

Evaluation of the ‘putative’ role of intraoperative intact parathyroid hormone assay during parathyroidectomy for secondary hyperparathyroidism. A retrospective study on 35 consecutive patients

Intraoperative iPTH assay during parathyroidectomy

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Received: 5 January 2012 / Accepted: 27 February 2012 / Published online: 16 March 2012
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Abstract In the surgical treatment of secondary hyperparathyroidism (2HPT) of chronic kidney disease (CKD), a parathyroidectomy (PTx) of 4 glands can only be presumed as ‘total’, and indications for autoimplantation are complex. Intraoperative rapid parathyroid hormone assay could be useful to predict a radical resection. We evaluated iPTH levels 20 min and 24 h after a 4-gland PTx in 35 patients to determine the predictive value of intraoperative iPTH assay. We analysed retrospectively 35 patients affected by 2HPT of CKD, 13 undergoing total parathyroidectomy (TP) and 22 TP + autoimplantation (TPai), after removing 4 glands in 33 cases and 5 glands in 2. Intact PTH assays were acquired after 40 min before induction of anaesthesia, after removing both ipsilateral glands, at 20 min after

surgery and on postoperative day 1. 20 min after 4-gland PTx, a decrease of iPTH levels >80 % of the preoperative value was observed in 27 of 35 cases (77.1 %) and <80 % in 8 of 35 cases (22.8 %). In 6 of these 8 patients, iPTH levels were within the normal range 24 h after surgery. Although the intraoperative iPTH assays are of interest in the treatment of 2HPT, the predictive value of this method is not entirely satisfactory. In fact, a 4-gland PTx ensures euparathyroidism in most cases, even when intraoperative iPTH assays are not trustworthy; however, intraoperative iPTH assay, although not a perfect ‘tool’, is a proved aid for the surgeon in making his decision.

Keywords Secondary hyperparathyroidism · Chronic kidney disease · Intraoperative intact parathyroid hormone assay · Total parathyroidectomy · Autoimplantation

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Introduction

The surgical treatment of secondary hyperparathyroidism (2HPT) of chronic kidney disease (CKD), associated in expert hands with minimal morbidity and excellent cure rates, is still a controversial issue under active research. Total parathyroidectomy (TP) with autoimplantation (TPai) and subtotal parathyroidectomy (sTP) are the procedures most frequently performed in order to restore an euparathyroid status and are associated with a variable rate of persistent or recurrent disease [1, 2]. TP is reserved for patients with aggressive forms of 2HPT, who are not on the waiting list for kidney transplantation, and it seems to be associated with a lower rate of long-term recurrence [3–6]. The extreme variability in the number and location of the

parathyroid glands, with hypertrophy of embryonic nests of parathyroid cells, especially in patients on dialysis, is responsible for the quite frequent cases of persistence or recurrence of disease. In case of 2HPT, the use of intraoperative quick intact parathyroid hormone (iPTH) assay, a standard of care procedure in the treatment of primary HPT [7], is still subject of research. In fact, the slow clearance of C-terminal PTH fragments in subject with CKD can lead to spurious elevation of iPTH results [8]. At present, according to Pitt [9], no consensus has been reached over the use of quick iPTH assay in 2 and 3HPT patients, and test implementation did not change current surgical strategy in 2HPT. Therefore, the utility of intraoperative iPTH monitoring in 2HPT remains questionable and its impact on operative management is still subject of study. Nevertheless, literature data showed that after a 4-gland parathyroidectomy (PTx), a decrease iPTH of >80 %, or equal to 10 % of the preoperative value, seems to be predictive of the effectiveness of the surgical procedure and, therefore, of remarkable assistance in determining a successful PTx, even though it causes the cost of treatment to increase significantly [10, 11].

