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ORIGINAL SCIENTIFIC REPORT

One-Hour Postoperative Parathyroid Hormone Levels Do Not Reliably Predict Hypocalcemia After Thyroidectomy

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Abstract

Introduction Hypocalcemia is a well-known complication after total thyroidectomy. Studies have indicated that the presence of low postoperative parathyroid hormone (PTH) levels can predict hypocalcemia. However, definitive study designs are lacking. The aim of this study was to determine whether postoperative PTH alone can accurately predict postoperative biochemical hypocalcemia.

Methods Under IRB approval, a prospective study of 218 consecutive patients who underwent total or completion thyroidectomy by two surgeons between June 2014 and June 2016 was performed. Biochemical hypocalcemia was defined as ionized calcium <1.13 mmol/L or serum calcium <8.4 mg/dL at any time postoperatively. Three PTH thresholds, <10, <20 pg/mL, and >50% drop in PTH 1 h postoperatively from baseline were examined.

Results Postoperative PTH < 10 pg/mL had a sensitivity of 36.5% (95% CI 27.4–46.3%) and a specificity of 89.2% (95% CI 81.9–94.3%). Postoperative PTH < 20 pg/mL had a sensitivity of 66.4% (95% CI 56.6–75.2%) and a specificity of 67.6% (95% CI 58.0–76.2%). Postoperative PTH decrease >50% had a sensitivity of 63.4% (95% CI 53.2–72.7%) and a specificity of 72.5% (95% CI 62.5–81.0%). Across all PTH thresholds, the false-negative rate was 33.6–63.5% indicating that up to 64% of patients with a normal PTH level could have been discharged without appropriate calcium supplementation. The false-positive rate was 10.8–32.4% indicating that up to 32.4% of patients with low PTH could have been treated with calcium supplementation unnecessarily.

Conclusion Following total thyroidectomy, PTH levels are unreliable in predicting hypocalcemia. Additional prospective studies are needed to understand the true utility of PTH levels post-thyroidectomy.

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Introduction

Hypocalcemia still remains the most common morbidity associated with thyroidectomy [1]. Transient and permanent hypocalcemia can occur in up to 50 and 9.3% of cases, respectively [2–7]. Postoperative hypocalcemia can be attributed to indirect or direct injury to the parathyroid glands by devascularization, stunning of the glands, or inadvertent parathyroidectomy [8, 9]. Although hypocalcemia occurs most commonly within the first 24–72 h after surgery, many centers, including our institution, discharge patients home within 24 h postoperatively [4, 10]. Additionally, there is a recent push to perform total thyroidectomy as an outpatient procedure as a result of low surgical morbidity rates coupled with the drive to lower health care costs [11]. To ensure patient safety, it is imperative that surgeons are able to accurately predict at the time of discharge which patients will develop hypocalcemia.

As a result, parathyroid hormone (PTH) levels have been investigated to predict hypocalcemia after thyroidectomy [12, 13]. Based on a plethora of heterogeneous literature advocating its use, measurement of a postoperative PTH level has become widely adopted in practice and national society guidelines. Current American Thyroid Association guidelines state the PTH "measurement taken in the recovery room 1–2 h after surgery has been proven informative" and recommends calcitriol supplementation in patients with postoperative PTH < 15 pg/mL [11]. However, among the studies evaluating PTH levels to predict hypocalcemia after thyroidectomy, there is significant variation in terms of thresholds to predict hypocalcemia, questioning the true value of measuring postoperative PTH [14–16]. Many studies that examine the predictive value of PTH empirically treated patients with calcium and sometimes vitamin D when the PTH level was below a specified cut off point or below the lower limit of the normal range [5, 17–21]. This circular logic not only masks the true incidence of hypocalcemia, but also hinders the ability to determine the number of patients being treated unnecessarily. Thus, these studies cannot definitively and accurately assess the predictive value of a subnormal PTH.

The aim of our prospective study was to determine whether serum intact PTH level obtained 1 h postoperatively can reliably predict biochemical hypocalcemia after thyroidectomy.

