Parathyroidectomy Versus Thermal Ablation Of Parathyroid Glands In Patients With Hyperparathyroidism: Randomized Controlled Trial

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KEYWORDS
Hyperparathyroidism; Parathyroidectomy; Radiofrequency ablation; Outcomes.

ABSTRACT

Background: Parathyroidectomy is the main treatment option for patients with primary hyperparathyroidism (HPT), while it is the second choice in patients with the secondary type after failed medical treatment. Despite the efficacy of surgery, it could be risky in these patients secondary to the underlying comorbidities (like renal failure). Recently, microwave ablation (MWA) was reported to be a safe and effective minimally invasive option in such cases. However, the outcomes of surgery versus MWA are rarely discussed in the literature. That was the aim of the current study.

Methodology: Twenty patients diagnosed with either primary or secondary HPT were enrolled in our prospective randomized trial, and they were divided into two groups; Group A (open parathyroidectomy) and Group B (ultrasound-guided MWA).

Results: MWA led to a significant decline in procedure time compared to parathyroidectomy. However, it was associated with higher postoperative pain scores. Both groups showed a significant decrease in parathyroid hormone, calcium, and phosphorus levels, but the decline was more prominent in the surgical group. Parathyroidectomy was associated with a higher incidence of postoperative hypocalcemia, while recurrence was significantly higher in the MWA group. In the MWA group, all patients with secondary HPT had postoperative recurrence, whereas all patients with primary HPT had resolution of their state.

Conclusion: Both parathyroidectomy and MWA could yield excellent outcomes in patients with primary HPT. Nonetheless, parathyroidectomy is superior to MWA in patients with secondary HPT, as the latter is associated with a high recurrence rate.

Introduction

Hyperparathyroidism (HPT) is a pathological condition that describes excess secretion of the parathyroid hormone (PTH) [1]. It has four main types: primary (mainly due to parathyroid gland adenoma), secondary (parathyroid hyperplasia resulting from chronic kidney disease), tertiary (autonomously functioning parathyroid glands after treating the underlying kidney disease), and quaternary (adenoma following tertiary HPT) [2].

Generally, the primary and secondary types are the most frequent types encountered in clinical practice [3]. HPT, whatever its type, has many distressing manifestations, including urinary tract stones,

pathological bone fractures, psychiatric, gastrointestinal, and musculoskeletal manifestations [4].

Open parathyroidectomy is the gold standard against which all treatment is compared, with a cure rate over 100%. However, open surgery remains an invasive technique another issues the potential risk for perioperative morbidity in several patients specially the elderly [5, 6]. To overcome this problem continued effort are being tried to find less invasive modalities for treatment of hyperparathyroidism that is as effective as surgery with lower morbidity.

Surgical intervention (parathyroidectomy) is the main management option for patients diagnosed with primary HPT, while it is reserved for secondary patients who have shown refractory to medical treatment [4, 7]. Therefore, there is a global trend towards applying minimally invasive techniques (MITs) to improve perioperative outcomes [8, 9].

These MITs include either thermal or chemical ablation of the diseased parathyroid gland. Chemical ablation is performed via ethanol injection, whereas thermal ablation could be performed via microwave ablation (MWA), radiofrequency, laser, or high-intensity focused ultrasound [7, 8, 10].

Although many studies have shown promising outcomes and a safe profile of MWA in patients with HPT [9, 11, 12], there is a clear shortage of studies comparing the outcomes of MWA vesus parathyroidectomy in these patients. The study was conducted to compare parathyroidectomy to MWA in managing Egyptian patients diagnosed with either primary or secondary HPT.

Patients and methods

This prospective randomized study was conducted at the “Endocrine Surgery Unit” of Mansoura University, Egypt, in the period from December 2019 to December 2023.

Consecutive adults affected by primary or secondary hyperparathyroidism were enrolled in the study the diagnosis was based on the following clinical criteria patients between 10 and 60 years with elevated serum PTH. Patients with ESRD and SHPT refractory to medical therapy.

