

Focused Parathyroidectomy Under Local Anesthesia – A Feasibility Study

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Abstract

Purpose: We conducted this study to evaluate the feasibility, patient satisfaction, and cost of performing focused parathyroidectomy under local anesthesia (LA) and mild sedation, administered and monitored by a surgeon. **Materials and Methods:** This was a prospective observational study of 30 patients with primary hyperparathyroidism (PHPT) undergoing a focused parathyroidectomy under LA and mild sedation at a single institution. The clinical features, gland weight, operating time, procedure time, postoperative pain scores, overall patient satisfaction, postoperative nausea and vomiting, analgesic requirements, complications, cost, and cure rates were documented. Data were analyzed using SPSS software version 17.0. **Results:** In two patients (6.7%), the procedure had to be completed under general anesthesia (GA). Postoperative temporary hypocalcemia was witnessed in 14 of 30 (46.7%), but only 1 required intravenous calcium infusion. About 21 of 30 (75%) were completely satisfied with LA, whereas 25 of 30 (89%) were completely satisfied with surgical procedure. Furthermore, all patients were keen to recommend this procedure under LA to their friends and family. Comparing the cost between performing the procedure under LA with that under GA, a significant difference was witnessed ($P = 0.001$). Among the 26 patients reviewed at 6 months, all had a normal serum calcium and parathyroid hormone levels indicating 100% cure rate. **Conclusion:** Performing focused parathyroidectomy under LA is feasible; additionally, this method can significantly reduce the cost of the procedure ($P = 0.001$).

Keywords: Focused parathyroidectomy, local anesthesia, minimally invasive parathyroidectomy, primary hyperparathyroidism

INTRODUCTION

In India, primary hyperparathyroidism (PHPT) is a commonly misdiagnosed condition. Routine calcium screening is not an established protocol across the country resulting in late presentation of patients with severe symptoms and an advanced disease.^[1-5] The majority (85%–90%) of PHPT in India are due to a single-gland disease, the adenoma being large and easily identifiable during surgery.^[2,3] Surgery is the treatment for PHPT, and focused parathyroidectomy has become the preferred modality in patients with a single-gland adenoma. This approach avoids unnecessary dissection of normal parathyroid glands. It is performed in patients who have a preoperative concordant imaging on at least two imaging modalities. This shift from cervical exploration to a minimally invasive procedure for the surgical treatment of a single gland disease has resulted in shorter duration of surgery, reduced postoperative pain, decreased morbidity, and hospital stay.^[6] Although these changes have benefitted

patients, there are other concerns that need to be addressed in low middle-income countries. These include the manpower constraints in trained anesthetists, availability of theater time, and the distance a patient needs to travel to attain reliable medical/surgical treatment, the expense for which is borne by them. Also, for a select group of patients in whom general anesthesia (GA) may be contraindicated or associated with a high risk, performing this procedure under local anesthesia (LA) may be the only solution. Therefore, we conducted this study to evaluate the feasibility, patient satisfaction, and cost of focused parathyroidectomy under LA and mild sedation administered and monitored by a surgeon.

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MATERIALS AND METHODS

Following approval by the institution review board and ethics committee, a prospective observational study of patients diagnosed with PHPT and undergoing a focused parathyroidectomy under LA between 1st October 2015 and 30th September 2016 was conducted.

Diagnosis of PHPT and management protocol

Patients with elevated serum calcium (>10.4 mg/dL; reference range: 8.2–10.4 mg/dL), low/low normal phosphorous (reference range: 2.5–4.6 mg/dL), and an inappropriately elevated parathormone (>74 pg/dL; reference range: 8–74 pg/dL) were diagnosed to have PHPT. These patients underwent ^{99m}Tc sestamibi scan and an ultrasound of the neck to localize the offending parathyroid lesion. Concordance in imaging was recorded when scintigraphy features were identical with anatomical imaging in site and number. Patients with concordant imaging, a body mass index ≤35, body habitus permitting adequate surgical exposure, and willing to undergo the procedure under LA were included in the study, whereas those with known allergies, sleep apnea, previous surgery in neck for disorders of the thyroid or parathyroid, and patients with clinical suspicion of parathyroid carcinoma were excluded.

