

Surgical Management of Primary Hyperparathyroidism in the Era of Focused Parathyroidectomy: A Study in Tertiary Referral Centre of North India

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Abstract

Background: Despite the benefits of focused parathyroidectomy (FPTx), few studies have questioned its durability with lower long-term cure rates than bilateral or conventional parathyroidectomy (CPTx). The objective of this study is to bring out the information on the type of surgical management versus cure rate, recurrence, and role of intra-operative parathyroid hormone (IOPTH) level monitoring of PHPT patients. **Material and Methods:** This was a retrospective study of all PHPT patients treated at our center based on operative approach (CPTx vs FPTx) or use of IOPTH. Treatment failure was divided into persistent or recurrent disease, based on documentation of hypercalcemia in combination with an inappropriate PTH within 6 months or more of surgery, respectively. **Results:** Overall, 50.78% patients underwent CPTx and 49.32% FPTx. 29 FPTx were converted to CPTx. Intention to treat analysis between CPTx and FPTx showed that the persistence rate was not statistically different at 2.54% and 4%, respectively ($P = 0.98$). Furthermore, when the persistence rate was scrutinized by a treatment received (TR) instead of ITT analysis, the persistence rate was higher for the patients who underwent TR-CPTx than for the patients subjected to TR-FPTx (3.22% vs 1.08%) but not significant statistically. We further analyzed the outcome of FPTx with IOPTH ($n = 213$) and FPTx without IOPTH ($n = 28$). The outcome did not differ between two groups statistically. **Conclusion:** FPTx yields a similar success rate as compared to CPTx even in symptomatic PHPT patients and can be performed safely even without intra-operative adjunct IOPTH in selected patients.

Keywords: Intra-operative PTH, parathyroidectomy, primary hyperparathyroidism

INTRODUCTION

Primary hyperparathyroidism is classically a symptomatic disease with “stones, bones, moans and groans”. However, the advent of a multichannel biochemical screening test in the early 1970s led to the clinical revolution of PHPT with recognition of a new entity of asymptomatic PHPT in the west.^[1] In the developing world most of the cases are still diagnosed only in symptomatic stage.^[2-6] Surgery is the only curative treatment available since the time of first successful parathyroidectomy performed by Felix Mandl in Vienna in 1925.^[7] This first surgery was a bilateral neck exploration (CPTx) and excision of single enlarged gland was performed, but patient had recurrent disease 6 years later and succumbed to the hypercalcaemic crisis.^[8] Surgery for PHPT has evolved over the time and also evolved back at few centers.

CPTx is considered the gold standard for PHPT. With the cure rate of 99.5%, the operative mortality 0.3%, persistent

vocal cord paralysis 0.8%, and permanent hypocalcemia 0.3%, it was surgery of choice till 1990s.^[9] Unilateral neck exploration (UNE) came into picture in 1980s, but initially it was not accepted widely due to less reliable localization studies. Minimally invasive surgical approach is now possible with the quality of non-invasive preoperative imaging techniques and rapid intra-operative PTH assays.^[10-14] It was reported that CPTx for all parathyroid patients is an operation for the history books.^[15] Focused approach became the standard of care in 2000s.^[16] Despite the benefits of focused

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parathyroidectomy (FPTx), few studies have questioned its durability with lower long-term cure rates than bilateral or conventional parathyroidectomy (CPTx).^[17]

The objective of this study is to bring out the relevant information on type of surgical management versus cure rate, recurrence, and role of intra-operative parathyroid hormone level monitoring of PHPT patients managed at our Institute over last 28 years.

MATERIAL AND METHODS

This was a retrospective study of all PHPT patients treated in the Department of Endocrine surgery, SGPGIMS, Lucknow between January 1990 to December 2017. The evaluation and diagnostic protocol at our institute has been published in our previous publications^[3,18,19] and [Doc S1]. The patient cohort was divided into 2 groups, based on operative approach (CPTx vs FPTx) or use of IOPTH (Intraoperative parathyroid hormone monitoring) vs. no use of IOPTH. All Patients with PHPT with a minimum follow up of 6 months between January 1990 and December 2016 were included and patients for whom all required data were not available, parathyroid adenomas detected incidentally during thyroidectomy, Multiple endocrine neoplasia patients, parathyroid carcinoma patients, secondary primary hyperparathyroidism, and tertiary hyperparathyroidism patients were excluded. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Approval from Institutional ethics committee was obtained on 3rd Feb 2017.

