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Original research

What is the most appropriate intraoperative baseline parathormone? A prospective cohort study

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HIGHLIGHTS

- Post induction PTH baseline was better than pre-induction baseline.
- Combination of 10 min post-induction and pre-excision PTH baselines was the best.
- ≥50% fall in post excision PTH from baselines predicted complete excision in 95.45%.

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ABSTRACT

Introduction: The time of drawing pre-incision intraoperative parathyroid hormone (ioPTH) is crucial to provide the right baseline for post-excision PTH measurement. The objective of this study was to identify the optimal time and the numbers of baseline PTH samples that best predict excision of all hypercellular parathyroid tissue when compared with 10-min post-excision PTH level.

Materials and methods: In this prospective study, two pre-incision (pre-induction and 10-min post-induction) baseline ioPTH samples along with pre- and post-excision ioPTH were collected and analyzed for 352 parathyroidectomies in 341 patients for sporadic primary hyperparathyroidism at a University hospital. Paired Wilcoxan signed rank test was used to compare the pre-incision ioPTH levels and their percent drop to 10-min post-excision levels. Sensitivity, specificity, predictive values and receiver operating characteristic (ROC) curves were used to compare the predictability of the two pre-incision levels.

Results: The difference between pre- and post-induction baseline PTH levels was highly significant ($p < 0.001$). In 4% cases the criterion of post-excision PTH drop of ≥50% was achieved only with the post-induction baseline PTH and not with pre-induction PTH measurement. Using pre-induction baseline, ioPTH had an overall accuracy of 90% whereas ≥50% fall in the post-excision PTH from the post-induction baseline PTH had the accuracy of 94.85%.

Discussion: There was a significant difference between pre- and post-induction PTH levels and Miami criteria was met in 95.45% cases with post-induction baseline.

Conclusions: The optimal time for drawing pre-incision baseline PTH sample is at 10 min post-induction of general anesthesia and positioning of patient.

1. Introduction

Primary hyperparathyroidism (PHPT) indicates over-activity of one or more parathyroid glands resulting in an increased production of serum parathormone (PTH). PHPT due to parathyroid adenoma is the most common parathyroid disorders. Typically it is asymptomatic and identified incidentally on routine bloodwork. Classical presentation loosely described as “stones, bones, abdominal groans, psychic moans, and fatigue overtones” are infrequently encountered in the western world [1]. “Classic” PHPT is the elevation of both calcium and PTH above normal serum levels whereas

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"mild" PHPT is the elevation of either calcium or PTH above normal or else an asymptomatic patient with mild elevations in both values [2]. Patients often experience a dramatic decrease in quality of life as they suffer from renal calculi, osteoporotic fracture, abdominal pain, depression, fatigue, and/or polyuria just to name a few. Nephrolithiasis, bone disease, and neuromuscular symptoms respond very well to surgery [1], and it is noted that many "asymptomatic" patients actually have neurocognitive symptoms that may be unmasked after successful surgery [3].

Since its inception, minimally-invasive parathyroidectomy (MIP) with adjunctive intraoperative parathyroid hormone (ioPTH) monitoring has become the treatment of choice for sporadic primary hyperparathyroidism [4]. Its results are similar to that of bilateral cervical exploration but with a smaller incision, faster recovery, shorter operative time, and hospital stay [5–8]. IoPTH monitoring allows for a limited dissection targeted to the diseased gland(s) by confirming complete excision of all hypercellular parathyroid tissue, thereby avoiding a revision surgery or bilateral cervical exploration [9]. Vienna [10], Rome [11], and Miami [12] criteria, used for surgical decision making regarding completeness of resection of hypercellular parathyroid tissue require a PTH fall of 50% or more from the baseline PTH for intra-operative prediction of cure [13]. However, there is a lack of consensus between head and neck surgeons regarding the appropriate timing of the baseline ioPTH sample(s) [14]. Choosing accurate baseline PTH is crucial as the post − excision drop is measured against it and an inappropriate baseline can result both in premature termination of surgery or unnecessary exploration.