Biochemical estimation

The biochemical estimation of serum calcium, phosphorous, and albumin was performed using photometric method (modular P800 automated analyzer; Roche, Germany), and intact parathyroid hormone (iPTH) was estimated by chemiluminescence (ADVIA centaur centre; Siemens).

Anesthesia protocol

All patients who consented for the study were counseled preoperatively with regard to the type of anesthesia and surgical procedure. They received 5 mg of diazepam and 20 mg of omeprazole as premedication in the ward followed by either injection diclofenac 75 mg or injection paracetamol 1 g in 100 mL of normal saline as an infusion (based on renal function tests). The availability of the duty anesthesiologist was checked in case there was any need during the surgery. The required equipment for resuscitation was checked and made available. All patients were monitored for saturation, heart rate, and electrocardiography intraoperatively.

Administration of the local anesthetic through superficial cervical block, mild sedation, and intraoperative monitoring was performed by the surgical team. The total dose of lignocaine permitted for a patient was calculated based on the patient's weight (4.5 mg/kg). This volume was divided between superficial cervical block and infiltration of the surgical site. A combination of 0.2% bupivacaine (2.5 mg/kg) and 2% lignocaine in a 1:1 ratio was infiltrated at the midpoint of the lateral border of the sternocleidomastoid muscle in cranial, caudal, and horizontal directions along the lateral border of the muscle for superficial cervical block. The patient was then sedated with 1 mg of midazolam and 25 µg of fentanyl.

The remaining volume of lignocaine was mixed with an equal volume of normal saline and this mixture was used for infiltration of the surgical site. Initially, 6–8 mL of this combination was infiltrated at the site of the incision. Once the incision was made and subplatysmal flaps were raised, a further 2–4 mL was infiltrated into the fascia between the sternocleidomastoid muscle and strap muscles. Additional infiltration of the surgical site and sedation with midazolam (up to 3 mg) and fentanyl (up to 100 µg) were performed when required. The total amount of local anesthetic, fentanyl, and midazolam used for each patient was recorded.

Operative procedure

Focused parathyroidectomy was performed by the lateral approach described by Agarwal *et al.*^[7] In brief, the steps of the procedure are as follows: after administration of local anesthetic and superficial cervical block, the skin was incised over the site of the parathyroid lesion and subplatysmal flaps were raised. The fascia over the medial border of the sternocleidomastoid muscle was opened and a space between this muscle and the strap muscles was created till the common carotid artery was identified. The thyroid lobe was then identified and retracted medially. The enlarged parathyroid gland was identified and dissected off the thyroid ligating its feeding vessels. After achieving adequate hemostasis, the wound was closed in layers.

Intraoperative adjuncts such as intraoperative PTH and intraoperative neuromonitoring are not performed for thyroid or parathyroid operations at our institution and were not used in this study either. Once the gland was removed, its weight was checked using a weighing scale. At the end of the procedure, the scar size was recorded at the time of skin closure. The “operating time” was calculated from the time of skin incision to skin closure. In the recovery bay, intraoperative pain experienced was assessed and documented. Pain score assessment was performed using the Visual Analogue Score (VAS; 0–10, 10 being worst pain). Also, the total duration of procedure – the “procedure time” – was measured from the “time out” done just prior to surgery to the end of the procedure when the patient was shifted out of theater. Finally, the overall patient's satisfaction with anesthesia and surgery were evaluated at end of the procedure on a score of 1–5, with 5 being most satisfied. All patients were also asked whether they would recommend this procedure to their friends or family (yes or no response), which was also an indicator of satisfaction with the procedure. All the recordings mentioned above were performed by the same individual.

