or termination of the procedure. Six patients (18.75%) reported transit voice change, but this resolved without any specific treatment within one day. All in all, flexible fiberoptic laryngoscopy examination was normal. This transit complication was attributable to lidocaine which was used for hydrodissection. One case of cellulitis requiring drainage and antibiotics was developed. There were no major complications requiring hospitalization.

4. Discussion

This study shows that MWA is a successful treatment modality and provides a rapid improvement in Ca and PTH values in a short period of 24 h. Both PTH and Ca levels returned to normal range in 28 of 32 patients (87.5%) and remained normal for 6 months. A similar success rate was observed in the literature [5,10]. In the study of Fan et al. [10], PTH and Ca decreased to normal levels in 19 of 22 patients (86.3%) and remained within the normal range for 12 months after MWA. In the study of Liu C et al.[5] all the fifteen patients had good response to initial therapy. However, 2 patients relapsed (5 months and 32 months after the initial therapy) and they underwent second MWA sessions. The authors argued that MWA can reduce nodule size, decrease serum PTH, and Ca levels in a single session in most patients, and the second session can be applied when necessary. In our study the procedure was not repeated in unsuccessfully treated lesions.

In the study by Liu et al. [9], comparing surgery and MWA, the success ratio of MWA and surgery were found to be similar in the sixth month of treatment (82.1%, 89.3%, respectively). While PTH levels in the surgery group decreased much faster than the MWA group in the first 3 months of treatment, no significant difference was detected between the two groups in the sixth month after treatment. There was no significant difference in mean serum Ca and P levels between the MWA group and the surgery group during the 6 months after treatment. Although the authors drew attention to literature data showing the cure rates of over 95% in centers specializing in parathyroid surgery, they declared similar clinical efficacy with MWA and surgery in PHPT.

Although the efficacy of MWA in secondary hyperparathyroidism has been found to be related to baseline PTH level in a study[15], a reason that can be directly associated with treatment success in PHPT has not been clearly revealed. In our study, there was no difference in PTH values between the groups in terms of treatment success.

Patient with the largest lesion diameter (4.8 cm diameter) did not respond to MWA in the study of Liu et al. [9]. Fan et al. [10] observed that treatment efficacy was not significantly associated with lesion size, PTH and Ca levels, as in our study. We argue that the main reason for not responding to treatment may be related to the procedure technique. Probably some parathyroid tissues could not be completely removed by this technique depending on the experience of radiologist applying the process.

This treatment procedure was well tolerated as we did not observe major complications or need for hospitalization during MWA or follow-up period. Complication rate in the present study was low. According to Society of Interventional Radiology Clinical Practice Guidelines[17], no major complications were observed except than the minor one of a case of cellulitis requiring drainage and antibiotics. Therefore, the MWA procedure was observed as safe.

The limitations of the study are the small sample size and the short follow-up period. Longer follow-up is required to determine the long-term effectiveness of the treatment and whether there will be a recurrence.

In conclusion, MW ablation is a safe and effective treatment method in the treatment of PHPT, and it can reduce Ca and PTH levels and nodule size. Although surgery is still the gold standard, it is an alternative for patients for whom surgeries are risky or who refuse surgery.

Author Contribution

The study conception and design were contributed by all the authors. M.S.E, B.C, B.O.P and I.K.S performed the material preparation, data collection and analysis. MSE and I.K.S wrote the first draft of the manuscript and all authors commented on previous versions of the manuscript.

CONFLICT OF INTEREST

The authors declare that they have no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICAL APPROVAL

University of Health Sciences Antalya Training and Research Hospital Ethics Committee approved this study. All patients gave their written informed consent before procedure.

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Table 1. Demographic data of the study population and the instrumental working conditions for the microwave ablation.

Baseline characteristics	All patients (n = 32)
Age (years)	55.88 ± 6.29 (51-61)
Gender (F:M) %	(28:4) 88%
Parathyroid adenoma volume (cc)	0.96 (0.85-1.40)
Location of parathyroid adenoma	
Left interior	15 (46.9)
Right interior	17 (53.1)
Ca (mmol/L)	2.92 ± 0.12
P (mmol/L)	0.93 ± 0.16
ALP (u/L)	85.63 ± 20.74
PTH (ng/L)	99.5 (86.00-152.00)
Vitamin D (nmol/L)	65.52 ± 19.97
Ablation time (sec)	141.56 ± 23.98
Ablation power (Watt)	32.19 ± 4.20

Values are reported as mean ± SD, percentages, and median (IQR) for continuous, categorical and numerical variables, respectively. PTH, parathyroid hormone.