Methods

Under IRB approval, data on all patients who underwent total or completion thyroidectomy between June 2014 and June 2016 were prospectively collected. Patients were excluded if they had a glomerular filtration rate <60 mL/min/1.73 m^2, underwent central lymph node dissection, concomitant parathyroid surgery, or had a history of gastric bypass surgery.

Total thyroidectomy consisted of total, bilateral, extracapsular removal of thyroid tissue. Completion thyroidectomy involved the removal of all residual thyroid tissue after previous thyroid lobectomy. Two endocrine surgeons (MAZ, AM) performed all surgical procedures at a tertiary medical center. Parathyroid auto-transplantation in the ipsilateral sternocleidomastoid muscle was performed in cases of vascular compromise or inadvertent excision. The majority of patients were admitted to a 23-h observation unit and discharged home by 9AM the following day. Prior to discharge, patients were educated about identifying symptoms of hypocalcemia and instructed to call the office. Phone calls were made to patients between post-op day (POD) 2–5 to assess for symptoms of hypocalcemia, and patients were seen in clinic 7–10 days postoperatively. Data were collected from electronic medical records of all patients and included patient name, age, gender, preoperative diagnosis, procedure date, type of operation, laboratory results, operative notes, pathology results, and whether parathyroid tissue was found in the specimen. Progress and nursing notes, emails, and patient calls were reviewed to determine the use of calcium supplementation, number of symptomatic episodes, or need to visit an emergency department.

Laboratory evaluation

For all patients, preoperative PTH and vitamin D levels were obtained at the time of the initial clinical consultation. All patients with vitamin D deficient levels (25(OH)D < 30 ng/ml) were given supplementation of 50,000 IU weekly for 6–8 weeks prior to surgery. Postoperative laboratory evaluation was part of a uniform institutional order set and included ionized calcium (iCa) and PTH; these were performed in the recovery room within 1 h of surgery and on the morning of POD 1. iCa (normal range 1.13–1.32 mmol/L) was measured using an ion selective electrode. Postoperative PTH (normal range 10–65 pg/mL) was measured using electrochemiluminescence immunoassays on the Cobas e602 analyzer from Roche Diagnostics (Indiana, USA).

Calcium treatment protocol

Although PTH levels were obtained as part of a standardized order set, patients were treated based upon calcium levels only. During the hospital stay, if an ionized calcium level was below normal range on any blood draw, one dose of 5200 mg of calcium carbonate was administered. If a patient experienced hypocalcemic symptoms, they were also treated with a onetime dose of 1300 mg of calcium carbonate at the nurse's discretion. On POD 1, if the ionized calcium was within the normal range, iCa > l.13 patients were not discharged home on calcium. The doses of calcium carbonate for the patients with biochemical hypocalcemia ranged from a 1300 mg three times daily to 2600 mg every 4 h upon discharge. No patient was sent home on calcium supplementation based solely upon PTH levels. Upon discharge, all patients were instructed to take 1300 mg of calcium carbonate if symptoms of hypocalcemia occurred and to report this to the surgical team. Due to ionized calcium not being readily available after discharge, either serum calcium or ionized calcium was used to determine biochemical hypocalcemia.

Data analysis

Hypocalcemia was defined as ionized calcium <1.13 mmol/L at any point during the hospital stay or after discharge, a serum calcium <8.5 mg/dL after discharge, or development of symptoms that were relieved with calcium supplementation. In line with current medical literature, we chose three postoperative PTH thresholds to analyze: <10, <20 pg/mL, or a postoperative decline >50% from the preoperative PTH value [22–24]. The sensitivity, specificity, positive and negative predictive value (PPV, NPV) of these PTH thresholds to predict the need for calcium supplementation were examined using Stata 13 (College Station, TX). Chi square was used to compare proportions and nonnormally distributed variables.

Results

Study population

Of the 248 patients who were identified, 30 patients were excluded from the study including a patient who misunderstood calcium supplementation instructions on discharge. Of the remaining 218 patients, 208 (95.4%) underwent a total thyroidectomy and 10 (4.6%) patients underwent a completion thyroidectomy (Table 1). The median age of the study population was 49 years and ranged from 15 to 80 years. The majority (87.2%) of patients were female. Preoperatively, 84 (38.5%) patients were diagnosed with vitamin D deficiency and were prescribed supplementation for 6–8 weeks prior to surgery. Final pathology was benign in 135 (61.9%) and malignant in 83 (38.1%) patients. Indications for surgery and preoperative diagnoses are listed in Table 1.