Exclusion criteria included the presence of ectopic parathyroid gland, previous parathyroidectomy or neck surgery, patient who received renal transplantation , patients with bone and mineral disease rather than ESKD , patients receiving corticosteroid therapy , failure of preoperative localization of parathyroid glands , presence of uncontrolled systemic comorbidities(ASA IV and V) [13].

The study protocol was approved by the “Institutional Review Board” of the same university (approval code: MD.24.04.847). All patients assigned written informed consent for participation in study. After explanation of the nature of disease and possible treatments. Patients were randomly assigned into the treatment groups either, open parathyroidectomy (group A) or MWA (group B). Randomization were performed by a nurse not involved in the study by sealed envolped method.

All patients subjected to preoperative preparation by careful history taking, clinical examination, investigation in the form of: Serum calcium (total and ionized) and phosphorus. Serum calcium was preformed using c311 automated device by ROCHE. Our reference range in Mansoura University biochemical laboratory was 8.5 to 10.2 mg/dl for total calcium and 1.15 to 1.35 mmol/L. The normal range of phosphorus 2.5 – 5 mg/dl.

Corrected serum calcium was calculated for patients with hypoalbuminemia as follows: corrected Ca value (mg/dL) = measured total calcium + 0.8 (4 − albumin) [14].

Serum parathyroid hormone level (reference range; 15 – 67 pg/dl). It was measured by chemiluminescence device c411 ROCHE.

Preoperative localization

All patients underwent preoperative high-frequency neck ultrasound. The parathyroid glands typically appear as small, oval, or bean-shaped iso- to hypoechoic structures located near the thyroid gland.

Sestamibi scintigraphy (technetium-99-sestamibi scanning): the adenomatous or hyperplastic glands appeared as hot spots in delayed imaging [15, 16]. In patients with false positive and negative results, neck CT and/or MRI was ordered.

Data were analyzed with the use of complied software package that automatically produced numeric reports and graphs.

The primary outcome measure was persistence or recurrence. The secondary outcome measures were procedure time, postoperative pain, procedure related complications (infection, hematoma, hypocalcemia, recurrent laryngeal nerve injury).

Patients reexamined with assay of PTH, Calcium, Phosphorus.

Unless stated otherwise, all data are expressed as mean± SD or as percentage. Descriptive inferential statiscal analysis were performed using both parametric and non-parametric procedure as appropriate. Comparison of categorical⁄ordinary variables were performed using chi- square analysis for traines. Criteria for statiscal significance was set at $P<0.05$.

During the study period, 20 patients met our inclusion criteria and accepted to participate in the study. The aim of the study, benefits, and possible adverse events of each intervention were explained to all patients. Their approval was documented in a written consent form that was signed by all participants prior to any intervention.

In group A (open parathyroidectomy), was performed under general anaesthesia. The surgical procedure was performed as described in literature [17, 18]. In patients with primary HPT, excision of the only diseased gland was done. In patients with secondary HPT, the four glands were excised, and half of the smallest one was implanted in the sternomastoid muscle (Figure 1). All specimens were sent to the histopathology laboratory for histological analysis.