The objectives of this study were to determine whether there is a difference between the pre-incision baseline PTH levels drawn pre-induction and 10-min post-induction of anesthesia and which of these two baseline PTH samples better predicts complete excision of all hypercellular parathyroid tissue when compared with 10-min post-excision PTH level.

2. Materials and methods

Our prospective study group included all 366 consecutive parathyroidectomies performed from January 1, 2008 to December 31, 2014 for PHPT in 355 patients at St. Boniface General Hospital (SBGH), Winnipeg, Canada. Ethics approval was obtained from the University of Manitoba Research Ethics Board. This work, carried out at a University teaching hospital, fully complies with the STROBE guidelines for reporting observational studies [15].

IoPTH samples were analyzed with Roche IntactPTH Immunoassay on the Cobas e601 analyser. The assay is affected by hemolysis $\geq$1.5 g/L and any sample that showed visible signs of hemolysis was not analyzed. The pre-induction ioPTH level was obtained before induction of general anesthesia. Ten minutes after the induction of general anesthesia and positioning of the patient, a post-induction ioPTH level was obtained from an arterial line in the patient's upper limb contralateral to the site of blood pressure cuff. IoPTH was drawn routinely at 10-min post-excision of hyperplastic parathyroid tissue. Data was collected from paper charts and electronic patient record and entered into specifically created database in SPSS Statistics 22.0. To ensure accuracy of the data, surgeons recorded the type of ioPTH sample measured (pre-induction, post-induction or post-excision) and this was compared with the intraoperative notes to record the time of induction of anesthesia and collection of the ioPTH sample. Persistent HPT or operative failure was defined as persistent hypercalcemia 6 months post-operatively [12].

The data were managed and analyzed using SPSS for Windows version 22.0 (SPSS Inc., Chicago, IL). After checking for normality assumption the mean and standard deviation were used to express normally distributed data and median with inter-quartile range (IQR) were used for non-normally distributed data. Categorical data were compared by using the Pearson χ^2 test with continuity correction, as appropriate. A p-value <0.05 was considered to indicate statistical significance and 95% confidence intervals were used to express reliability in the estimates. Differences between the pre-induction, post-induction and post-excision PTH levels were analyzed by paired Wilcoxan signed rank test. The percent change from pre-incision baseline (pre-induction or post-induction) was calculated as (pre-incision baseline−post-excision PTH) X 100%/pre-incision baseline PTH. Sensitivity, specificity and positive predictive value (PPV) and overall accuracy were used to compare $\geq$50% percentage change in post-excision PTH from pre- or post-induction baseline with eucalcemia at 6-month post-parathyroidectomy. ROC curves and area under the curve were used to compare the predictability of 6-month post-parathyroidectomy eucalcemia by using the percentage change in the post-excision PTH from the two pre-incision baseline levels.

3. Results

Of 366 parathyroidectomies in 355 patients, 14 patients had tertiary hyperparathyroidism and they were excluded from the study. Of the remaining 352 image guided minimally invasive parathyroidectomies in 341 patients, 314 (89.2%) patients had a single adenoma, 16 (4.5%) double adenoma and 11 (3.9%) had multigland hyperplasia. Eleven patients had two parathyroid procedures, two for missed adenomas and nine for involvement of multiple parathyroid glands. The mean age of our patients in this subset was 60.8 ± 12.9 years and 77.2% patients were female. Imaging by sestamibi scans, ultrasound, and multiphase computerized tomography was successful in localizing abnormal parathyroid tissue in 318 (93.3%) patients and 298 (94.9%) of 314 solitary parathyroid adenomas. Surgical cure, defined as eucalcemia for at least 6 months postoperatively, was achieved in 341 (96.9%) parathyroidectomies including 22/23 (94.4%) cases of failed image-localization and 190/194 (97.9%) patients with concordant sestamibi scan and ultrasound findings.