Statistical analyses

All statistical analyses were performed using SPSS (version 16.0; SPSS Inc, Chicago, Illinois). The data are expressed as means SD, except for data those do not have a normal distribution, which are expressed as median (range). Variables were tested for normality using the Kolmogorov-Smirnov Z statistic. Parametric and nonparametric tests were used as required to see the significance.

RESULTS

A total of 408 patients underwent parathyroidectomy in our department during the study period, and 373 of them were included in the present study. Patients with parathyroid carcinoma, parathyroid adenomas detected incidentally during thyroidectomy and multiple endocrine neoplasia were excluded.

Prevalence and clinical presentation

Over the past 27 years 265 women (median age 49 years; range 12–70 years) and 108 men (median age 52 years; range 13–75 years) underwent parathyroidectomy. The clinical profile of the patients is summarized in Table S1. Symptomatic patients ($n = 341$, 91.42%) still predominate in Indian setting and most of the patients present with bony pain (88.26%) followed by proximal myopathy ($n = 277$, 81.23%), renal stones ($n = 134$, 39.29%), and fractures ($n = 101$, 29.61%).

Palpable neck mass was present in 17.59% of the patients and 54 patients (15.83%) presented with hypercalcaemic crisis.

Some form of localization was undertaken in all patients. Overall, 358 patients had high resolution ultrasonography of the neck, 347 patients underwent SestaMIBI scan and six patients had contrast enhanced computed tomography of the neck. The sensitivity and positive predictive value for sestamibi scintigraphy were 86% and 94%, respectively, whereas ultrasonography had 80% and 88%, respectively.

Surgical management

50.78% ($n = 189$) patients underwent CPTx and 49.32% ($n = 184$) FPTx. 29 FPTx were converted to CPTx. Eight procedures were performed under regional anesthesia and frozen section biopsy was utilized in 58.98% ($n = 220$) cases. Rate of temporary recurrent laryngeal nerve palsy (RLN) was 3.21% and permanent RLN palsy was 0.53%. The median hospital stay was 8.6 +/- 4 days [Table 1]. The overall cure rate was 97.31% ($n = 363$). Eight patients had persistent disease and two patients had recurrent disease.

Surgical approach and outcome

To investigate outcome based on operative approach, 2 groups was formed on the basis of ITT (Intention to treat) analysis and they comprised 213 ITT-FPTX cases, including 29 conversions, and 157 ITT-CPTX cases. Baseline characteristics and operative data showed that the patient age was similar between the 2 groups, mean serum calcium and ALP levels were higher in the ITT-CPTX group. This analysis showed that the persistence rate was not statistically different at 2.54% and 4%, respectively ($P = 0.98$) [Table 2]. Furthermore, when the persistence rate was scrutinized by a treatment received (TR) instead of ITT analysis, rate of persistent PHPT was higher for the patients who underwent TR-CPTX than for the patients subjected to TR-FPTX (3.22% vs. 1.08%) but the difference was not significant statistically [Table 3].

IOPTH and outcome

Cure rate did not differ significantly whether IOPTH was used or not. Out of 247 cases when IOPTH was used, 233 had curative

Table 1: Surgery and complications

	Frequency (Percentage)
CPTx	160 (42.89)
FPTx	184 (49.32)
FPTx->CPTx	29 (07.77)
Failures	10 (2.68)
Regional Anaesthesia	8 (02.14)
FSB	220 (58.98)
IOPTH	247 (66.21)
RLN palsy (temp)	12 (03.21)
RLN palsy (perm)	2 (0.53)
Hypoparathyroidism (temp)	38 (10.00)
Wound infection	11 (02.94)
Plueral injury during block	1 (0.26)
Hospital Stay (days)	8.6+/-4.7

Table 2: Intention to treat analysis CPTx Vs FPTx

	ITT CPTx (n=157)	ITT FPTx (n=213)	P
Age	42.66 (SD 18.4)	45.5 (SD 15.3)	0.11
Sex (M:F)	1:2.16	1:2.22	0.96
Parathyroid hormone level (11-55 pg/mL)	812.89 +/- 782.48	735.74 +/- 444.98	0.23
Serum Calcium level (8.5-10.8 mg/dL)	12.85 +/-1.54	12.30 +/- 1.67	0.004
Alkaline Phosphatase level (35-150 IU/L)	865 +/- 1150	514.8 +/- 318.89	0.001
Serum Creat (0.5-1.6 mg/dL)	1.4±0.6	1.2±0.6 0.87	0.6
S. Vit D (50-250 ng/dL)	14.31 +/- 7.61	19.16 +/- 14.12	0.3
Median weight of gland resected (mg)	6,717±1,265	4,848±630 0.173	0.13
Persistent/Recurrent Disease	4 (2.54)	4 (4.03)	0.98

