ORIGINAL RESEARCH

Use of Prophylactic Steroid to Prevent Hypocalcemia in Patients Undergoing Thyroidectomy: A Randomized Controlled Trial from a High-volume Tertiary Care Center in North India

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Abstract

Background: Thyroidectomy is a widely performed surgical procedure globally with respect to the benign and malignant disorder of thyroid gland. Total thyroidectomy, one of the most commonly performed procedures in India, carries inherent risks, predominantly hypocalcemia, voice disturbances, and other complications. Our study explores the role of steroids in potentially reducing these complications.

Aim: To evaluate the effectiveness of prophylactic steroids in preventing hypocalcemia in patients undergoing total thyroidectomy. Additionally, the study examines other parameters, including pain and voice changes.

Method: This randomized controlled double-blind trial included two arms: A placebo group and a steroid group, comparing outcomes between the two groups.

Results and conclusion: Our study demonstrated a noticeable difference, with fewer patients in the steroid group developing hypocalcemia; however, the results were not statistically significant. Importantly, no complications due to steroid use were observed. We noted statistically significant benefits in the steroid group regarding reduced postoperative voice dysfunction and pain. A study with a larger sample size is needed to draw more definitive conclusions.

Keywords: Hypocalcemia, Post-thyroidectomy complication, Steroid in thyroid surgery, Thyroidectomy.

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Introduction

Thyroid gland diseases are prevalent endocrine disorders significantly impacting Indian healthcare. Thyroidectomy with respect to the benign and malignant disorder of the thyroid gland, is a widely performed surgical procedure worldwide, particularly total thyroidectomy in India. While goiter is the most common benign indication, suspicion or confirmation of malignancy is the primary malignant indication for thyroidectomy. This surgery, despite its therapeutic benefits, carries inherent risks such as hypocalcemia and voice disturbances.[1–3]

Postoperative hypocalcemia is the most common complication, with incidence rates ranging from 0.5 to 65%.[4] Temporary hypocalcemia occurs in 43–63% of cases, while permanent hypocalcemia affects 1–2% of patients. The primary cause is inadvertent removal or injury to the parathyroid glands during surgery, leading to hypoparathyroidism. Factors like surgical site inflammation and vascular spasms also contribute to transient hypocalcemia. Preventative measures include preoperative calcium supplementation, careful surgical techniques, early postoperative parathyroid hormone (PTH) measurement, and prophylactic calcium and vitamin D supplementation.[5–8] Once hypocalcemia is established, it is managed with calcium and vitamin D3 supplements.[9–11]

Voice alterations, including hoarseness, are frequent post-thyroidectomy complications, affecting 80–90% of patients, although most recover fully over time. Injury to the recurrent laryngeal nerve or/and the external branch of the superior laryngeal nerve could cause significantly amount of distress and morbidity in patients, although experienced surgeons report low incidence rates of nerve injury (1–2%).[12–15] Other factors, such as surgical site inflammation, vocal cord injury from intubation, and inflammation of anterior strap muscles also contribute to postoperative voice changes and swallowing difficulties.[16,17]

Thyroidectomy is also associated with complications like surgical site hematoma, seroma, infection, tracheal injury, hypertrophic scars, keloids, and nonspecific issues, such as postoperative nausea and vomiting.[18,19] Corticosteroids, particularly dexamethasone, are widely used due to their potent anti-inflammatory, analgesic, and anti-emetic properties.[20–22] Dexamethasone, with its high

