Open Journal of Endocrine and Metabolic Diseases, 2025, 15(6), 91-100
https://www.scirp.org/journal/ojemd
ISSN Online: 2165-7432
ISSN Print: 2165-7424

Initial Experience with Indocyanine Green Fluorescence during Total Thyroidectomy in Mexico: The Postoperative Hypocalcemia Index Decreases?

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How to cite this paper: Montalvo-Hernández, J., Palacios, D.M., Mata, C.J., Jordan, E., Álvarez-López, J.A. and Carrasco-Tobón, J.G. (2025) Initial Experience with Indocyanine Green Fluorescence during Total Thyroidectomy in Mexico: The Postoperative Hypocalcemia Index Decreases? *Open Journal of Endocrine and Metabolic Diseases*, **15**, 91-100.
https://doi.org/10.4236/ojemd.2025.156009

Received: May 19, 2025
Accepted: June 27, 2025
Published: June 30, 2025

Abstract

Background: Postoperative hypocalcemia is the most common complication of total thyroidectomy. Recently, new techniques have emerged for identifying the parathyroid glands, such as indocyanine green (ICG) fluorescence, which has been well accepted by various groups of expert surgeons internationally. In this study, we use this technique to assess the viability of the parathyroid glands after total thyroidectomy using the angiographic images it provides. **Methods:** This is a cohort study that includes patients who underwent total thyroidectomy during the pandemic period in 2020 using ICG fluorescence. These patients were evaluated for transient and permanent (>6 months) hypocalcemia postoperatively. Additionally, the results were compared with historical controls, which included patients treated by a low-volume thyroid surgeon (group A) and those treated by a high-volume thyroid surgeon (group B). Several variables were included and analyzed between the groups, such as the number of auto-transplanted parathyroids, postoperative serum calcium levels, and symptoms of hypocalcemia. The main aim of the study was to determine whether the use of ICG fluorescence is associated with a lower rate of postoperative hypocalcemia. **Results:** A total of 18 patients were operated using ICG fluorescence. Of them, 14 (75%) cases were females and median age was 54 ± 13.5 years. 29 patients were included in group A (operated by a low-volume thyroid surgeon) and 50 patients in group B (by a high-volume thyroid surgeon). Autotransplantation was not necessary in ICG group compared with 3 and 1 in the groups A and B, respectively. Thyroid cancer was confirmed in

58 (59%) of cases by histopathology. Postoperative calcium levels were higher in ICG fluorescence group compared with groups A and B from day 1 to 6 months of follow-up (p = NS). Statistical analysis showed a significant difference in transient hypocalcemia and permanent hypoparathyroidism rates (p = 0.011 and p = 0.002, respectively) when contrasted between groups. The subanalysis showed that ICG fluorescence reached slight significance for transient hypocalcemia but did not achieve statistical significance for permanent hypocalcemia when compared to the high-volume surgeon group (Group B) (p = 0.039 and p = 0.28, respectively). **Conclusions:** ICG fluorescence technique was associated with lower incidence of postoperative hypocalcemia, especially when it is compared to low-volume thyroid surgeon.

Keywords

Thyroidectomy, Indocyanine Green Fluorescence, Postoperative Hypocalcemia, Parathyroid Glands

1. Introduction

Total thyroidectomy (TT) is the main surgical procedure for the treatment of malignant, and some benign thyroid diseases. Although morbidity and mortality rates associated with this procedure have decreased in the last century, surgical complications represent an important negative impact on the patient's quality of life. Common surgical complications of TT include cervical hematoma, transient/permanent vocal cord palsy, and transient/permanent hypoparathyroidism, being the latter being the most frequent, with an incidence of 1.6% - 60% and 1% - 32%, respectively [1] [2].

Postoperative hypoparathyroidism (PHP) is caused by a loss of parathyroid hormone (PTH) secretion as a result of operative ischemia of the parathyroid glands (PGs). Direct thermal lesion and mechanical injury of the PGs are both frequent causes of operative ischemia during thyroid surgery. Another cause of PHP is inadvertent resection of one or more PGs (partial or complete removal), usually because they were not visualized during surgery [3] [4].

