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Original Article

Betamethasone to Prevent Symptomatic Hypocalcaemia and Other Complications after Total Thyroidectomy: a Case-control Study

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Conflict of Interest
No potential conflict of interest relevant to this article was reported.

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ABSTRACT

Purpose: The study aims to determine whether postoperative infusion of betamethasone reduces the risk of symptomatic hypocalcaemia (SHC) and other complications after total thyroidectomy.
Methods: We compared a group of patients receiving betamethasone (beta group) postoperatively to a group without any perioperative glucocorticoid infusion (no beta group). Plasma levels of parathyroid hormone, total calcium, and C-reactive protein (CRP) were measured pre- and postoperatively. Complications were recorded within a 30-day follow-up. Postoperative SHC was the primary outcome.
Results: In the beta group and the no beta group, 54 patients and 47 patients were included, respectively. In the beta group, the incidence of SHC (4 pts vs. 14 pts in the no beta group; P=0.003) was reduced. In the beta group, serum calcium levels were higher on postoperative day 1 (8.6 mg/dL vs. 8.2 mg/dL in the no beta group; P=0.001) and day 2 (8.7 mg/dL vs. 8.1 mg/dL in the no beta group; P<0.000). In the beta group, serum C-reactive protein levels were lower postoperatively. In a univariate analysis, American Society of Anaesthesiology score > I (odds ratio [OR], 0.19; P=0.002), no betamethasone treatment (OR, 0.19; P=0.006), and parathyroid glands remaining in situ (PGRIS) score <3 (OR, 6.00; P=0.005) were related to postoperative SHC; in a multivariate analysis, betamethasone treatment (OR, 0.09; P=0.007) and PGRIS score <3 (OR, 8.41; P=0.045) were related to postoperative SHC. No difference was observed in postoperative complications.
Conclusion: Postoperative use of betamethasone reduces the incidence of SHC after thyroid surgery without affecting other complications.

Keywords: Thyroidectomy; Complications; Hypocalcemia; Betamethasone

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INTRODUCTION

Total thyroidectomy is commonly recommended for both benign and malignant thyroid diseases. Thyroid surgery is associated with serious complications, which may be increased when total thyroidectomy is performed. Hypocalcaemia (HC) and recurrent laryngeal nerve (RLN) palsy are the most common complications after thyroid surgery.

HC is common in the immediate postoperative period, with a reported incidence of 27% (19–38) in the literature; however, permanent HC is rare, with an incidence of 1% (0–3) (1). HC is a major cause of prolonged postoperative recovery and hospital care costs (2). Therefore, preventing these 2 complications is a main issue in thyroid surgery.

Surgical trauma is a recognized cause of these complications. Even if the surgical procedure is well performed, parathyroid glands may be accidentally removed or devascularized, leading to impairment of their function (3).

Glucocorticoids are well known as effective anti-inflammatory agents and may be important biologic modifiers of perioperative inflammatory responses, leading to improvement of surgical outcomes and reduction of complications (4). Regarding the use of steroids in thyroid surgery, there is little and conflicting information in the literature. Preoperative infusion of dexamethasone reduces postoperative HC occurrence without any significant evidence (5).

The goal of this study was to determine if a postoperative infusion of betamethasone reduces the risk of postoperative HC; RLN and other common complications were also assessed as secondary outcomes.

MATERIALS AND METHODS

This study was a retrospective analysis of a prospective database including consecutive adult patients undergoing total thyroidectomy or completion thyroidectomy from January 2018 to June 2020 in the Department of Surgery at "A. Fiorini" Hospital in Terracina. After approval by local bioethics committees and informed consent obtained preoperatively upon hospital admission, all patients were included regardless of the surgical indication for malignant or benign pathology. A diagnosis of thyroid malignancy was made if a malignancy of any size was documented on final pathology. Informed consent was obtained from all individual participants included in the study. A matched case-control study was designed according to the presence or absence of any parathyroid gland in the final specimen.