Table 3: Persistent disease according to actual treatment received group

	TR CPTx (n=186)	TR FPTx (n=184)	P
Age	39±15	40±14	0.43
Sex (M:F)	1:2.16	1:2.22	0.96
Parathyroid hormone level (11-55 pg/mL)	823.11 +/- 682.48	791.74 +/- 564.98	0.23
Serum Calcium level (8.5-10.8 mg/dL)	12.63 +/-1.54	12.12 +/- 1.67	0.04
Serum Creat (0.5-1.6 mg/dL)	1.3±0.6	1.2±0.6 0.87	0.6
Median weight of gland resected (mg)	5976±1,265	4356±630	0.13
Persistent/Recurrent Disease	6 (3.22%)	2 (1.08%)	0.258

fall, according to Miami criteria. But one patient out of this 233 continued to have hypercalcaemia (persistent disease). Fourteen patients did not have a curative fall in IOPTH, out of which 10 patients were cured [Figure 1]. Overall sensitivity, positive predictive value and accuracy was 95.87%, 99.57%, and 95.55% respectively. IOPTH was false negative in 10 cases and true positive in 04 cases. IOPTH correctly predicted cure in 95.5% and persistence in 1.6%. Overall three cases had unnecessary conversions due to non-curative fall in IOPTH and four cases were converted and cured due to non-curative fall in IOPTH.

We further analyzed the outcome of FPTx with IOPTH (n = 213) and FPTx without IOPTH (n = 28). The outcome did not differ between two groups statistically. Two patients had persistent disease and one had recurrent disease in the group where IOPTH was used as compared to no failures in the group without IOPTH [Table S2]. However, patients who underwent FPTx without IOPTH had 100% concordance (anatomical and functional) as compared to the group who underwent FPTx with IOPTH which had 78% concordance rate.

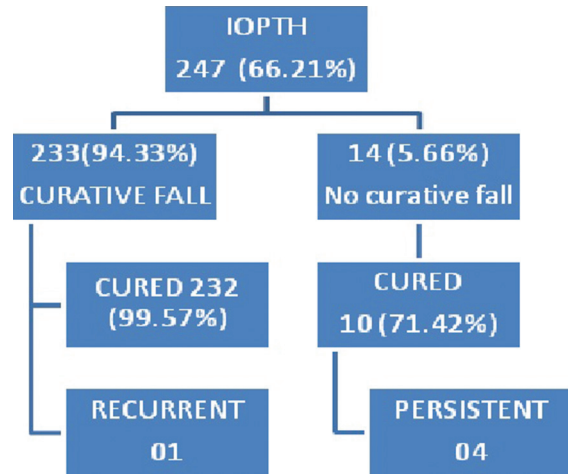


Figure 1: Summary of IOPTH during parathyroid surgery

DISCUSSION

We have previously reported the unique clinical characteristics of PHPT from India.^[3] Indian primary hyperparathyroidism patients with parathyroid carcinoma do not differ in clinico-investigative characteristics from those with benign parathyroid pathology.^[18] Similar findings have been reported from other centers from developing countries.^[20-23] This study too has brought out similar findings with regard to younger age of presentation, high rate of palpable neck mass (17.59%), and the high incidence of hypercalcaemic crisis (15.83%) in benign PHPT. The exact cause of this type of presentation is still elusive. Suboptimal Vitamin D nutrition is linked with parathyroid adenoma growth^[24] and vitamin D deficiency in this part of the world may be a causative factor. Another theory is increased awareness in western countries^[25] but only increased awareness cannot explain the drastically opposite presentation of PHPT in developing countries.