Many surgical strategies and techniques have been described to avoid permanent PHP, such as the subcapsular dissection technique (to preserve vascular pedicle of the PGs), and auto-transplantation of the PGs whenever it is required [5]-[8]. A relatively novel technique is indocyanine green (ICG) fluorescence to PGs identify and preserve its viability by intraoperative angiography. ICG is a sterile, anionic, water-soluble, tricarbocyanine molecule used as dye for medical diagnostics. After IV injection, it rapidly binds to plasmatic proteins and under near infrared light (around 800 nanometers), becomes fluorescent [9] [10]. This technique requires the intravenous (IV) administration of 1.25 or 2.5 mg of ICG and a special imaging capture system allowing parathyroid gland identification, as well as parathyroid gland viability assessment (vascular supply) before and after surgical manipulation of the glands during thyroid resection.

More recently, surgeons' experience correlates with fewer surgical complications after thyroid surgery, including less hypocalcemia. A threshold of >50 thyroidectomies per year has been used to define the minimum volume of procedures that a surgeon should perform to improve patient outcomes [11] [12].

The main outcome of this study was to compare PGs's associated complications (incidental parathyroidectomy, transient and permanent hypoparathyroidism) between a prospective group of patients surgically treated with TT using ICG fluorescence and historical controls of patients treated by a high-volume thyroid surgeon (>50 thyroidectomy per year) or treated by a low volume experienced surgeon (<50 thyroidectomy per year). Until today and based on the published scientific literature available regarding this technique, this is the first Mexican experience.

2. Patients and Methods

This is a comparative study of a prospectively collected cohort of consecutive patients who underwent TT using ICG fluorescence (case group) for parathyroid gland identification and preservation from January to December 2020 at a tertiary-level hospital in Mexico. Selection criteria included patients older than 18 years with benign or malignant thyroid disease treated with TT with or without central/lateral neck lymph node dissection. All patients were informed of the potential adverse reactions of ICG use and provided consent for its use during the procedure. Pre-operative serum vitamin D levels were not routinely measured. Serum calcium and albumin levels were measured during hospitalization (24 hours postoperatively) and at 1 month and 6 months after discharge. Postoperative oral calcium or vitamin D supplementation is not given routinely, but only when indicated by serum calcium levels or symptoms of hypocalcemia, typically assessed 24 hours after surgery. Patients with a thyroid resection volume less than a total thyroidectomy, previous thyroid surgery, or concomitant primary or secondary hyperparathyroidism were excluded from the study. The Institutional Review Board of Ethics approved the study (DCAS-SSS-HCN-ENS-140-20).

For the analysis, the following operative definitions were established

Transient hypocalcemia: symptomatic hypocalcemia (albumin-corrected serum calcium < 8.6 mg/dL) and the need for oral/intravenous calcium or vitamin D supplementation after thyroidectomy for a period of less than 6 months after surgery.

Permanent hypocalcemia: albumin-corrected serum calcium < 8.6 mg/dL or the need for oral/intravenous calcium or vitamin D supplementation due to symptoms of hypocalcemia at 6 months after thyroidectomy.

Inadvertent parathyroidectomy: identification of one or more parathyroid glands in the surgical specimen in the final histopathological report.

Auto-transplantation of parathyroid glands: parathyroid tissue was removed and auto-transplanted into the ipsilateral sternocleidomastoid muscle after confirming their histology by frozen section.

ICG fluorescence technique

After thyroid lobe mobilization and visualization of the tracheoesophageal groove, a 1 mL dose of ICG (Indocyanine Green; VERDYE 2.5 mg/mL, Diagnostic Green) was administered to the patient through peripheral intravenous (IV) access. Real-time images were obtained two minutes after IV ICG administration using the Diagnostic Green IC-FLOW™ device (**Figure 1(A)**) at a distance of 15 cm from the surgical wound to identify the PGs (**Figure 1(B)**). Based on the fluorescence images obtained, the decision to autotransplant one or more PGs was left to the discretion of the surgeon. The PGs were labeled as devascularized (ICG score 0), moderately vascularized (ICG score 1), or well vascularized (ICG score 2), according to Vidal Fortuny *et al.* [9]. Therefore, the parathyroid gland that did not exhibit fluorescence was excised and autotransplanted. This procedure was similarly performed on the contralateral side in each patient.