We retrospectively report our results from a series of 35 patients who underwent surgery for 2HPT of CKD, after the removal of at least 4 hyperplastic parathyroid glands, in the attempt to evaluate the putative predictive value of intraoperative iPTH assay, in terms of successful PTx by measuring iPTH with the standard assay. Results were evaluated subsequently, and the rate of euparathyroidism was analysed. In other words, the results obtained with the standard measurement were utilized to calculate the rate of success. Twenty-two patients, all on the kidney transplant waiting list, underwent TPai, and 13, not on the waiting list, underwent TP. In every patient, an iPTH assay was assessed preoperatively, before the induction of anaesthesia, after the removal of 2 ipsilateral glands, 20 min after the removal of at least 4 glands, on postoperative day 1, and after a long-term follow-up (1 year). The aim of this study was to analyse the predictive value of intraoperative iPTH assay in determining surgical success by evaluating and comparing iPTH levels 20 min after TP and TPai, and on postoperative day 1.

Materials and methods

Data were collected from 35 consecutive patients (18♂ and 17♀), affected by 2HPT of CKD, on standard three times weekly hemodialysis, and observed between January, 2006 and 2009.

Patients' mean age was 52.02 ± 10.9 years, and the mean dialysis vintage was 8.4 ± 4.2 years.

Fifteen patients (42.85 %) suffered from coexisting thyroid pathology. All of the patients reported diffuse itching, arthromyalgia and mood alterations, while cardiovascular disease was found in 60 %. No cases of calciphylaxis were reported.

High-resolution ultrasound examination of the neck, ENT examination, technetium-99m-sestamibi scintigraphy of the neck and mediastinum were the main preoperative diagnostic procedures. Intact parathyroid hormone, serum calcium (Ca), serum phosphate (P), alkaline phosphatase (ALP) and FT3, FT4, TSH, thyroglobulin were measured along with fine needle biopsy of the thyroid nodules. Computed bone mineralometry (CBM), a whole body X-ray and a cardiologic testing were performed preoperatively and 12 months after surgery.

According to both K/DOQI 2003 guidelines and Tomi-naga [12, 13], PTH levels higher than 600 pg/mL, Ca levels higher than 10.2 mg/dL, serum phosphate levels higher than 6.5 mg/dL, a Ca \times P product higher than 55 and worsening symptoms resistant to medical therapy were considered indications for surgical treatment.

In every patient, the intraoperative iPTH level was acquired after 40 min, in 3 blood samples: the first, baseline (T0), before induction of anaesthesia; the second (T1), 10 min after the removal of two ipsilateral parathyroid glands and the third (T2), 20 min after the removal of the 2 contralateral glands. The day after surgery, iPTH and serum calcium levels were measured. An additional measurement was done after 1 year. The Liaison®N-Tact®PTH Assay (DiaSorin Inc-Stillwater, MN, USA), based on chemiluminescence immunoassay (CLIA), was used for the quantitative determination of iPTH (coefficient of variation: CV% intra assay 1.7–3.7; CV% inter assay 2.6–5.9; limit of detection 0.07 pmol/L). In the present series, following Barczynskis' criteria [14], a decrease of 80 % of iPTH baseline value at 20 min postoperatively was chosen as predictivity cutoff. Patients with a 20-min iPTH ≤ 10 % of the baseline value were also evaluated.

Concerning the surgical procedures, 13 patients underwent TP and another 22, on a kidney transplant waiting list, underwent total parathyroidectomy with autotransplantation (TPai) of 9–15 fragments of non-nodular glandular tissue, in 3 subcutaneous pockets of the non-dominant forearm.

In 15 of 35 patients (42.85 %) with thyroid gland disease, 12 total thyroidectomy and 3 hemithyroidectomy procedures were performed. Four parathyroid glands were always removed—confirmed via intraoperative histological examination—with the thyrothymic ligament and the thymic projections; the carotid sheaths were explored in order to rule out ectopic and supernumerary glands.

In only a few cases, a dialysis treatment was required immediately after surgery, due to an electrolyte imbalance.

The majority of patients required intravenous administration of calcium, due to severe postoperative hypocalcaemia (<1.99 mmol/L). Patients who underwent autoimplantation completed long-term follow-up monitoring iPTH from the implantation site and from the contralateral arm, to evaluate the gradients.