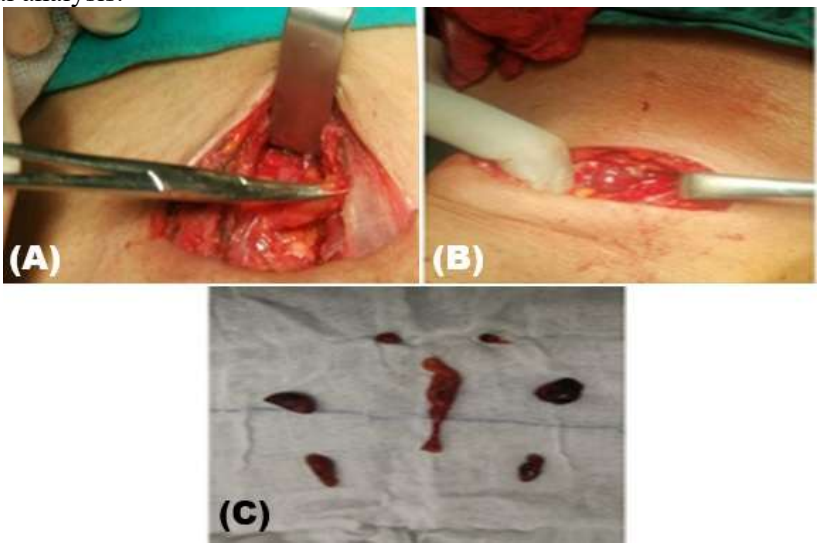

Figure (1): A case of parathyroid hyperplasia (secondary HPT) that underwent excision of the four parathyroid glands.

In group B, the MWA was performed by Prof. Elrakhawy using the KY2000 ablation system equipped with a two-mm antenna and a 0.5-mm tip (Nanjing Kangyou Research Institute, Nanjing, China). The MWA device was set at a frequency of 2450 MHz. Initially, a neck ultrasonography was done to determine the vascularity of the parathyroid gland and to choose the ablation pathway. Local anaesthesia (5 ml lidocaine 2% diluted in 15 ml normal saline 0.9%) was injected around the parathyroid nodule to protect the nearby blood vessels and nerves. Under ultrasound guidance, the MWA needle was inserted towards the parathyroid nodule. The device's power was set between 25 and 35 watts according to the nodule size. The ablation process continued until the whole nodule turned hyperechoic by ultrasound, and its blood flow signal disappeared by Doppler imaging (Figure 2).

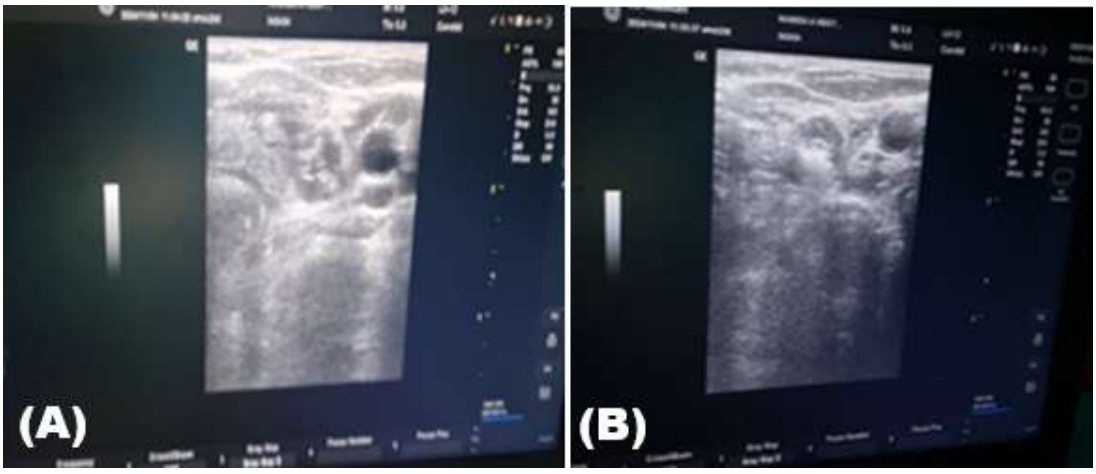

Figure (2): (A) Enlarged parathyroid gland before MWA, (B) The parathyroid gland after MWA.

In both groups, all patients were transferred to the surgical ward after the procedure. Serum PTH, calcium, and phosphorus were repeated on the first postoperative day. Pain was evaluated using the "visual analogue scale" (VAS) [19]/ 2 hrs, and the mean value of these readings was calculated and recorded. Any adverse events were recorded and managed. Most patients were discharged on the second day unless adverse events were encountered. The previous laboratory parameters were repeated after one week, then after one, six, and twelve months.