Median pre- and post-induction as well as pre-excision baseline PTH values are summarized in Table 1 and the differences between the pre-incision (pre- or post-induction) baseline PTH levels and the post-excision PTH levels were highly significant ($p < 0.001$). There was also a significant difference in the post-induction PTH level from the pre-induction ($p < 0.001$) and pre-excision levels ($p = 0.004$). The percent change in post-excision PTH level was significantly more from post-induction baseline PTH as compared to the pre-induction baseline PTH ($p = 0.041$) or the pre-excision baseline PTH ($p = 0.092$). There was an insignificant difference between pre-induction and pre-excision baseline PTH levels ($p = 0.772$) as well as in the percent change in post-excision PTH level from pre-induction or pre-excision baseline PTH levels ($p = 0.135$).

Post-excision PTH decreased to a normal level (below 50 pg/ml) in 10 min in 238 (67.6%) cases and all these patients achieved surgical cure. In 11 parathyroidectomies post-excision PTH levels fell by <50% from pre-incision and pre-excision baseline levels and they underwent bilateral neck exploration for hyperplastic parathyroid tissue,. A fall of $\geq$50% in post-excision PTH from the baseline PTH level was considered to be indicative of excision of all hypercellular parathyroid tissue. In 14 (4.0%) cases the post-excision PTH fell by $\geq$50% only from the post-induction baseline and not from the pre-induction PTH baseline level, following complete resection of all hyperplastic parathyroid tissue whereas in 2 (0.6%) cases it fell by $\geq$50% only from pre-excision level. Using $\geq$50% fall in the post-excision PTH from baseline, pre-induction,

Table 1
Comparison of pre-incision (pre- and post-induction) and pre-excision baseline PTH.

		Pre-induction PTH	Post-induction PTH	Pre-excision PTH
Median		126.5 pg/ml	158.0 pg/ml	128.0 pg/ml
Interquartile range		97.0–198.3 pg/ml	121.0–269.8 pg/ml	100.0–205.0 pg/ml
Change in post-excision PTH levels from baseline		<0.001	<0.001	<0.001
% change in post-excision PTH levels	Median	69.0%	75.1%	69.7%
	IQR	55.5–78.3%	64.2–81.8%	58.3–76.4%
Area under ROC curve(95% CI)		0.93 (0.88–0.98)	0.98 (0.95–1.00)	0.96 (0.91–1.00)

Table 2
Sensitivity, specificity and predictive values of pre- and post-induction baseline PTH levels.

	Pre-induction PTH	Post-induction PTH
Sensitivity (95% C.I)%	90.3 (87.11–93.5)	94.9 (92.7–97.2)
Specificity (95% C.I)%	86.36 (72.0–110)	100
PPV (95% C.I)%	99.0 (97.9–100)	100
NPV (95% C.I)%	37.3 (24.0–50.5)	56.4 (40.9–71.9)

ioPTH had an overall accuracy of 90.3% for predicting eucalcemia at 6-month post-parathyroidectomy, whereas the post-induction baseline PTH demonstrated accuracy of 94.3% (Table 2). In combination with pre-excision PTH (Miami criteria), the post-induction baseline PTH had accuracy of 95.4%, whereas the accuracy of pre-induction baseline PTH remained unchanged. Sensitivity, specificity, negative predictive value (NPV) and positive predictive value (PPV) are summarized in Table 3.

Using the ROC curve, the best prediction of surgical cure was achieved at ≥49.6% fall in 10-min post-excision PTH from post-induction baseline and ≥53.4% fall from pre-induction baseline. The area under ROC curve was significantly higher for post-induction PTH baseline than pre-induction PTH ($p = 0.03$, one sided) but not from pre-excision PTH levels. Frozen section examination of the excised parathyroid tissue was also done in 175 patients and in 7 (4.0%) of them PTH did not normalize 6 months postoperatively. Frozen section alone was insufficient to predict complete resection of 4 double adenomas and one four gland hyperplasia as 5/7 (71.4%) of these frozen section had confirmed hypercellular parathyroid tissue and surgery might have been completed, if ioPTH was not used.