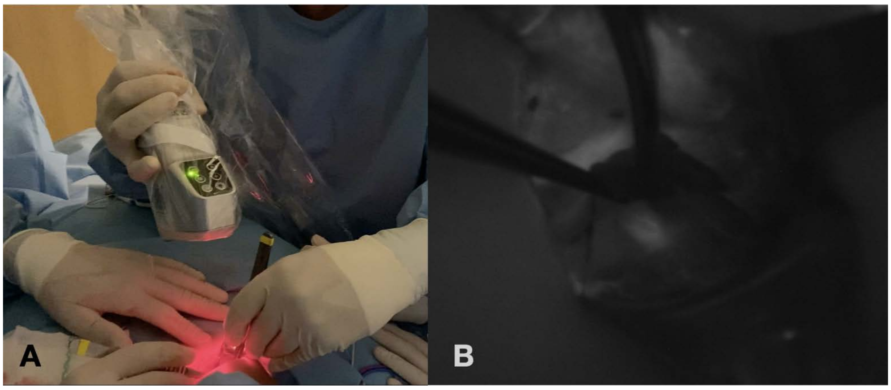

Figure 1. (A) Diagnostic Green IC-FLOW™ device at 15 cm distance from the surgical wound. (B) Highly fluorescent (bright) parathyroid gland.

For comparative analysis, two groups of historical control patients were included. All control patients were older than 18 years and treated with TT with/without neck lymph node dissection. Control A group was patients surgically treated by a low-volume thyroid surgeon (with training in neck surgery) and the control B group was treated by a high-volume thyroid surgeon (endocrine surgeon).

The main comparative outcomes included transient and permanent hypocalcemia, the number of inadvertent resected parathyroid glands and the number of autotransplanted glands, based on the aforementioned operative definitions.

Statistical description and inference were performed according to the natural scaling of all included variables. Proper statistical tests were employed for contrasting groups. The Fisher exact test was used to compare the categorical variables. For the correlation between two continuous variables, the Pearson correlation test was performed. Due to the multiple hypothesis tested between the groups of the study, any p value < 0.05 was considered statistically significant for a two-tailed hypothesis test. Mathematical data was analyzed with IBM® SPSS© Statistics version 25 (SPSS©, Chicago, IL, USA). Data representation was elaborated with

Numbers® Apple© version 2.3.

3. Results

A total of 97 patients were included in the study. Mean age (±standard deviation) of the entire cohort was 55.2 (±14.4), and gender distribution was 79 (81.4%) females and 18 (18.5%) males. Indications for surgical treatment were as follows: 35 (36%) indeterminate nodules (Bethesda III/IV), 31 (32%) preoperative diagnosis of malignant thyroid disease (Bethesda VI), 23 (23%) multinodular goiters (18 of them were compressive goiter), 3 (3%) suspicious of malignancy (Bethesda V), 3 (3%) non-diagnostic biopsied thyroid nodules (Bethesda I), and 2 (2%) uncontrolled hyperthyroidism cases (Table 1). Final report of histopathology showed 58 (59%) cases of thyroid cancer.

Table 1. Surgical indications for total thyroidectomy.

TOTAL THYROIDECTOMY INDICATIONS (n = 97)	# cases	(%)
indeterminate nodules (*Bethesda III y IV)	35	(36)
Thyroid cancer (Bethesda VI)	31	(32)
Multinodular goiter	23	(23)
Suspicious of malignancy (Bethesda V)	3	(3)
Nondiagnostic or unsatisfactory (Bethesda I)	3	(3)
Hyperparathyroidism	2	(2)

*Diagnostic categories of the Bethesda System for Reporting Thyroid Cytopathology (TBSRTC).

Surgical procedures were performed as follows: 77 (79%) patients required TT, 12 (12%) TT plus central compartment lymph node dissection (CCLND) and 8 (8%) TT + CCLND plus lateral compartment lymph node dissection. Eighteen patients (18.5%) were treated using the ICG fluorescence technique during the pandemic period in 2020. Control group A was 29 (30%) patients treated between February 2018 to December 2019, and control group B was 50 (51.5%) patients treated between January 2019 to December 2019. Demographic, preoperative and operative features for each group are shown in Table 2. Adverse reactions were not observed in the ICG fluorescence technique group.

Transient hypocalcemia was present in only 3 (16.6%) patients in the ICG group, in contrast to 15 (55%) in control group A and 22 (44%) in control group B ($p = 0.011$). All these patients were supplemented with oral calcium carbonate. We performed a statistical subanalysis comparing the results of ICG cases with control groups. The subanalysis showed a great significant difference when ICG-Fluorescence cases were compared with control group A ($p = 0.009$) and a limited difference when they were compared with control group B ($p = 0.039$), as shown in Table 3.

Regarding permanent hypocalcemia, no cases were identified in ICG group in contrast to control groups (p = 0.002). The statistical subanalysis that we made showed a great significant difference when the results of ICG group were compared with control group A, 0 vs 9 (31%) respectively (p = 0.008). On the other hand, there was no statistical significance when compared with control group B (p = 0.28), as shown in Table 4.