The range 1.06–6.89 pmol/L was taken as the reference range for normal intact PTH levels based on which eu-, hypo-aparathyroidism, and persistence or relapse of disease were determined.

Statistics

A unpaired student's *t* test was performed to compare means.

Results were analysed with the statistic software GraphPad Prism, Version 4.0 for Macintosh (GraphPad Software, San Diego, CA, USA). All results are presented as the mean values (SE).

Results

Mean preoperative iPTH was 158.64 ± 85.69 pmol/L (n.v. = 1.06–6.89 pmol/L), and the mean Ca level was 2.54 ± 0.35 mmol/L (n.v. = 2.09–2.54 mmol/L).

Surgical treatment produced a benefit in terms of itching, a substantial improvement in osteoarticular symptoms, an increase of muscular strength, and a substantial improvement first in mood patterns, and later in sleep disorders, associated with a statistically significant reduction in iPTH levels (Fig. 1).

None of the patients was found to be aparathyroid, and in case of severe hypocalcaemia, sometimes as low as ≈ 1.49 mmol/L, hypocalcaemic seizures were never observed.

The removed glands resulted hyperplastic; 2 patients (5.71 %) had 5 hyperplastic glands; 11 patients (31.42 %) had an associated multinodular goiter, 2 (5.71 %) an adenomatous goiter and 2 (5.71 %) a papillary carcinoma, which included one small papillary cancer (<1 cm).

All patients reported a dramatic decrease of intraoperative iPTH levels as a consequence of the removal of two ipsilateral parathyroid glands (Tables 1, 2).

Regarding intraoperative iPTH levels at 20 min, there was a >80 % reduction in 27 of 35 cases (77.1 %), 18/22 TPai pts and 9/13 TP pts. In 8 of 35 patients (22.8 %), 4 of whom had undergone TPai and 4 TP, there was a 20 min <80 % decrease of iPTH levels. In 19 of 35 patients (54.2 %), a 20-min iPTH level ≤ 10 % of the baseline value was observed.

Postoperative day 1 state of eu-hypoparathyroidism or persistent 2HPT relative to results of intraoperative iPTH

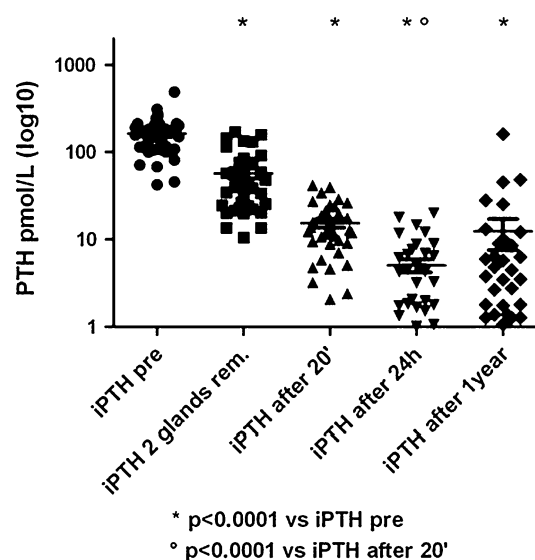


Fig. 1 iPTH levels pre (before surgery), 2 glands removed (after resection of two ipsilateral glands), after 20' (20 min after parathyroidectomy), after 24 h (on postoperative day 1) and after 1 year

level decrease (>80 , <80 % and ≤ 10 % of the baseline value) is reported in Table 3. Even if a higher eu-parathyroidism rate was achieved in ≤ 10 % of iPTH baseline value cases, a similar postoperative 24 h persistent hyperparathyroidism (≈ 20 %) was observed in the three groups of patients (>80 %, <80 % and ≤ 10 % of the baseline value).

Irrespective of the type of surgery, the values were even lower postoperatively after 24 h in 34 of 35 cases.