Table 2. Features of the patient population in terms of treatments success

Characteristics	Response (28)	No response (4)	P value
Age (years)	56.14 ± 6.40	54 ± 5.94	0.475
Gender			0.431
Female	25 (89.3%)	3 (75%)	
Male	3 (10.7%)	1 (25%)	
Parathyroid adenoma (pre volume)	1.18 ± 0.66	1.70 ± 1.08	0.346
Parathyroid adenoma (post volume)	0.39 ± 0.22	0.70 ± 0.60	0.492
Ablation power (Watt)	32.14 ± 4.18	32.50 ± 5.00	0.874
Ablation time (sec)	143.86 ± 24.56	125.50 ± 11.00	0.160
Baseline level of serum Ca (mmol/L)	2.91 ± 0.12	3.01 ± 0.05	0.042
Baseline level of serum P (mmol/L)	0.93 ± 0.87	0.96 ± 0.20	0.864
Baseline level of serum ALP (u/L)	87.21 ± 21.56	74.50 ± 8.70	0.210
Baseline level of serum PTH (ng/L)	122.19 ± 42.69	92.25 ± 11.32	0.266
Vitamin D level (nmol/L)	64.45 ± 20.12	73.01 ± 18.89	0.361
Location of parathyroid adenoma			0.319
Left inferior	12 (42.9%)	3 (75%)	
Right inferior	16 (57.1%)	1 (25%)	

Table 3. Changes in the followed parameters after MWA in time.

Period	**Ca (mmol/L)**	**P (mmol/L)**	**ALP (u/L)**	**PTH (ng/L)**
Baseline	2.94 (2.81-2.98)	0.87 (0.82-1.01)	82.00 (73.25-97.75)	99.50 (86.00-154.00)
1 day	2.28 (2.21-2.37)*	1.10 (0.94-1.22)*	78.00 (67.25-94.25)	34.00 (26.00-54.25)*
1 month	2.36 (2.26-2.51)*	1.20 (1.07-1.35)*	74.00 (59.00-85.00)*	48.50 (39.00-53.75)*
6 months	2.38 (2.28- 2.50)*	1.16 (1.00-1.31)*	69.50 (54.00-84.25)*	50.00 (46.00-58.00)*

Data are presented as median (IQR) for numeric variables. "*" indicates a statistically significant difference compared to baseline serum levels (*P <0.001).

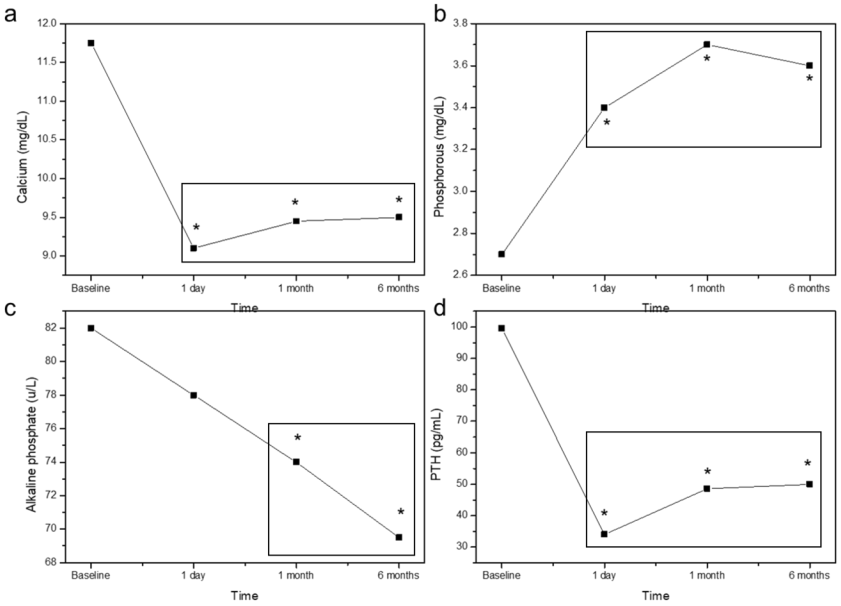

Figure 1. Changes in the followed parameters after MW ablation in the followed period of time. $^*P < 0.001$. Windows at the inset of the figures show where the difference in time stays continuously as statistically significant.