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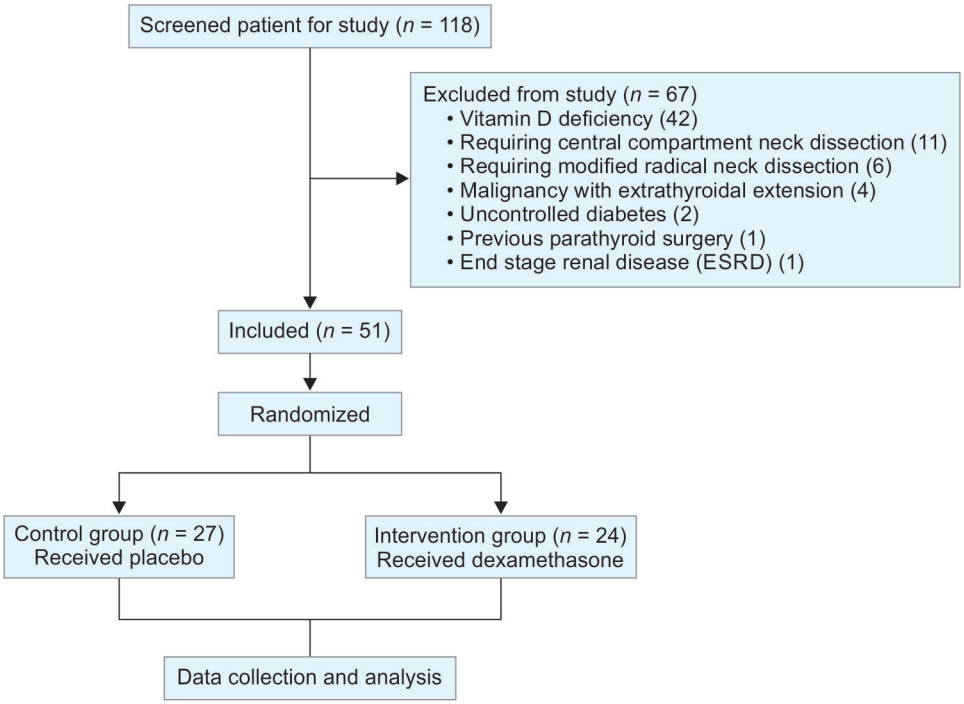

Fig. 1: Consort diagram

glucocorticoid activity, has shown efficacy in reducing symptomatic hypocalcemia, postoperative nausea, vomiting, and pain when administered preoperatively.[23–26]

However, the routine use of dexamethasone in thyroidectomy patients is not yet established. While its benefits in addressing postoperative voice changes, nausea, and vomiting are documented, its impact on hypocalcemia needs further evaluation. Given the common occurrence of thyroidectomy among young to middle-aged individuals, understanding the comprehensive benefits of preoperative dexamethasone is crucial for improving postoperative quality of life.

Materials and Methods

This single-centered, two-arm, parallel-design, double-blinded prospective randomized controlled trial to primarily assess the effectiveness of prophylactic steroids in preventing hypocalcemia in patients undergoing total thyroidectomy. Randomization of the participants was done to either the placebo group (Arm A) or the dexamethasone group (Arm B). The placebo group received 2 mL of 0.9% normal saline through an intravenously route 60 minutes before the induction of anesthesia, while the dexamethasone group was given 0.1 mg/kg body weight of dexamethasone (~ 2 mL of an 8 mg solution) intravenously 60 minutes before the induction of anesthesia. The study was conducted in the Department of Surgical Disciplines at AIIMS, New Delhi after obtaining approval from the Institutional Ethics Committee (Ref-IECPG-10/27.01.2022, RT-21/24.02.2022). The trial was registered with the Clinical Trials Registry India (CTRI/2022/03/041396). The study was conducted from March 2022 to October 2023, with some delays due to the COVID-19 pandemic.

As per previous literature available, the rate of hypocalcemia was supposed to be 27% in the placebo group and the dexamethasone group 13.5%, with consideration for 50% reduction. The estimated risk difference between the two proportions was 0.135, with a confidence level of 95%, an alpha error of 5%, a power of 80%, and a beta error of 20%. Sample size was calculated to be 138 patients in each arm but due to the pandemic and specific inclusion/exclusion criteria, we recruited 51 patients in total, with 27 patients in Arm A and 24 in Arm B (Fig. 1).

Eligible participants were adults aged 18–65 years with no preoperative corrected hypocalcemia or voice dysfunction, requiring total or near-total thyroidectomy, and having normal preoperative serum calcium, vitamin D, and iPTH levels. Exclusion criteria included refusal to consent, history of head and neck surgery or irradiation, known vocal cord dysfunction on laryngoscopy, contraindications to dexamethasone, history of stomach or duodenal ulcer disease, and the use of medications affecting calcium metabolism, such as antiresorptive drugs, anabolic drugs, thiazide diuretics, furosemide, proton pump inhibitors, and antacids. Additionally, patients undergoing staged thyroidectomy or those with thyroid malignancy involving extrathyroid extension or requiring lymph node dissection were not considered in the study.

Eligible patients were randomized in a 1:1 ratio using mixed block randomization via NQ advance software and allocation was performed using sequentially numbered sealed envelopes.