The following data were collected for each patient prospectively: sex, age, body mass index, presence of comorbidities, procedural indication, American Society of Anaesthesiology (ASA) score, type of surgery, duration of surgery, postoperative recovery, final pathology, and presence of any parathyroid gland in the final specimen; moreover, the number of parathyroid glands remaining in situ (PGRIS) score was calculated using the formula: 4 minus parathyroid glands found in the specimen. Patients were then classified according to the PGRIS number as group 1–2 (one or 2 PGRIS), group 3 (3 PGRIS) or group 4 (all 4 glands remaining in situ). All patients received preoperative flexible laryngoscopic examination of the vocal cords.

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An experienced surgeon carried out all operations under general anaesthesia with orotracheal intubation. Total thyroidectomy was performed in a standardized manner. The technique was performed by seeking, identifying, and exposing the RLN with all branches and following its course with care until it entered the larynx. All parathyroid glands were identified, if possible. Two suction drains were used in all patients.

Plasma levels of parathyroid hormone (PTH) (reference range, 15–65 pg/ml), total calcium (reference range, 8.4–10.4 mg/dL) and C-reactive protein (CRP) (reference range, 0–0.5 mg/dL) were measured preoperatively and on the first, second and third postoperative days. HC was defined as at least one serum calcium measurement below 8.0 mg/dL. Symptomatic hypocalcaemia (SHC) was defined as the presence of the following signs and symptoms associated with HC: numbness of the extremities, facial paraesthesia, muscular spasms, and Chvostek's or Trousseau's signs. Biochemical hypoparathyroidism (hPT) was defined as a low intact PTH level below the lower limit of the reference range, accompanied by HC. Clinical hPT was defined as biochemical hPT that is accompanied by symptoms and/or signs of HC. Oral calcium supplementation with vitamin D analogue was given if patients developed HC. An intravenous calcium gluconate infusion (10%) was administered for significant HC symptoms or when oral therapy proved inefficacious.

A numeric rating scale (NRS) for pain from 0 (no pain) to 10 (worst pain imaginable) was completed by each patient 24 hours after surgery. Intravenous infusion of paracetamol 1 g t.i.d. was administered to every patient on the first postoperative day.

Patients were discharged when the serum calcium level was higher than 8.0 mg/dL. A 30-day follow-up for morbidity was performed in all cases.

From January 2018 until June 2019, patients received intravenous betamethasone, 4 mg (Bentelan; Alfasigma SpA, Bologna, Italy) 2 hours after surgery and 1.5 mg on postoperative days 1, 2 and 3 (beta-group); from July 2019 to June 2020, no perioperative glucocorticoids were administered (no beta-group).

1. Statistical analysis

Data were analysed using MedCalc® Release 14.8.1 (MedCalc Software Ltd., Ostend, Belgium). The characteristics of the study group are reported as the median and interquartile range for continuous non-parametric variables and as the number (percentage) of patients for categorical variables. The Mann-Whitney test was used to compare continuous non-parametric variables, and 2-sided χ^2 and Fisher's exact tests, where appropriate, were used to compare categorical variables. Associations of SHC with dichotomic variables were assessed with univariate and multivariate analyses. Multivariate analysis was performed by means of a binary logistic regression model, entering all variables in one single step. The odds ratios (ORs) are presented with 95% confidence intervals (CIs) and P values. An OR higher than unity implies a higher probability of an event compared to the reference group. P values <0.05 were considered statistically significant.

RESULTS

A total of 101 patients were analysed (**Table 1**). There were 54 patients in the beta group and 47 patients in the no beta group. Demographic and clinical characteristics were similar in both groups.

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Table 1. Demographic and clinical characteristics of the study group