Table 1 Patient characteristics and pathology findings

Patient characteristics	$n = 218$ (%)
Gender	
Female	190 (87.2%)
Male	28 (12.8%)
Mean age ± SD [range]	48.3 ± 14.7 [15–80]
Operation	
Total thyroidectomy	208 (95.4%)
Completion thyroidectomy	10 (4.6%)
Preoperative diagnosis	
Nontoxic cervical multinodular goiter	39 (17.9%)
Nontoxic substernal multinodular goiter	34 (15.6%)
Toxic cervical multinodular goiter	29 (13.3%)
Toxic substernal multinodular goiter	6 (2.8%)
Indeterminate or suspicious nodule	77 (35.3%)
Papillary thyroid cancer	32 (14.7%)
Benign nodule	1 (0.5%)
Final pathology	
Benign	135 (61.9%)
Malignant	83 (38.1%)

Postoperative PTH and biochemical hypocalcemia

Of the 218 patients, 107 (49.1%) patients had at least one laboratory value at any point documenting hypocalcemia (Fig. 1). No patients had critical hypocalcemia (iCa < 0.94 mmol/L). There was a statistical difference in the recovery room versus POD#1 calcium values of .06 mmol/L (1.19 and 1.13 mmol/L, respectively; $p < 0.05$). Six patients underwent parathyroid auto-transplantation and, of those, four patients were hypocalcemic.

Of the 107 hypocalcemic patients, 51 had PTH < 10 pg/mL, 107 had PTH < 20 pg/mL, and 91 had 50% drop. PTH ranged from 3 to 94 pg/mL with a mean of 17.1 pg/mL and standard deviation of 14.0 pg/mL. Table 2 lists the sensitivity, false-negative rate, specificity, false-positive rate, PPV, and NPV of each PTH threshold. The sensitivity and specificity of PTH < 10 to detect post-thyroidectomy hypocalcemia was 36.5% (95% CI 27.4–46.3%) and 89.2% (95% CI 81.9–94.3%) respectively, of PTH < 20 was 66.4% (95% CI 56.6–75.2%) and 67.6% (95% CI 58.0–76.2%), and of 50% decline were 63.4% (95% CI 53.2–72.7%) and 72.5% (95% CI 62.5–81.0%) (Table 2).

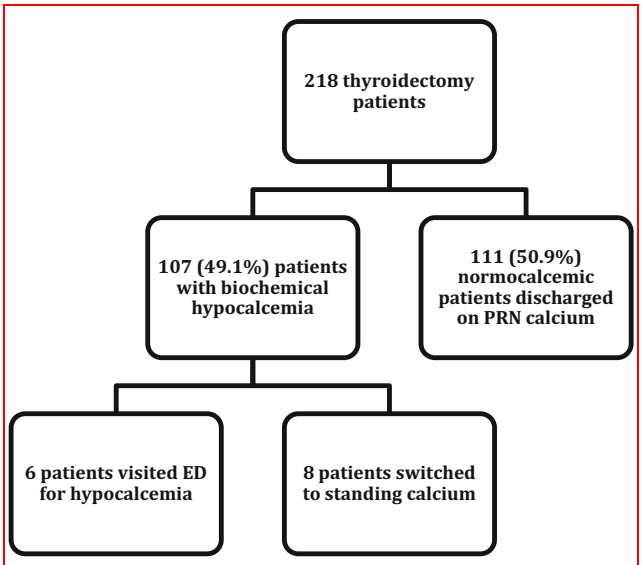

Fig. 1 Patient flowchart. Figure illustrates our study population. Out of 218 patients, 107 had biochemical hypocalcemia, of which six patients visited the ED for hypocalcemia and eight patients switched to standing calcium

Therefore, using a PTH < 10 pg/mL as a predictor of post-thyroidectomy hypocalcemia would have led to overtreatment of 12 (10.8%) patients and would have missed 68 (63.6%) patients with hypocalcemia who otherwise would have been sent home without calcium supplementation. Treating all patients with a PTH < 20 pg/mL would have led to overtreatment in 35 patients (32.4%) and would have missed 36 hypocalcemic patients (33.6%). Furthermore, the use of postoperative PTH decrease >50% would have led to overtreatment in 27 patients (27.6%) who did not develop hypocalcemia and would have missed 37 hypocalcemic patients (36.6%).