Postoperative period and follow up

In the postoperative period, the presence of nausea and vomiting was documented. Serum calcium, phosphorous, albumin, and PTH were checked for all patients the day after the surgery, serum calcium and phosphorous alone being repeated on the second day after surgery. Patients were monitored for symptoms and signs (Chvostek's or Trousseau's) of hypocalcemia. Symptomatic patients were initiated on oral calcium carbonate

and active vitamin D supplements. Intravenous infusion of calcium was administered for patients with severe symptoms or those who developed spontaneous carpal spasms. Once there was improvement of symptoms and an increase in serum calcium, they were discharged. Postoperative hypocalcemia was defined as patients with symptoms/signs of hypocalcemia or those in whom postoperative corrected calcium was < 8 mg/dL. Patients were reviewed in the outpatient clinic 1 week later with a serum calcium and phosphorous. The development of postoperative hematoma, recurrent laryngeal nerve injury, and wound infection, if any, were documented. Patients in whom the postoperative PTH failed to fall more than 50% compared with the preoperative value with persistently elevated corrected serum calcium the day after surgery were documented as a failed procedure. Finally, the total duration of stay in hospital and the total cost incurred were noted. A cost analysis was performed between patients who underwent parathyroidectomy under LA and those under GA. The cost analysis included the bed and nursing charges for the entire duration of hospital stay, the operation fee, anesthesia charges, and theater charges. Patients were reviewed 6 months after surgery. Those in whom PTH, calcium, and phosphorous were within the laboratory reference range at 6 months review were deemed cured.

Statistical analysis

The SPSS software version 17.0 was used for all statistical analysis. For continuously distributed data, descriptive statistics were presented, whereas for categorical data the number of observation and percentage were presented. Based on the normality of data, *t*-test or nonparametric Mann–Whitney test was performed.

RESULTS

Demography

A total of 65 patients were diagnosed with PHPT during the study period. Eight underwent unilateral exploration, six underwent bilateral cervical exploration, whereas three patients underwent total thyroidectomy along with parathyroidectomy for a suspicious thyroid nodule. Eighteen patients underwent focused parathyroidectomy under GA, whereas the remaining 30 underwent focused parathyroidectomy under LA with mild sedation. The demographic and clinical profiles of the 30 patients operated under LA are depicted in Table 1. Among the 30, a majority (63.3%) presented in the third and fourth decades. Histopathology was reported as adenoma in 28 and atypical adenoma in 2. The gland characteristics, scar size, duration of procedure, and length of hospital stay are depicted in Table 2.

Postoperative pain and nausea

On VAS, the median pain score on the first 2 postoperative days was 2 (1–4) and 2 (1–2), respectively. None of the patients developed postoperative nausea or vomiting.

Analgesic and sedation requirements

Table 3 depicts the median dosages of analgesic and sedation used during the procedure.

Table 1: Demographic and clinical profile of patients with PHPT operated under LA

| | |
|---------------------------------|--------------------------------------|
| Median age (range) | 42.6 ± 15 years (19-80 years) |
| Gender (M:F) | 19:11 |
| Presenting symptom | No. of patients (%) |
| Renal/ureteric calculi | 19 (63.3%) |
| Bone pain/pathological fracture | 8 (27%) |
| Osteoporosis on BMD | 9 (30%) |
| Myalgia/fatigue | 8 (27%) |
| Psychiatric disturbances | 4 (13%) |
| Pancreatitis | 3 (10%) |
| Acid peptic disease | 5 (16.7%) |

PHPT: Primary hyperparathyroidism; LA: Local anesthesia; BMD: Bone mineral density

Table 2: Gland characteristics, scar size, duration of procedure, and length of hospital stay

| | |
|----------------------------|---------------------------|
| Variable | Value |
| Gland size (range) | 2.4 ± 0.93 (1-4.2 cm) |
| Gland weight (range) | 2.52 ± 2.11 g (0.2-8.7 g) |
| Scar size (range) | 4 (2.5-6.5 cm) |
| Operation time (range) | 50 (37.5-67.5 min) |
| Procedure time (range) | 70 (55-85 min) |
| Length of stay in hospital | 3 (2-8 days) |