Results

The study flow chart is shown in (Figure 3), of 29 consecutive patients seen during study period were assessed for eligibility, and nine were excluded. The remaining 20 patients were finally enrolled in the study.

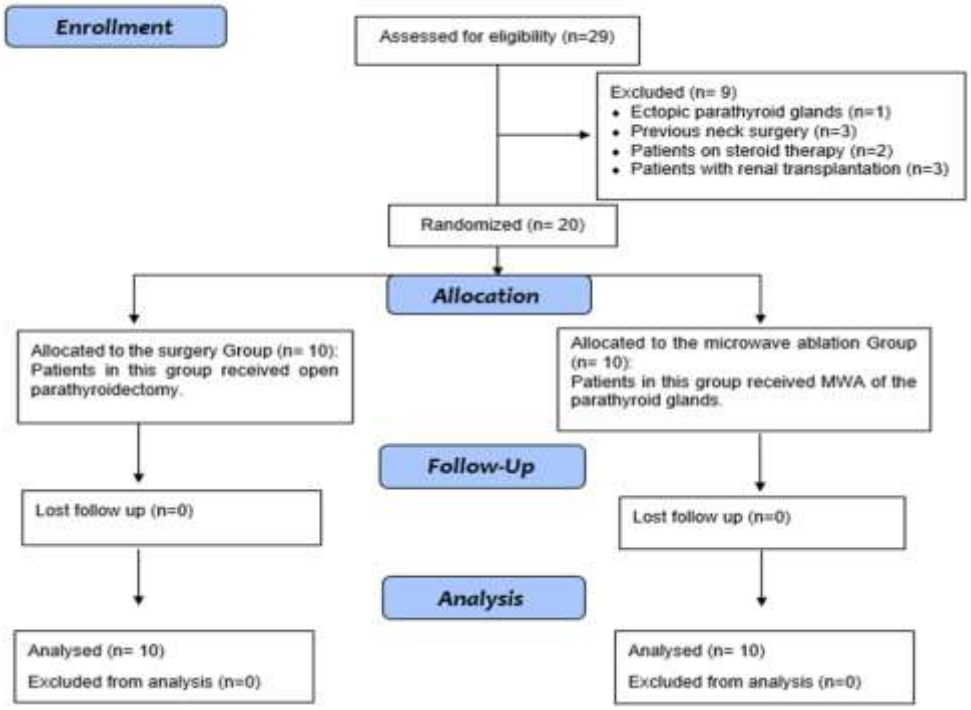

Figure (3): Flowchart of the study cases.

The mean age was group A (52.40±4.30)44 to 58 years, the mean age of group B (52.50±4.03) 42 to 57 years. They were group A (7 male and 3 female), group B (8 male and 2 female). Mean BMI in group A 27.09±3.99 and 26.32±3.59 in group B. Randomization of patients into two groups was done: open parathyroidectomy group included 10 and MWA group included 10. The patient characteristic was comparable between two study groups. The most common symptoms in both groups were bone pain, pruritis, and abdominal pain (Table 1).

Table (1): Demographic data, preoperative clinical data, and the type and aetiology of HPT in the study groups.

		Group A (n = 10)	Group B (n = 10)	P
Age (years)		52.40±4.30	52.50±4.03	0.958
Sex	Male	7(70.0%)	8(80.0%)	0.606
	Female	3(30.0%)	2(20.0%)	
BMI (kg/m2)		27.09±3.99	26.32±3.59	0.655
Clinical data				
Complaint	Bone and joint pain	9(90.0%)	10(100.0%)	0.305
	Pruritus	5(50.0%)	5(50.0%)	1
	Excessive urination	5(50.0%)	3(30.0%)	0.36
	Abdominal pain	4(40.0%)	2(20.0%)	0.329
	Weakness	7(70.0%)	5(50.0%)	0.361
	Depression	2(20.0%)	0(0.0%)	0.136
	Nausea	4(40.0%)	2(20.0%)	0.329
Type of HPT				
Primary		1(10.0%)	3(30.0%)	0.264
Secondary		9(90.0%)	7(70.0%)	
Duration of kidney disease (years)		4(2–10)	2(1–10)	0.219
Cause of chronic kidney disease	Diabetes	2(22.22%)	2(28.57%)	1
	Hypertension	4(44.44%)	3(42.86%)	0.949
	Glomerulonephritis	2(22.22%)	1(14.29%)	0.687
	Drug-induced	1(11.11%)	1(14.29%)	1