Six (2.8%) patients presented to the emergency department (ED) with symptoms of hypocalcemia and subsequently found to have biochemical hypocalcemia, and, of those, two (0.9%) patients had documented clinically significant hypocalcemia (ionized calcium <0.94 mmol/L). Additionally, eight other patients who were not discharged on calcium had symptomatic hypocalcemia requiring addition of calcium regimen. The PTH values for these 14 patients ranged from 7 to 41 pg/mL. Three out of six ED patients presenting with hypocalcemia had not been discharged with calcium supplementation and required intravenous calcium in the ED; one patient had refused to take oral calcium prescribed on discharge due to odynophagia. No patients required readmission for hypocalcemia.

Complications

Among our cohort, a total of eight patients (3.7%) presented to the ED, including six (2.8%) due to symptoms of hypocalcemia. One (0.5%) patient required drainage for a neck hematoma after resuming antiplatelet therapy 10 days following surgery and was discharged the following morning. One (0.5%) patient presented to the ED with severe constipation requiring disimpaction. Five patients (2.3%) experienced postoperative complications. One (0.5%) patient developed negative pressure pulmonary edema resulting from laryngospasm during extubation. Two (0.9%) patients had temporary recurrent laryngeal nerve (RLN) paresis.

Discussion

In summary, our study represents one of the largest studies evaluating the role of post-thyroidectomy PTH levels to predict hypocalcemia. We assessed PTH values measured

Table 2 PTH postoperative day 0 measures of diagnostic accuracy in patients with biochemical hypocalcemia

	Biochemical hypocalcemia		Diagnostic value			
	No	Yes				
PTH < 10						
PTH	Negative	99	68	Se 36.5%	FN 63.5%	PPV 76.5%
	Positive	12	39	Sp 89.2%	FP 10.8%	NPV 59.3%
PTH < 20						
PTH	Negative	75	36	Se 66.4%	FN 33.6%	PPV 66.4%
	Positive	36	71	Sp 67.6%	FP 32.4%	NPV 67.6%
PTH decrease > 50%[a]						
PTH	Negative	71	37	Se 63.4%	FN 36.6%	PPV 70.3%
	Positive	27	64	Sp 72.5%	FP 27.5%	NPV 65.7%

Se Sensitivity; *Sp* specificity, *FN* false negative, *FP* false positive, *PPV* positive predictive value, *NPV* negative predictive value

[a]Data for calculation of decline in PTH were only available for 199 patients

within 1 h after surgery, at which time these values are undisturbed by possible interference from oral or intravenous calcium supplementation. Postoperative serum intact PTH had a relatively high specificity (67.6–89.2%) and a low sensitivity (36.5–66.4%) in predicting post-thyroidectomy hypocalcemia for all thresholds. If the decision to treat had been based upon PTH measures alone, as many as 63.5% of hypocalcemic patients would have been discharged without appropriate calcium supplementation and up to 32.4% of patients who did not develop hypocalcemia would have been treated unnecessarily with calcium supplementation. Therefore, a low 1-h postoperative PTH value is not a reliable predictor of hypocalcemia.

While both mild hypocalcemia and overtreatment with calcium due to a false low PTH value may not have major clinical significance, discharging patients without calcium who need it is highly concerning. Interestingly, among our patient sample, no critically low values of post-op ionized calcium (<0.94 mmol/L) were reported with the lowest value reported was 1.06 mmol/L. In our study, PTH < 10 pg/mL in the recovery room showed the highest specificity (89.2%) and therefore might be a useful adjunct for surgeons to incorporate in discharge decision making. However, used alone, PTH < 10 pg/mL is a poor predictor for identifying hypocalcemic patients because of its low sensitivity (36.5%).