Patients were assessed at 6 hours postoperatively, and subsequently at 24 hours, 48 hours, and 2 weeks after surgery. The following parameters were evaluated:

- Symptoms of hypocalcemia, voice change, pain, nausea, and vomiting
- Clinical examination for signs of hypocalcemia
- Voice assessment using the GRBAS scale
- Laboratory investigations, including total and ionized calcium, albumin, magnesium, phosphorus, vitamin D (6 hours and 2 weeks), and iPTH.
- Length of hospital stay

Table 1: Demography

	Control group (n = 27)	*Intervention group (n = 24)*	*p-value*
Age (mean ± SD) in years	44.1 ± 10.6	44 ± 10.1	0.95
Male	5 (19%)	8 (33%)	0.22
Female	22 (81%)	16 (67%)	0.22

Low calcium levels were defined as a corrected serum calcium level below 8.4 mg/dL. Hypocalcemia was classified as laboratory hypocalcemia (corrected serum calcium <8.4 mg/dL or ionized calcium <1.1 mmol/dL) and clinical hypocalcemia (symptoms like tingling, numbness, muscle, and carpopedal spasm). Patients with symptoms or corrected serum calcium <8 mg/dL were treated with calcium and Vitamin D3 supplements. Voice assessment was conducted by a blinded assessor using the GRBAS scale, and postoperative pain was assessed using the visual analogue scale (VAS). Nausea and vomiting intensity were evaluated using a verbal rating scale.

Data were entered into an MS Excel sheet and analyzed using STATA version 16. Comparisons of parametric data were performed using the Student's *t*-test, and non-parametric data were analyzed using the Chi-square test or Mann–Whitney *U*-test as appropriate. A *p*-value of < 0.05 was considered significant.

Results

After meticulous application of inclusion and exclusion criteria, a total of 51 patients were randomized between two groups: the control group ($n = 27$) receiving a placebo, and the intervention group ($n = 24$) receiving dexamethasone. The patients were aged between 30 and 60 years, with a mean age of 44 ± 10.3 years. Females were more prevalent in both the groups, comprising 75% ($n = 38$) of the total patients (Table 1).

Incidence of Postoperative Hypocalcemia

Postoperatively, at 6 hours, 3% ($n = 1$) of the control group and 4% ($n = 1$) of the intervention group exhibited symptomatic hypocalcemia. Laboratory hypocalcemia was observed in 14% ($n = 4$) of the control group and 8% ($n = 2$) of the intervention group ($p > 0.05$). At 24 hours, 37% ($n = 10$) of the control group showed both symptomatic and laboratory hypocalcemia, compared with 16% ($n = 4$) symptomatic and 32% ($n = 8$) laboratory hypocalcemia in the intervention group ($p > 0.05$). At 48 hours, 25% ($n = 7$) of the control group had symptomatic hypocalcemia, and 29% ($n = 8$) had laboratory hypocalcemia. The intervention group showed similar rates with 25% ($n = 6$) symptomatic and 29% ($n = 7$) laboratory hypocalcemia ($p > 0.05$). During the two-week follow-up, only one patient in the control group had laboratory hypocalcemia ($p > 0.05$) while none showed any symptomatic hypocalcemia. The mean calcium levels between the two groups showed no statistically significant difference ($p > 0.05$) (Table 2).

Pain and Voice Changes

Pain scores, measured using the VAS, were higher in the control group at 6, 24, and 48 hours postoperatively, with a statistically significant pain score at 24 hours ($p = 0.01$) (Table 3). Voice changes, assessed using the GRBAS scale, were more prevalent in the control group, with a significant difference from the interventional group at 48 hours postoperatively ($p = 0.04$). The intervention group consistently showed lower median voice scores, with significant differences at 6 hours ($p = 0.05$) and 24 hours ($p = 0.03$) (Table 4). Other measured parameters are mentioned in Table 5.

Nausea and Vomiting

Only a single patient in the control group had nausea and vomiting within 6 hours post-surgery, while no such symptoms were observed in the intervention group.

Operative Time and Other Parameters

The average operative time was 90 ± 13 minutes for the control group and 91 ± 12 minutes for the intervention group ($p = 0.77$). No intraoperative parathyroid or nerve injuries were identified in either the study arm. Magnesium and phosphorus levels remained within normal limits, with no significant differences between groups ($p > 0.05$). Both groups had comparable serum PTH levels ($p > 0.05$). The mean hospital stay was 3.5 ± 1.6 days for the control group and 3.3 ± 1.1 days for the intervention group ($p = 0.65$).

Adverse Effects of Steroids

No unintended effects, such as surgical site infections, postoperative blood glucose derangements, gastritis, or agitation, were observed due to dexamethasone use.

Discussion

Thyroidectomy is a commonly performed surgical procedure, often accompanied by postoperative complications such as hypocalcemia, voice changes, nausea, vomiting, pain, and surgical site hematoma. Steroids, known for their anti-inflammatory and immunomodulatory properties, may reduce post-thyroidectomy morbidity. This study evaluates the role of steroids in preventing these complications and reducing the associated morbidity.