4. Discussion

Hypercalcemia is identifiable in approximately 0.5% of the general population and PHPT is the most common cause of hypercalcemia in non-hospitalized patients [1]. The disease occurs at all ages but it is most commonly seen in women in their seventh decade [16]. PHPT results from single adenomas in 80–85% cases, double adenomas in 2–3%, multi-gland hyperplasia in 12–15% and rarely from carcinoma. In our study, multi-gland hyperplasia was identified at a lower rate which is likely due to practice pattern in a public-funded healthcare system. Preoperative imaging studies are of utmost importance in planning minimally invasive parathyroid surgery and in our study imaging was successful in localizing abnormal parathyroid tissue in 93.3% patients and precisely localizing 94.9% solitary parathyroid adenomas. Almost 97% patients with preoperative, localizing sestamibi scans and concordant ultrasound results were reported to have successful excision with removal of the localized gland [3,17]. In our study 98% of these patients were eucalcemic for at least 6 month after surgery. Operative success has been reported to be over 99% when ioPTH monitoring is used in addition to preoperative localization [18].

Table 3
Sensitivity, specificity and predictive values of pre- and post-induction baseline PTH levels in combination with pre-excision PTH level (Miami criterion).

	Pre-induction PTH	Post-induction PTH
Sensitivity (95% C.I)%	90.3 (87.1–93.5)	95.4 (93.2–97.7)
Specificity (95% C.I)%	86.4 (72.0–110)	100
PPV (95% C.I)%	99.0 (97.9–100)	100
NPV (95% C.I)%	37.3 (24.0–50.5)	59.5 (43.6–75.3)

Traditionally, surgeons had opted for bilateral neck exploration where all four parathyroid glands would be identified and excised based on their size. This approach has largely been replaced by minimally invasive parathyroidectomy, where surgeons opt for uniglandular exploration based on preoperative localization and aided by ioPTH monitoring. Currently, over 90% of high-volume parathyroid surgeons use ioPTH monitoring to guide parathyroidectomy in patients with sporadic PHPT [18]. IoPTH monitoring is superior to frozen section in that it can detect residual hyper functioning parathyroid tissue. Frozen section confirms that the tissue removed is hyperplastic parathyroid tissue; however, it cannot provide information regarding the presence of additional hyper-functioning parathyroid tissue [14,19,20]. In our study frozen section of parathyroid alone would have failed to predict incomplete excision of all hyperplastic parathyroid tissue in 5 (2.9%) cases.

There is a lack of consensus on optimal timing for pre-incision ioPTH monitoring [19]. Some surgeons use one baseline PTH [10] value while others use two baseline levels [12]. Similarly the PTH levels may be drawn a day prior to surgery, on the day of surgery before or at the time of induction of anesthesia, or just before surgical incision [19]. The Vienna criterion requires PTH fall of 50% at 10 min from gland resection from the baseline pre-incision PTH sample acquired before neck manipulation [10]. The Rome criterion requires a 50% fall from the highest pre-excision PTH level, and/or a PTH level within normal range at 20 min post-excision, and/or a PTH level 7.5 pg/L lower than the 10-min post-excision level [11]. The Miami criterion uses both pre-incision and pre-excision PTH levels drawn after manipulation of the gland and a ≥50% post-excision PTH fall from either the highest pre-incision or pre-excision level at 10 min denotes a successful operation [12]. Timing of pre-incision baseline used in these criteria is open to interpretation. It is important to define the time of drawing pre-incision baseline PTH as the airway manipulation, associated with general endotracheal anesthesia, increases circulating catecholamine levels, which in turn influences ioPTH measurements [21] as catecholamines increase PTH levels in humans [22]. Propofol used for induction of anesthesia can negatively interfere with the PTH assay [23], as a result we recommend waiting for 10 min after induction and drawing PTH from an arterial line in the contralateral upper limb. Standard guidelines to the practice of anesthesia prepared and revised by the Canadian Anesthesiologists' Society were followed in all cases [24].