Similar to our study, previously published studies demonstrated that PTH alone is unreliable [25, 26]. A prospective study by Lombardi et al. [26] included 523 consecutive patients who underwent thyroidectomy investigated the accuracy of a 4-h postoperative PTH level in predicting hypocalcemia. The authors reported that PTH < 10 pg/mL had a low sensitivity and high specificity of 64.8 and 89.5%, respectively. Furthermore, among the 163 patients with 4-h postoperative PTH < 10 pg/mL, 34 (21%) were normocalcemic. The authors concluded that low PTH levels at 4 h post-thyroidectomy alone did not accurately predict clinically relevant hypocalcemia. Sywak et al. [22] also studied PTH threshold levels of 10 ng/mL obtained 4 h postoperatively in 100 patients. In contrast to Lee et al., Sywak recommended the use of PTH < 10 pg/mL, which had a sensitivity, specificity, and likelihood ratio of 90, 84, and 6.0%, respectively. Thus, disagreement exists surrounding the diagnostic utility of PTH threshold levels. Other studies have also demonstrated that PTH value alone is not as accurate as when used in conjunction with calcium levels to predict hypocalcemia [27–29]. Payne et al. [28] utilized a cutoff PTH level of greater than 28 ng/L in addition to ionized calcium greater than 2.14 mmol/L to predict normocalcemia in thyroidectomy patients suggesting that perhaps both laboratory evaluations should be taken into account. Ironically, however, to suggest that PTH and calcium levels both be checked to predict hypocalcemia is illogical as one would speculate that measuring simply calcium should be sufficient.

On the contrary, many studies have advocated for the potential clinical usefulness of postoperative PTH in the prediction of hypocalcemia with varying degrees of success [22, 30–32]. However, these studies used various PTH thresholds measured at various time points, making it difficult to fully understand the relationship between PTH measurement and the risk of hypocalcemia. A systematic review by Noordzij et al. analyzed pooled data from nine observational studies that did not treat based on PTH levels. They found tremendous variation in the nine studies examined including four different assay types as well as different definitions of hypocalcemia and variability in the timing and site of measurement. Therefore, the study was only able to examine a percentage decrease in PTH levels as opposed to an absolute value. They reported a sensitivity and specificity of 96.4 and 91.4%, respectively, thereby concluding that a decline by 65% after 6 h postoperatively may be used as an adjunct for risk stratification. However, it is unclear, if this threshold can be applied universally with similar results. In order to better understand the relationship between PTH and hypocalcemia, a prospective randomized trial is necessary to validate these findings.

Our study has several limitations. First, surgeons were not blinded to patient PTH laboratory results. This may have led to some bias toward discharging patients home on calcium, although all patients discharged on calcium had documented concomitant hypocalcemia. However, our definition of hypocalcemia, regardless of the need for calcium supplementation, however, was quite strict and still PTH was not a reliable indicator.

Second, the preoperative PTH values were ordered at the surgical consultation office visit, which occurred 2 weeks to 2 months before the time of surgery and, in many cases, was measured in laboratories at outside laboratories. Each laboratory uses different assays for PTH measurement which may cause variability between PTH measurements [33, 34]. Ideally, the timing of preoperative PTH measurement levels would have been during the immediate preoperative setting in order to accurately calculate the PTH drop. We recognize that these limitations may deter our study from being widely adopted; however, our aim was to show a lack of direct correlation between 1-h post-thyroidectomy PTH levels and biochemical hypocalcemia.

In conclusion, the utility of single low PTH within 1 h of surgery in and of itself is an unreliable predictor of post-thyroidectomy hypocalcemia. In our study, relying on PTH levels alone, PTH < 10 pg/mL, PTH < 20 pg/mL, or a postoperative PTH decrease of >50% following total thyroidectomy, not only would have led to the overtreatment of a substantial proportion of patients who did not develop

hypocalcemia, but also would have missed a significant number of patients who needed treatment. The main limitation of a postoperative PTH measurement is obtaining a normal or above threshold value in patients who ultimately develop symptomatic hypocalcemia (false negative). Before practice can be standardized across all institutions, further research in larger blinded cohorts is required to fully understand the relationship between PTH levels and biochemical hypocalcemia after thyroidectomy.

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