Table 3: Median dosages of analgesic and sedation used during the procedure

| | |
|--|------------------------------------|
| Drug | Volume/dose, median (Q1-Q3) |
| Superficial cervical block: bupivacaine + lignocaine | 5 (4-10) mL |
| Surgical site infiltration - lignocaine | 8 (2-10) mL |
| Midazolam | 2 (1-3) mg |
| Fentanyl | 50 (25-100) µg |

Complications

Fourteen of the 30 (46.7%) patients developed postoperative hypocalcemia. Ten of the 14 (71.4%) had symptomatic hypocalcemia alone; among them, 7 patients had mild intermittent symptoms for which calcium carbonate supplements were administered as and when required, whereas the remaining 3 patients had significant symptoms requiring daily calcium and active vitamin D supplementation. Four of the 14 (28.6%) developed biochemical hypocalcemia with symptoms; only 1 patient needed intravenous calcium infusion. Therefore, overall 7 of 30 (23.3%) developed significant postoperative hypocalcemia.

Conversion of the procedure from LA to GA had to be performed in two patients (6.7%). The reason for conversion in one patient was intraoperative bleeding arising from the capsule of the parathyroid adenoma which obscured adequate visualization. Once converted to GA, the adenoma was excised without further complications. The other patient developed bradycardia and hypotension following superficial cervical

block and skin infiltration. Intravenous fluids were rushed and the patient was placed in reverse trendelenberg position with which he recovered. The procedure was abandoned under LA and he was later operated successfully under GA. Other complications witnessed included superficial wound infection in one patient (3.3%) and voice change in another (3.3%). The recurrent laryngeal nerve was seen draped over the adenoma in this patient and had to be dissected free. Postoperative nasopharyngolaryngoscopy (NPL) confirmed a vocal cord paresis. Her voice normalized 1 month later, and a repeat NPL at 6 months review confirmed normal bilateral vocal cord function.

Total cost involved

The mean cost of performing focused parathyroidectomy under LA and GA was INR 40,158 (INR 31,178–53,740) and INR 55,345 (INR 43,225–70,678), respectively. Six patients who underwent focused parathyroidectomy under GA during the study period were used for this comparison. There was a significant difference in the cost incurred by performing this procedure under LA versus GA ($P = 0.001$).

Patient satisfaction

In all, 21 (75%) patients were completely satisfied with LA, whereas 25 (89%) showed a similar satisfaction for the procedure [Figure 1]. All the patients were keen to recommend this procedure under LA to their friends or family.

Cure rate

The two patients in whom parathyroidectomy was completed under GA were excluded from this analysis. In the immediate postoperative period, normalization of corrected serum calcium with a more than 50% fall in the postoperative PTH level was witnessed in the remaining 28 patients. About 26 of the 28 patients were followed up at 6 months, all of whom had normal serum calcium and PTH values. Hence, the cure rate among the patients reviewed at 6 months was 100%.

DISCUSSION

The difference in the spectrum of patients managed in this study compared with those in high-income countries is evident from the demographics and gland characteristics. This cohort included a male preponderance, presented a decade or two

earlier and were all symptomatic. The excised parathyroid glands were larger and heavier, 93% being adenomas and 7% atypical adenomas. All these characteristics are expected from patients presenting in India except for the male preponderance which is difficult to explain, possibly a result of the small cohort.