Vienna criterion recommends drawing pre-incision PTH before any neck manipulation. Our results show that a PTH level drawn 10-min after induction of anesthesia and positioning of the patient to

be more accurate baseline as compared to the one drawn before induction of anesthesia. Although the pre-induction PTH levels were drawn from the venous lines and the post-induction PTH levels were drawn from the arterial lines, they are unlikely to be the reason for this difference, as reported earlier [25]. The post-induction PTH level was found to be significantly higher than the pre-induction level, and the percent change from post-induction to post-excision was also significantly higher than from pre-induction to post-excision PTH levels (Table 1). This is vital because the surgical decision-making operates on the principle of percent change in post-excision PTH level from the baseline PTH. In the current study 4% of the paired samples met the Miami criterion only with the post-induction sample and the surgery was considered successful after a $\geq$50% 10-min post-excision drop in PTH from post-induction levels. Serum calcium levels remained within normal range for at least 6-months post-operatively in all these cases. Use of a pre-induction sample as the pre-incision baseline measurement would have resulted into a possible unnecessary additional neck exploration due to a $\leq$50% 10-min post-excision drop. We recommend collection of pre-incision baseline PTH sample preferably 10 min after induction of anesthesia and positioning of the patients in order to prevent any factitious changes in the baseline level. A randomized trial did not show any difference between the PTH concentrations at 10 min post-induction in patients with primary hyperparathyroidism irrespective of the type of anesthesia (Propofol vs. Sevoflurane) [26].

A pre-excision PTH level drawn immediately before adenoma excision is also recommended as additional gland manipulation during surgery may significantly spike or drastically reduce PTH level due to devascularization of the gland. We found Miami criteria to be better than Vienna criteria for both pre-incision (pre- and post-induction) baseline PTH values. Overall, the post-induction PTH was the more reliable pre-incision baseline level for both Vienna and Miami criteria (Table 3). Carneiro-Pla suggests collecting samples in the operating room before the skin incision is made (pre-incision), before the blood supply to the suspicious gland is ligated (pre-excision), 5 min, 10 min, and occasionally 20 min after excision of the suspected abnormal gland [18]. As the turn-around time of the post-excision ioPTH sample largely determines the duration of the procedure, the faster the post-excision results are received, the more efficient is the operating room utilization and the duration of general anesthesia is reduced. The cost of the procedure also depends on rapid PTH assay used and the length of the turn-around time. We do not routinely draw 20-min post-excision sample for time constraints. As Rome and Halle [10] criteria are based on PTH estimation beyond 10-min post-excision, our study was not designed to evaluate their validity. This was the limitation of this study. All patients were operated under general anesthesia and the results cannot be extrapolated to local anesthesia. However, a baseline PTH level drawn 10 min after infiltration of local anesthetic and prior to intraoperative neck manipulation in patients operated should be an appropriate baseline that needs to be studied further.

This study was designed to identify optimal time and numbers of baseline PTH samples and we recommend drawing a baseline pre-incision PTH sample on the day of surgery at 10 min after induction of general anesthesia and neck manipulation and a second sample immediately before excision of parathyroid as the manipulation of the parathyroid tumor can dramatically decrease or increase the ioPTH level.

Ethical approval

Research Ethics Board University of Manitoba (H 2009:081).

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Author contribution

Lauren Garbutt; Study design, data collections, data analysis, writing.

Heather Sigvaldason: Data collections, data analysis, Mohammed H.T. Sharaf Eldin: Data collections, writing.

Tom Dembinski: Data collections, writing.

Richard W Nason: Writing.

Kumar A. Pathak: Study design, data collections, data analysis, writing.

Conflicts of interest

None.

Guarantor

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