As illustrated in Table 2, preoperative laboratory data were comparable between the two groups.

Table (2): Preoperative laboratory and procedure time.

		Group A (n = 10)	Group B (n = 10)	P
Laboratory data	PTH (pg/ml)	2005.5(914-3665)	2551(1324-3795)	0.821
	Calcium (mg/dl)	13.94±1.55	13.69±1.21	0.699
	Phosphorus (mg/dl)	7.22±1.30	7.78±1.78	0.432
	Albumin (gm/dl)	3.42±0.46	3.44±0.41	0.920
	Haemoglobin (gm/dl)	12.18±1.40	11.80±1.16	0.518
	Creatinine (mg/dl)	6.8(1.3-13)	6.8(1.3–14.3)	0.996

Procedure time was significantly longer in group A than in group B ($P < 0.001$). Hospital stays, hematoma, wound infection and hoarseness of voice were insignificantly different between the two groups. However, VAS, hypocalcaemia, and recurrent HPT were significantly higher in group B than in group A. Regarding our primary outcome measure (persistence or recurrence), it was significantly higher in Group B ($p = 0.001$) (Table 3).

Table (3): Postoperative data and incidence of complications.

		Group A (n = 10)	Group B (n = 10)	P
Procedure time (min)		76.10±8.23	31.50±5.74	< 0.001*
Postoperative data	Hospital stays (days)	2(2–5)	2(2–5)	0.738
	VAS	4(3–5)	5(4–7)	0.007*
Complications				
Hematoma		0(0.0%)	0(0.0%)	1
Hypocalcaemia		10(100.0%)	3(30.0%)	0.001*
Wound infection		0(0.0%)	0(0.0%)	1
Hoarseness of voice		0(0.0%)	2(20.0%)	0.136
Persistent or recurrent HPT		0(0.0%)	7(70.0%)	0.001*

Baseline serum PTH, calcium, and phosphorus were statistically comparable between the two study groups, and it showed a significant decline in the subsequent assessments in both groups when compared to their corresponding baseline value. Nonetheless, the decline was more evident in association with parathyroidectomy than MWA (Table 4).

Table (4): Changes in serum PTH, calcium and phosphorus.

	Group A (n = 10)	Group B (n = 10)	P
PTH			
Basal value	2005.5(914-3665)	2551(1324-3795)	0.821
One-day reading	576(412-1134)	1602.28(779.4-2747)	0.002*
P	< 0.001*	0.005*	
One-week reading	442(229–819)	1436(658–2322)	< 0.001*
P value	< 0.001*	< 0.001*	
One-month reading	335.24(263.5-795)	1130.1(312.8-2495.56)	0.004*
P value	< 0.001*	< 0.001*	
Six-month reading	141.9(91-205)	1475.27(99.85-2878.23)	0.005*
P value	< 0.001*	0.001*	
Twelve-month reading	85.25(64.89-99.66)	1708.96(71.25-2918.23)	0.004*
P value	< 0.001*	0.012*	
Calcium			
Basal value	13.94±1.55	13.69±1.21	0.699
One-day reading	7.93±1.43	12±2.19	< 0.001*
P value	< 0.001*	0.049*	
Three-month reading	7.53±2.18	11.70±2.54	0.001*
P value	< 0.001*	0.050*	
Six-month reading	7.53±2.17	11.75±3.15	0.003*
P value	< 0.001*	0.088	
Twelve-month reading	7.45±1.18	11.84±3.27	0.001*
P value	< 0.001*	0.094	
Phosphorus			
Basal value	7.22±1.30	7.78±1.78	0.432
One-day reading	4.58±1.07	5.85±1.59	0.051
P value	< 0.001*	0.062	
Three-month reading	4.12±1.03	5.52±1.61	0.032*