The total number of participants in this randomized controlled trial was 51, with a predominance of females (75%). This aligns with other studies demonstrating a higher incidence of thyroid disease in females, likely due to an increased predisposition to autoimmune diseases and hormonal factors.[23,24]

No preoperative hypocalcemia was observed among the enrolled patients, and none were on calcium-altering medications. Postoperatively, no significant difference in symptomatic or laboratory hypocalcemia was noted between the groups. The control group exhibited higher rates of symptomatic and laboratory hypocalcemia at 24 hours, but this was not statistically significant. By 48 hours, both groups showed similar rates of hypocalcemia, and at the two-week follow-up, no symptomatic hypocalcemia was observed, with only one patient in the control group showing laboratory hypocalcemia. Analysis of corrected calcium values illustrated no significant differences between the groups at any time point. Similarly, PTH levels showed no significant variation between the groups. Notably, all patients with symptomatic hypocalcemia had decreased calcium and iPTH levels, suggesting that symptomatic hypocalcemia occurs when calcium levels drop below a certain threshold. Dhahri et al. found a significant reduction in hypocalcemia in the dexamethasone group, likely due to the inclusion of vitamin D-deficient patients, a common issue in South Asian populations.[23] Kolahdouzan et al. conducted a randomized controlled trial with 128 patients, finding no statistically significant difference in hypocalcemia

Table 2: Hypocalcemia at different interval

		Control group (n = 27)	*Intervention group (n = 24)*	*p-value*
6 hours interval	Symptomatic hypocalcemia	1 (3%)	1 (4%)	0.93
	(Calcium mg/dL)	(7.6)	(8.3)	
	(iPTH pg/mL)	(5.8)	(10)	
	Laboratory hypocalcemia	4 (14%)	2(8%)	0.67
	(Mean Calcium ± SD mg/dL)	(7.9 ± 0.30)	(8.2 ± 0.13)	
	(Mean iPTH ± pg/mL)	(13.4 ± 3.1)	(6.7 ± 4.6)	
24 hours interval	Symptomatic hypocalcemia	10 (37%)	4 (16%)	0.10
	(Mean Calcium ± SD mg/dL)	(8.1 ± 0.23)	(8.0 ± 0.19)	
	(Mean iPTH ± pg/mL)	(9.2 ± 5.1)	(12.1 ± 6.3)	
	Laboratory hypocalcemia	10 (37%)	8 (32%)	0.67
	(Mean Calcium ± SD mg/dL)	(8.1 ± 0.23)	(7.9 ± 0.21)	
	(Mean iPTH ± pg/mL)	(9.2 ± 5.1)	(14.3 ± 4.9)	
48 hours interval	Symptomatic hypocalcemia	7 (25%)	6 (25%)	0.94
	(Mean Calcium ± SD mg/dL)	(8.0 ± 2.3)	(8.1 ± 1.8)	
	(Mean iPTH ± pg/mL)	(13.8 ± 9.6)	(15.9 ± 4.8)	
	Laboratory hypocalcemia	8 (29%)	7 (29%)	0.97
	(Mean Calcium ± SD mg/dL)	(8.0 ± 2.4)	(8.1 ± 2.1)	
	(Mean iPTH ± pg/mL)	(13.6 ± 10.1)	(16.1 ± 6.1)	
2 weeks	Symptomatic hypocalcemia	0	0	0
	Laboratory hypocalcemia	1 (3%)	0	1
	(Calcium mg/dL)	(8.2)		
	(iPTH mg/dL)	(11)		
Corrected calcium value	Time period	Mean ± SD (mg/dL)	Mean ± SD (mg/dL)	*p*-value
	Preoperative	9.3 ± 0.37	9.2 ± 0.33	0.31
	6-hour postoperative	8.8 ± 0.50	8.9 ± 0.35	0.70
	24-hour postoperative	8.5 ± 0.71	8.7 ± 0.59	0.18
	48-hour postoperative	8.6 ± 0.69	8.6 ± 0.74	0.91
	2-week postoperative	9.0 ± 0.36	9.1 ± 0.29	0.32

Table 3: Pain score by visual analogue scale

Time period	*Control group (n = 27) (Mean ± SD)*	*Intervention group (n = 24) (Mean ± SD)*	*p-value*
6-hour postoperative	3.8 ± 0.9	3.4 ± 0.7	0.06
24-hour postoperative	3.4 ± 0.8	2.9 ± 0.6	0.01
48-hour postoperative	2.5 ± 0.8	2.1 ± 0.85	0.06