Immediate (on postoperative day 1) and 1-year TP/TPai results are reported in Tables 4 and 5. A similar immediate (postoperative day 1) postoperative hypoparathyroidism rate was observed after TP/TPai in patients undergoing thyroidectomy.

No significant peri- or postoperative complications were observed.

Nineteen patients (54.28 %) required intravenous administration of calcium gluconate due to hypocalcemia (<1.99 mmol/L), seldom severe, with a minimum value of 1.42 mmol/L, but notwithstanding never associated with hypocalcemic seizures.

Seven of 35 patients (20 %), 2 TPai, successfully underwent renal transplantation.

One year later, CBM and skeletal X-rays showed an important decrease of osteodystrophy in all of the patients, irrespective of the procedure carried out. Long-term pathological fractures were not reported.

Discussion

2HPT largely impacts the quality of life in patients affected by CKD and is associated with a high-mortality rate,

Table 1 Age, hemodialysis (HD) vintage, calcium and iPTH levels after TPai (22/35 patients)

Age (years)	HD vintage (years)	Preoperative		Intraoperative		Postoperative		Ca ²⁺ postop day 1	Number of removed hyperplastic glands	
		Ca ²⁺ (mmol/L)	iPTH (pmol/L)	iPTH ^a	iPTH ^b (pmol/L)	iPTH ^c	iPTH ^d (pmol/L)			
Means (±SE)	52 ± 2.4	7.9 ± 0.8	2.55 ± 0.08	169.33 ± 18.18	68.08 ± 10.87	15.14 ± 2.14	5.11 ± 1.02	16.41 ± 7.45	2.02 ± 0.06	4

TPai total parathyroidectomy plus subcutaneous autoimplantation, HD hemodialysis

^a iPTH levels after 2 glands removed

^b iPTH levels 20 min after TPai

^c Postoperative day 1 iPTH levels after TPai

^d iPTH levels 1 year after TPai

Table 2 Age, hemodialysis (HD) vintage, calcium and iPTH levels after TP (13/35 patients)

Age (years)	HD vintage (years)	Preoperative		Intraoperative		Postoperative		Ca ²⁺ postop day 1	Number of removed hyperplastic glands	
		Ca ²⁺ (mmol/L)	iPTH (pmol/L)	iPTH ^a	Iph ^b (pmol/L)	iPTH ^c	iPTH ^d (pmol/L)			
Means (±SE)	53 ± 3.2	9.3 ± 1.4	2.55 ± 0.09	153.73 ± 23.12	37.24 ± 7.42	15.70 ± 3.07	4.88 ± 1.59	5.51 ± 2.12	2.07 ± 0.09	4.2 ± 0.1

TP total parathyroidectomy, HD hemodialysis

^a iPTH levels after 2 glands removed

^b iPTH levels 20 min after TP

^c Postoperative day 1 iPTH levels after TP

^d iPTH levels 1 year after TP

Table 3 Postoperative day 1 state and 20 min iPTH levels

20' iPTH level	No. pts	I° p.o.	%
>80 % b.v. ^a	27/35	15 Eu	55
		6 Pers	22.4
		6 Hypo	22.4
<80 % b.v. ^a	8/35	5 Eu	62.5
		2 Pers	25
		1 Hypo	12.5
≤10 % b.v.	19/35	15 Eu	78.94
		4 Pers	21.06

b.v. iPTH baseline value, *Eu* euparathyroidism, *Hypo* hypoparathyroidism, *Pers* persistent 2HPT

^a iPTH reduction of the baseline value

Table 4 iPTH levels after TP

	Eu (%)	Hypo (%)	Persistence (%)	Relapse (%)
20'	23.07	–	76.9	–
1 p.o.	61.5	23.07	15.38	–
1 year	61.5	23.07	7.69	7.69

20' iPTH levels 20' min after TP, *I p.o.* iPTH levels 24 h after TP, *1 year* iPTH levels 1 year after TP, *Eu* euparathyroidism, *Hypo* hypoparathyroidism

Table 5 iPTH levels after TPai

	Eu (%)	Hypo (%)	Persistence (%)	Relapse (%)
20'	18.18	–	81.81	–
1 p.o.	54.54	18.18	27.27	–
1 year	54.54	4.54	18.18	22.7

20' iPTH levels 20' min after TPai, *I p.o.* iPTH levels 24 h after TPai, *1 year* iPTH levels 1 year after TPai, *Eu* euparathyroidism; *Hypo* hypoparathyroidism

especially because of untractable cardiovascular complications [15–17].