P value	< 0.001*	0.035*	
Six-month reading	4.63±1.03	5.78±1.62	0.074
P value	< 0.001*	0.056	
Twelve-month reading	3.83±0.81	5.98±2.17	0.009*
P value	< 0.001*	0.070	

In Group B, all patients with preoperative secondary HPT had postoperative recurrence (100%), whereas all patients with primary HPT had resolution of their state after MWA. In Group B, 70% of patients developed recurrent HPT, and only three patients (30%) showed resolution of their hyperparathyroid state. On comparison between the previous subgroups, patients with recurrence had significantly higher PTH, serum calcium, and serum phosphorus during follow-up, compared to patients with no recurrence (Table 5).

Table (5): The relationship between recurrence and the type of preoperative HPT and preoperative and postoperative values of PTH, calcium, and phosphorus levels in Group B.

	No recurrence (n = 3)	Recurrence (n = 7)	P
Type of HPT			
Primary	3(100.0%)	0(0.0%)	< 0.001*
Secondary	0(0.0%)	7(100.0%)	
PTH			
Basal value	2108(1624-2232)	2931(1709- 3795)	0.138
One-day reading	998.4(779.4-1595.87)	2135.6(1126.52-2747)	0.043*
One week reading	520.45(465.5– 1290.6)	2022.02(1250.45–2848.63)	< 0.001*
One-month reading	423.14(312.8-635.8)	1857.65(998.36-2495.56)	0.017*
Six-month reading	156.3(99.85-232.45)	2156.3(1325.69-2878.23)	0.017*
Twelve-month reading	86.78(71.25-96.78)	2224.14(1420.69-2918.23)	< 0.001*
Calcium			
Basal value	13.70±1.87	13.69±1.02	0.989
One-day reading	8.98±0.49	13.30±0.78	< 0.001*
Three-month reading	8.36±0.88	13.14±1.21	< 0.001*
Six-month reading	7.30±0.77	13.65±0.75	< 0.001*
Twelve-month reading	7.13±0.21	13.86±0.40	< 0.001*
Phosphorous			
Basal value	8.99±0.58	7.26±1.89	0.170
One-day reading	3.95±1.07	6.66±0.93	0.004*
Three-month reading	3.61±1.07	6.34±0.95	0.004*
Six-month reading	3.86±1.07	6.61±0.96	0.004*
Twelve-month reading	3.03±0.47	7.24±0.90	< 0.001*

Discussion

The current Egyptian study compared perioperative and one-year outcomes of parathyroidectomy versus MWA in patients with primary or secondary HPT. Our study has many privileges. That comparison is rarely discussed

in the previous literature, which poses a great advantage in favour of our research, which discusses a unique scientific point. Additionally, our study carries a little risk of bias as the reader could notice no significant differences between the two groups regarding all preoperative parameters.

We noted that MWA was associated with a significant shortening in the procedure time compared to parathyroidectomy. Similarly, Wei et al. also reported a significant prolongation in the procedure time in the surgical group (60 vs. 30 minutes for MWA, $p < 0.001$) [11]. In addition, Liu et al. reported that the procedure time had mean values of 77.8 and 22 minutes in the surgery and MWA groups, respectively [20].

Our findings showed that MWA was associated with increased postoperative pain scores compared to surgery, despite the former being minimally invasive. No previous studies have compared both interventions regarding postoperative pain. Although surgery is considered more invasive than MWA, a previous report has highlighted that MWA in the neck region could result in severe postprocedural pain [21].