Table 2. Demographic, preoperative and operative features for ICG fluorescence treated patients, controls treated by high-volume thyroid surgeon and by a low-volume thyroid surgeon.

	ICG fluorescence group (n = 18)	Low-volume thyroid surgeon, A group (n = 29)	High-volume thyroid surgeon, B group (n = 50)	p value
Gender				0.21
Female n (%)	14 (75%)	22 (76%)	43 (86%)	
Male n (%)	4 (25%)	7 (24%)	7 (14%)	
Age (years)	54 ± 13.5	56 ± 12.1	57.5 ± 14.6	0.76
Surgical procedure				0.41
Total thyroidectomy n (%)	13 (72%)	25 (86%)	39 (78%)	
TT + CCLND n (%)	4 (22%)	4 (14%)	4 (8%)	
TT + CCLND + LCLND n (%)	1 (5.5%)	0 (0%)	7 (14%)	
Operative time (min)	110 ± 28.5	130 ± 42.8	120 ± 53.7	0.06
Blood loss (mL)	30 ± 36.6	75 ± 47.9	35 ± 41.3	0.001*
Hospital stay	1.5	2	1.5	NS
Autotransplantation of parathyroid tissue	0	3	1	NS
Calcium Level at 24 h (mg/mL)	8.6 (7.7 - 9.3)	8.1 (7.2 - 9.0)	8.4 (6.9 - 9.8)	NS
1 month (mg/mL)	9.4 (8.7 - 10)	8.8 (6.7 - 9.8)	9.2 (8.2 - 9.9)	NS
6 months (mg/mL)	9.2 (8.8 - 9.7)	9.0 (6.5 - 11.1)	9.1 (7.3 - 10.0)	NS
Histopathological report				0.2
Malignant disease	9 (50%)	22 (75%)	27 (54%)	
Benign disease	9 (50%)	7 (24%)	23 (46%)	

*Statistically significant

TN: thyroid nodule, TT: total thyroidectomy, CCLND: central compartment lymph node dissection, LCLND: Uni-lateral compartment lymph node dissection.

Table 3. *TRANSIENT HYPOCALCEMIA* using ICG-Fluorescence. Comparative results with Low- and High thyroid surgeon (A and B respectively).

(A) Transient Hypocalcemia ICG-Fluorescence versus Low-volume thyroid surgeon (n = 47)	No	Yes
ICG-Fluorescence cases	15 (84%)	3 (16%)
Control group A (low volume thyroid surgeon)	13 (45%)	16 (55%)
p = 0.009		

Continued

(B) Transient Hypocalcemia ICG-Fluorescence versus High-volume thyroid surgeon (n = 68)	No	Yes
ICG-Fluorescence cases	15 (84%)	3 (16%)
Control group B (high volume thyroid surgeon)	28 (56%)	22 (44%)
p = 0.039		

The surgeons are high- and low-volume in thyroid procedures: As regards autotransplantation of parathyroid glands, no statistically significant differences were found between the groups studied (χ^2; p = 0.549). No parathyroid glands were autotransplanted in the ICG fluorescence group (none with Vidal-Fortuny category 0). However, 4 parathyroid glands were autotransplanted due to their ischemic appearance (based on the surgeon's visual assessment and judgment). Same results were observed in inadvertent parathyroidectomy (χ^2; p = 0.563), histopathological diagnosis of malignant disease (Fisher's exact test; p = 0.81) and type of surgical procedure (χ^2; p = 0.32).

Table 4. *PERMANENT HYPOPARATHYROIDISM* using ICG-Fluorescence. Comparative results with Low- and High thyroid surgeon (A and B respectively).

(A) Permanent Hypoparathyroidism ICG-Fluorescence versus Low-volume thyroid surgeon (n = 47)	No	Yes
ICG-Fluorescence cases	18 (100)	0 (Ø)
Control group A (low volume thyroid surgeon)	20 (69)	9 (31)
p = 0.008		
(B) Permanent Hypoparathyroidism ICG-Fluorescence versus High-volume thyroid surgeon (n = 68)	No	Yes
ICG-Fluorescence cases	18 (100)	0 (Ø)
Control group B (High volume thyroid surgeon)	47 (94%)	3 (6%)
p = 0.288		

4. Discussion

Our data show that the ICG fluorescence technique is associated with a lower incidence of transient and permanent hypocalcemia, especially when compared to low-volume thyroid surgeons. A significant statistical difference was observed in the ICG group compared to low-volume surgeons, but only a slight difference was noted when compared to high-volume surgeons (Group B) regarding transient hypocalcemia. Permanent hypocalcemia rates were similar only in Group B (p = 0.28). These findings likely reflect the difference in experience between high- and low-volume thyroid surgeons.