There are no two thoughts on the surgical management as the only curative modality for the symptomatic PHPT. However, world literature is somewhat divided on the extent of surgical exploration. Norman *et al.* have questioned the utility of limited explorations and pointed it to be suitable for only a minority of PHPT cases.^[17] Their long term follow up study showed that Regardless of surgical adjuncts (scanning, intra-operative parathyroid hormone), unilateral parathyroidectomy will carry a 1-year failure rate of 3% to 5% and a 10-year recurrence rate of 4% to 6%. Allowing rapid analysis of all 4 glands through the same 1-inch incision has caused them to abandon unilateral parathyroidectomy. Norlen *et al.* performed a multicenter retrospective study to look for the best surgical approach for PHPT.^[26] The patient cohort was divided into 2 groups, FPTx and CPTx, based on intention-to-treat analysis the primary outcome measure was the persistence of PHPT. A total of 4569 patients (3585 females) were included. The overall persistence and recurrence rates were 2.2% and 0.9%, respectively, after a median follow-up of 6.5 years. There were 2531 FPTx cases and 2038 CPTx cases. The long-term recurrence rate was not different (5-year, 0.6% vs. 0.4%,

log-rank $P = 0.08$). However, complications were more common in CPTx than in FPTx (7.6% vs. 3.6%, $P < 0.001$). In our study the overall persistence and recurrence rates were 2.14% and 0.53%, which is similar to the world literature. Surgical outcome did not differ between CPTx and FPTx groups and complication rates were also non-significant. Several other groups have also examined their results with surgical exploration and outcomes and their results are similar to our findings.^[27-30] Most of these studies are from developed countries where the clinical profile of PHPT patients is totally different^[31] as compared to developing world. Although clinical profile of PHPT is changing in the developing world^[19] but it continues to be a symptomatic disorder with skeletal, renal and metabolic complications at a much younger age.^[3,18,21-23,32-35] Most of the studies demonstrating non-superiority of CPTx over FPTx have been done in a patient population where the majority of the cases are asymptomatic screen detected PHPT. Our study is probably the first study done in symptomatic PHPT with severely deranged biochemical profile, showing comparable results with CPTx and FPTx. Additionally, use of IOPTH did not influence the outcome in FPTx group. FPTx can be safely performed in resource limited settings where IOPTH is not available.

Reason for prolonged hospital stay at our center (8.6+/-4.7 days) as compared to developed countries is lack the of robust primary health care system. We discharge our patients only when their serum calcium comes up to within normal limits with oral calcium supplements.

CONCLUSION

FPTx yields a similar success rate as compared to CPTx even in symptomatic and young PHPT patients and can be performed safely even without intra-operative adjunct IOPTH in selected patients.

Limitations

The retrospective nature of the study is a major limitation in itself and lack of long-term follow up data for patients operated in the current decade is another limitation. Results of FPTx has been compared with CPTx group which includes a retrospective cohort when FPTx was not being performed at our center. This may introduce an inherent bias.

Informed consent

Informed written consent was obtained from the patient.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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SUPPLEMENTAL Doc S1

Surgical management protocol

Over the past 28 years total seven surgeons have been operating on these patients, but the usual departmental protocol is followed by them regarding the extent of exploration. Our departmental protocol prior to the year 2000 was conventional four gland exploration. This involved visual identification of at least four parathyroids and excision of enlarged glands. No intraoperative adjuncts were used during this time period. After the year 2000 departmental protocol changed to conventional four gland exploration only if both the anatomical and functional imaging (ultrasound/computerized tomography [CT] and Tc99 m sestamibi scans) of the neck were discordant. If the results of these two imaging techniques are concordant, we use a focused, lateral, minimally invasive approach, except when large palpable tumors are detected, in which case standard unilateral exploration is done. A few endoscopic (total endoscopic and video assisted) procedures were carried out as part of surgical workshop; hence, such procedures are not part of department protocol. The follow-up protocol included biochemical evaluation (S calcium, phosphorus, and alkaline phosphatase). All the patients who attained postoperative normocalcemia were defined as cured. Persistent disease was defined as failure to attain normocalcemia, postoperatively. Patients who became hypercalcemic 6 months after a curative surgery were defined as having recurrent disease.

Table S1: Overall clinical profile

Presentation (n=373)	Number	Percentage
Asymptomatic	32	8.58
Symptomatic	341	91.42
Proximal myopathy	277	81.23
Bone pain	301	88.26
Fractures	101	29.61
Renal Stones	134	39.29
Pancreatitis	27	7.91
Hypercalcaemic crisis	54	15.83
Nueropsychiatric Symptoms	57	16.71
Palpable Neck mass	60	17.59
Median weight of excised Adenoma	3600 mg	20-63000 mg (Range)
Hyperplasia	18	4.82
Double Adenoma	6	1.6
Atypical adenoma	14	3.74

Table S2: FPTx with or without IOPTH

	Group 1 (without IOPTH)	Group 2 (with IOPTH)	P
	28 (15%)	151 (85%)	
Persistent Disease	0	2 (1.32%)	NS
Recurrent Disease	0	1 (0.66%)	NS
Concordance	100%	78%	