Under LA, focused parathyroidectomy in 23 of 28 (82.1%) patients was performed by a trainee under supervision. This may account for the longer duration of the procedure witnessed compared with other reports in literature.^[8,9] Postoperative pain is an issue many patients are apprehensive about after any surgery. Interestingly, this cohort of patients experienced minimal postoperative pain as recorded by VAS and this was corroborated by the minimal postoperative analgesic requirement recorded. Furthermore, none of the patients developed postoperative nausea or vomiting. The lack of requirement for morphine may have contributed to this finding. Similar results were also reported in studies conducted on patients undergoing total thyroidectomy/parathyroidectomy under LA.^[10,11]

As mentioned earlier, one of the advantages of minimally invasive parathyroidectomy is the shorter duration of hospital stay – most centers currently discharge patients within 24 h of surgery.^[6,8,12-14] In comparison, we have witnessed a prolonged hospitalization following surgery, and the mean duration of stay was 3 days. This may be attributed to multiple reasons. First, a higher rate of postoperative hypocalcemia (47%) which is possibly secondary to the severe bone disease present in a subset of patients (30%) and the rampant prevalence of vitamin D deficiency in India. Similar rates of hypocalcemia following parathyroidectomy have been reported in other centers in India.^[1,3,5] Second, in low middle-income countries like India, the patients do not want to be discharged on the same day of surgery because of the absence of effective return to hospital mechanism in case of severe postoperative hypocalcemia or hemorrhage. Most patients feel safe and prefer to stay in the hospital for an additional day. Though a high rate of postoperative hypocalcemia was seen, only one patient required intravenous calcium infusion.

Performing this procedure under LA may be limited by the lack of patient compliance, inadequate exposure, concomitant thyroiditis, intraoperative hemorrhage, and rarely intolerance to local anesthetic. This may result in conversion of the procedure to GA in up to 10% of cases.^[6,8,9,12,15] We witnessed similar conversion rate (6.7%). Other complications such as temporary recurrent laryngeal nerve palsy and wound infection were also similar to rates in literature.^[9,16]

In the absence of insurance coverage for a majority of patients in India, the cost of surgery is a burden. Although the number of patients in the compared cohorts is small, we have depicted a significant difference ($P = 0.001$) in the total cost involved between performing the surgery under LA versus under GA. The majority of patients were satisfied with LA (75%) and the procedure (89%), and all patients were happy to recommend

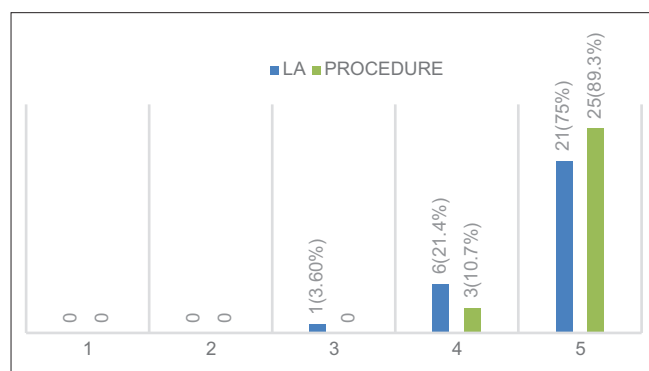


Figure 1: Satisfaction scores for LA and the surgical procedure

the procedure under LA to their friends and family, similar to other reports in literature.^[16,17] Finally, the success of this procedure is dependent on the cure rate achieved. Cure rates for patients with PHPT secondary to a single-gland disease in experienced hands is reported to be >95%.^[18,19] In this cohort, review at 6 months showed a (100%) cure rate emphasizing the safety and feasibility of this procedure under LA.

Limitations

We acknowledge the lack of a comparative cohort of patients in whom this procedure has been performed under GA as well as the restricted sample size as possible limitations of this study.

CONCLUSION

Focused parathyroidectomy performed under LA is feasible and can be monitored and performed safely by a surgeon ensuring adequate patient satisfaction and cure. Furthermore, we have shown that this strategy can significantly reduce the cost of the procedure ($P = 0.001$), a beneficial outcome in low-middle income countries.

Compliance with ethical standards

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

This article does not contain any studies with animals performed by any of the authors.

Informed consent: Informed consent was obtained from all individual participants included in the study.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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