Similarly, in a prospective study, Papavramidis *et al.* [13] did not find a statistically significant difference in the incidence of postoperative hypocalcemia (r =

0.156; p = 0.233) or hypoparathyroidism (measured by serum parathyroid hormone levels) (r = 0.009; p = 0.948) when using ICG fluorescence, and they emphasized that the three participating surgeons were experts in thyroid surgery (performing > 50 thyroidectomies/year). The experience of the surgeon has been shown in global medical literature not only to reduce the risk of hypocalcemia but also to eventually lower the cost of conventional total thyroidectomy [14].

The definition of postoperative hypoparathyroidism is a broad and complex topic, as more than 20 different definitions have been identified in recent publications by Harsløf T, as mentioned in the 2019 systematic review [15]. In our study, the complications of transient and permanent hypocalcemia were defined using both biochemical criteria (serum calcium levels below normal) and clinical criteria (symptoms related to hypocalcemia and/or the need for oral calcium supplementation), as PTH levels were not routinely measured in all patients. Therefore, it is important to acknowledge that the definition of postoperative hypocalcemia (hypoparathyroidism) may influence our reported incidence of postoperative hypocalcemia and may differ from other published results.

Thyroid malignancy and central neck dissection are well-known factors associated with transient and permanent hypocalcemia. However, both were similarly distributed across each of our study groups (p = 0.20 and p = 0.41, respectively). For this reason, we included all these cases in the statistical analysis to minimize the risk of bias.

On the other hand, Zaidi *et al.* [16] reported a higher identification rate of parathyroid glands using ICG fluorescence (between 1 and 20 minutes after IV ICG administration) in a cohort of patients with well-differentiated thyroid carcinoma or Graves' disease. Furthermore, in a comparative study, Yu *et al.* [17] demonstrated a significantly lower rate of incidental parathyroidectomy in the ICG fluorescence group (0/22) compared to the control group (7/44) in patients undergoing surgery for papillary thyroid carcinoma using the BABA robotic approach.

In our early experience with the use of ICG fluorescence, we evaluated the parathyroid glands at the end of each thyroid lobe mobilization. It is worth mentioning that we have recently modified the technique using ICG fluorescence, as we now locate the parathyroid glands before completing the full mobilization of the thyroid lobe. This allows us to clearly observe the primary vascular supply (vascular anatomy) of each gland and identify those in a subcapsular position. By doing so, we optimize gland dissection and preserve its vascular supply (post-dissection viability). We did not find a statistical difference in the incidence of inadvertent resection of parathyroid glands (p = 0.563) nor in the number of them identified in the surgical field.

There are limitations in the methodology of our study and it is important to mention them: it is not randomized, the number of patients included in the study is low (especially in the case group), and the historical controls may be susceptible to selection bias.

Our study included a single case group with thyroidectomies performed by a high-volume surgeon, so our inferences and conclusions are limited to the lack of results from the use of fluorescence in low-volume surgeons. By including this additional group, we could find out if there is a real role for ICG in low-volume surgeons, since most of the studies carried out in this regard have been carried out in groups of expert surgeons and the results may not be evident.

Finally, this represents our learning curve in the use of ICG fluorescence, so the major benefits may not be fully realized until we achieve more experienced and consistent use of the technique. Moreover, we anticipate that this technique could have a greater impact in hospitals with trainee residents and less experienced surgeons (such as recent graduates), particularly for localization, tissue confirmation, and proper dissection of the parathyroid glands, as it highlights their arterial supply with fluorescence.

5. Conclusion

Our results demonstrated that the use of ICG fluorescence reduces the incidence of transient and permanent hypocalcemia. However, the results from more experienced surgeons (high-volume thyroid surgeons) showed a slight statistical significance regarding transient hypocalcemia, with no significant difference in the rate of permanent hypocalcemia. These findings should be evaluated through prospective randomized studies.

Acknowledgements

No funding was received for this article; however, we appreciate the Deputy Director of Health Services of Petróleos Mexicanos for providing the means to perform the surgical procedures on the patients.

Conflicts of Interest

Informed consent was obtained from all individual participants included in the study. No competing financial interest exists.

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