In our study, both procedures had statistically comparable postoperative hospitalization periods, which is in accordance with previous two studies that noticed the same two interventions did not have significantly different postoperative hospitalization periods [11, 20].

Our findings showed that no hematoma occurred in patients in both groups. On the other hand, Ren et al. reported that hematoma occurred in three (5.66%) and one patient (2.13%) in the surgery and thermal ablation groups, respectively ($p > 0.05$) [22].

In the current study, no wound infection occurred in either group. In the study reported by Ren et al., infection occurred in 39.6% of surgical cases compared to only 6.4% of the thermal ablation cases [22].

In our study, the incidence of postoperative hypocalcemia was 100% in group A and 30% in group B, which yielded a significant difference. Our research was comparable to that of Wei et al., who reported a significant increase in hypocalcaemia in association with surgery [11]. However, Diao et al. showed no significant difference in the incidence of hypocalcemia between surgery and MWA [23].

In our study, hoarseness of voice was encountered in no patients in group A versus 20% in group B ($p > 0.05$). Diao et al. reported that the same complication developed in one (5.56%) and two cases (11.11%) in the MWA and parathyroidectomy groups, respectively, with no statistical difference between the two groups [23].

When looking at our postoperative adverse events and comparing them with the literature, one could accept some differences between studies. That could be secondary to differences in sample size, expertise of the operator (either the surgeon or the radiologist), and the definition of the complication.

In the current study, we noticed a significant decline in serum PTH, calcium, and phosphorus in both groups, but that decline was more prominent in the surgical group. In the same context, Diao et al. found that PTH levels were significantly lower in the parathyroidectomy group than in the MWA group for all nine follow-up visits [23].

The mean PTH level decreased significantly after MWA, which is consistent with previous studies [24, 25]. The efficacy of MWA could be explained by its ablative effect, which, when adequately applied to the diseased parathyroid gland, leads to thermal destruction of its tissues [12].

Regarding our primary outcome, the incidence of recurrence showed a significant increase in Group B (70%) compared to no cases (0%) in Group A. Our findings are supported by those reported in the meta-analysis of Gong et al., who reported that thermal ablation increased the risk of recurrence after secondary HPT compared with parathyroidectomy [26]. After MWA, some parathyroid cells and tissue most likely survived. This is because ultrasound guides the percutaneous ablation procedure rather than direct vision. In individuals with secondary HPT, MWA was performed on the largest gland only. Consequently, PTH is still secreted by the other three.

On the other hand, Wei et al., denied any significant difference between the two approaches regarding recurrence rates. Recurrent hyperparathyroidism occurred in 3.4% and 6.9% of cases in the surgery and MWA groups respectively [11]. All patients in the previous study had primary hyperparathyroidism and that could explain the equal efficacy as the incriminated gland was attacked by either approach, with the remaining glands are healthy in contrast to its hyperplasia in secondary cases.

The results of surgical parathyroidectomy were noticeably superior to those of MWA, especially in patients with secondary HPT. This was demonstrated by a reduction in both postoperative pain and postoperative

recurrence. The MWA procedure's only benefits were that it took less time and was performed under local anesthesia, which could be dangerous for individuals with certain comorbidities like kidney disease.

In patients with primary HPT, both surgery and MWA have equal recurrence rates. However, surgical intervention has the advantage of less postoperative pain and less incidence of hoarseness of voice, and the specimen was sent for histopathological analysis to confirm its removal.

Although we discussed a unique surgical topic, our study has some limitations. The main drawbacks are the limited sample size, collecting patients from a single center, and lack of long-term follow-up. The upcoming studies should address these limitations.

Conclusion

Both parathyroidectomy and MWA are viable, effective, and safe options for patients with primary HPT. However, parathyroidectomy is markedly superior to MWA in patients with secondary HPT. Therefore, primary cases could be managed by either parathyroidectomy or MWA, whereas secondary cases are better managed by parathyroidectomy to decrease the risk of postoperative recurrence.

Conflicts of interest: Nil.

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