Table 4: Voice changes postoperative period

Time period	*Control group (n = 27) N (percentage)*	*Intervention group (n = 24) N (percentage)*	*p-value*
6-hour postoperative	18 (66%)	11 (45%)	0.26
24-hour postoperative	18 (66%)	10 (41%)	0.17
48-hour postoperative	15 (55%)	7 (29%)	0.04
2-week postoperative	9 (33%)	6 (25%)	0.51
	Median voice score		
	Median (p25, p75)	*Median (p25, p75)*	
6-hour postoperative	2 (0,3)	0 (0,2)	0.05*
24-hour postoperative	2 (0,3)	0 (0,2)	0.03*
48-hour postoperative	1 (0,2)	0 (0,1.5)	0.14*
2-week postoperative	0 (0,1)	0 (0,0.5)	0.51*

**N*, no of patient developing voice dysfunction after thyroidectomy

rates between control and dexamethasone groups.[24] Similar findings were reported by Feroci et al., Tarantino et al., and Abdel et al., although hypocalcemia was a secondary objective in these studies.[25–27]

Voice changes were more prevalent in the control group, with hoarseness being the most common symptom. At 48 hours, the rate of voice dysfunction was significantly lower in the dexamethasone group ($p = 0.04$). Lower voice dysfunction in the dexamethasone group may be due to reduced inflammation and edema. The GRBAS voice severity score was higher in the control group at 6 hours ($p = 0.05$) and significantly lower in the dexamethasone group at 24 hours ($p = 0.03$). These findings are consistent with a meta-analysis by Kim et al., which demonstrated the beneficial effect of steroids in preventing post-thyroidectomy voice changes.[28]

Pain scores were higher in the control group, with a statistically significant difference at 24 hours ($p = 0.01$). By the two-week follow-up, no pain was reported in either group. The reduced pain in the dexamethasone group may be attributed to decreased inflammation. A similar finding was seen in various meta-analyses and randomized controlled trials.[29–34]

Table 5: Serum magnesium, phosphorous and PTH level in both the study arms

	Time period	*Control group (n = 27)* *(Mean ± SD)*	*Intervention group (n = 24)* *(Mean ± SD)*	*p-value*
Serum magnesium levels (mg/dL)	Preoperative	2.0 ± 0.22	2.0 ± 0.19	0.70
	6-hour postoperative	1.8 ± 0.17	1.9 ± 0.17	0.16
	24-hour postoperative	1.9 ± 0.14	1.9 ± 0.19	0.65
	48-hour postoperative	1.9 ± 0.24	2.0 ± 0.14	0.46
	2-week postoperative	1.9 ± 0.16	2.0 ± 0.12	0.38
Serum PTH (pg/mL)	Preoperative	37.6 ± 15.4	35.6 ± 13.7	0.63
	6-hour postoperative	16.8 ± 11.8	16.2 ± 12.2	0.87
	24-hour postoperative	18.6 ± 12.2	18.3 ± 13.3	0.93
	48-hour postoperative	23.8 ± 15.4	19.9 ± 13.9	0.34
	2-week postoperative	28.4 ± 17.1	27.8 ± 13.8	0.88
Serum phosphorus levels (mg/dL)	Preoperative	3.6 ± 0.61	3.5 ± 0.55	0.47
	6-hour postoperative	3.5 ± 0.71	3.5 ± 0.69	0.93
	24-hour postoperative	3.7 ± 0.66	3.7 ± 0.53	0.99
	48-hour postoperative	3.9 ± 0.47	3.8 ± 0.37	0.18
	2-week postoperative	3.9 ± 0.49	3.8 ± 0.70	0.82

No significant differences were found in preoperative and postoperative magnesium, phosphorus, or PTH levels between the groups. Limited literature exists on the effect of steroids on these parameters post-thyroidectomy, necessitating further research. Kolahdouzan's study reported higher phosphorus levels in the dexamethasone group but no difference in iPTH levels, consistent with our study findings.[24]

Conclusion

Our study indicates a visual trend of lower hypocalcemia rates in the steroid group, though not statistically significant. We observed a significant reduction in postoperative voice dysfunction and pain in the steroid group without any adverse effects as compared with the placebo group. To draw more definitive conclusions further study with a larger sample size is required.

Limitations

The study's small sample size, partly due to the COVID-19 pandemic's impact on elective surgeries and outpatient duties, limits the robustness of the results. Future studies with consideration for a larger sample size is essential for validation of these findings.

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