Surgery, required in approximately 1–2 % of patients each year [18], can offer a higher long-term survival rate as well as a better quality of life, also improving bone mineral density [2, 5, 12, 13, 19]. At present, the intraoperative quick iPTH measurement is very useful in determining surgical cure of primary hyperparathyroidism when a fall of intraoperative iPTH by 50 % occurs after 15 min [20]. In the same way, in the treatment of 2HPT, the rapid assay is characterised by a considerable diagnostic accuracy and, when the cut-off exceeds by 80 %, or when the final iPTH level is 10 % of the baseline value, it may be predictive of successful surgery. The predictive value of quick iPTH assay, according to the published reports, can differ a lot among series. According to Lorenz and Dralle [21],

72 pg/mL at 15 min is adequate, while Chou et al. [22] reports a decrease >85 % of the baseline value at 30 min, Koeberle-Wuehrer et al. [23] of 77 %, Matsuoka et al. [24] a value as low as 10 % of the baseline value at 10 min, Lokey et al. [25] a drop of <50 % at 20 min, Seehofer et al. [26] an iPTH level ≤150 pg/ml or down to 30 % of baseline at 15 min, Weber et al. [27] a postoperative reduction of at least 90 % of baseline at 15 min after PTx, and Barczynski et al. [14] a decrease of >80 % at 20 min postoperatively. The anaesthetic technique has also an impact on intraoperative iPTH measurement, and the first baseline assay should be drawn before induction of anaesthesia [28].

However, the use of the assay method, also reducing neck exploration time, leads to a significant increase in terms of costs due to the price of the necessary equipment and kits.

The aim of the present study was to analyse the predictive role of intraoperative iPTH assay in determining a successful PTx and in modifying surgical strategy in 2HPT. According to our results, in some patients with a <80 % baseline iPTH level decrease, in which a further neck exploration should be indicated, a eu-parathyroid state was achieved 24 h after surgery. Therefore, extensive neck dissection, based only on the intraoperative assay, would have been vain.

Study results lead to the following observations.

A cautious neck exploration permits PTx of 4 glands, which was associated with good functional outcomes in our hands.

Rapid iPTH measurement can be of great assistance in confirming whether a PTx for 2HPT is really 'total'. When the iPTH decrease at 20 min is <80 % of the preoperative level, accessory glands should be suspected and a further neck exploration should be considered.

If values of iPTH up to 26.52 pmol/L are considered acceptable in the immediate postoperative period, in the treatment of 2HPT [29], all the patients in our series could be considered cured by surgery (Tables 1, 2). In this case, even a reduction of iPTH of <80 % at 20 min can be predictive of successful treatment.

In light of these data, and considering that in some cases there are 3 parathyroid glands (≈3 %), or there might be a difficult to access supernumerary gland (≈13 %), rapid iPTH assays can help to indicate whether PTx is successful and whether autoimplantation is required, avoiding useless and debilitating neck dissection. However, when the iPTH does not drop of >80 % under the preoperative level, it is debatable if a more extensive neck exploration may be useful in every case.

Sometimes, a further decrease of iPTH levels is reported even after 20 min, and probably a further additional assay should be recommended [22]. Therefore, the indication to look for a supernumerary gland implied by the iPTH value obtained at 20' could be misleading.

The small number of the observed patients and retrospective data were the main limits of present analysis.

Additional studies are needed to confirm the role of intraoperative iPTH assays, and to establish the reference values on the basis of which 4-gland PTx can be considered successful.

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