Characteristics	Total (n=101)	Beta group (n=54)	No beta group (n=47)	P
Sex, female	74 (73.3)	37 (68.5)	37 (78.7)	0.250
Age (yr)	57.0 (49.0–69.0)	60.0 (50.0–71.0)	54.0 (48.2–61.5)	0.061
Age >50 yr	68 (67.3)	38 (70.4)	30 (63.8)	0.487
BMI (kg/m^2)	26.8 (23.3–30.2)	26.3 (22.3–29.4)	26.9 (24.3–30.6)	0.320
BMI >30 kg/m^2	26 (25.7)	13 (24.1)	13 (27.7)	0.682
Co-morbidities	81 (80.2)	44 (81.5)	37 (78.7)	0.723
Preoperative diagnosis				0.420
Multinodular goiter	69 (68.3)	35 (64.8)	34 (72.3)	
Other*	32 (31.7)	19 (35.2)	13 (27.7)	
PTH (pg/mL)	72.0 (58.5–94.0)	68.0 (57.5–94.2)	76.0 (59.2–94.0)	0.507
Serum calcium (mg/dL)	9.5 (9.1–9.7)	9.5 (9.4–9.6)	9.4 (9.2–9.7)	0.071
CRP (mg/dL)	0.15 (0.09–0.35)	0.12 (0.10–0.41)	0.16 (0.09–0.32)	0.926
ASA				0.273
I	19 (18.8)	8 (14.8)	11 (23.4)	
> I†	82 (81.2)	46 (85.2)	36 (76.6)	
Operation				0.861
Total thyroidectomy	95 (94.1)	51 (94.4)	44 (93.6)	
Completion thyroidectomy	6 (5.9)	3 (5.6)	3 (6.4)	
Duration of surgery (min)	80.0 (65.0–85.0)	80.0 (70.0–85.0)	75.0 (65.0–85.0)	0.332
Postoperative recovery (days)	3 (3–3)	3 (3–3)	3 (3–3)	0.096
Final pathology				0.119
Benign	88 (87.1)	51 (94.4)	40 (85.1)	
Malignant	10 (9.9)	3 (5.6)	7 (14.9)	
Parathyroid present in final specimen	41 (40.6)	21 (38.9)	20 (42.6)	0.710
PGRIS score				0.936
1 or 2	10 (9.9)	6 (11.1)	4 (8.5)	
3	31 (30.7)	15 (27.8)	16 (34.0)	
4	60 (59.4)	33 (61.1)	27 (57.4)	

Data are presented as number (percentage) or median (interquartile range).
Beta = betamethasone; BMI = body mass index; PTH = parathyroid hormone; CRP = C-reactive protein; ASA = American Society of Anaesthesiology; PGRIS = parathyroid glands remaining in situ.
*Toxic multinodular goitre 15 pts, indeterminate or suspicious nodule 12 pts; †ASA II 71 pts, ASA III 11 pts.

1. HC

HC occurred in 36 (35.6) pts, and SHC was present in 18 (17.8) pts. In the beta group, the incidence of HC was reduced during recovery (15 [27.8] pts vs. 21 [44.7] pts in the no beta group; P=0.078); the incidence of SHC was significantly reduced at the postoperative follow-up (4 [7.4] pts vs. 14 [29.8] pts in the no beta group; P=0.003). Biochemical hPT was reported in 24 (23.8) pts and was associated with clinical hPT in 10 (9.9) pts; no significant difference was reported in the occurrence of biochemical hPT (14 [25.9] pts vs. 10 [21.3] pts; P=0.586) or in the number of patients with clinical hPT (3 [5.5] pts vs. 7 [14.9] pts in the no beta group; P=0.116) in the beta group. Serum calcium, PTH and CRP levels in the 2 study groups during recovery are reported in **Fig. 1**. In the beta group, serum calcium levels were significantly higher on postoperative day 1 (8.6 [8.0–8.8] mg/dL vs. 8.1 [7.7–8.6] mg/dL in the no beta group; P=0.001) and day 2 (8.7 [8.3–8.8] mg/dL vs. 8.1 [7.8–8.3] mg/dL in the no beta group; P<0.000). With respect to serum PTH, no significant difference was observed between the 2 study groups. In the beta group, serum CRP levels were significantly lower on postoperative day 2 (0.5 [0.2–1.1] vs. 1.9 [0.9–2.5] in the no beta group; P=0.015) and day 3 (0.3 [0.1–0.4] vs. 1.3 [0.7–2.1] in the no beta group; P=0.008).

2. Predictors of patient-reported HS symptoms

Both univariate and multivariate analyses were performed to assess the predictors of SHC (**Table 2**). In univariate analysis, factors that significantly increased the risk of developing SHC were ASA score > I (OR, 0.19 [95% CI, 0.06–0.59]; P=0.002), no betamethasone treatment (OR, 0.19 [95% CI, 0.06–0.62]; P=0.006), and PGRIS score <3 (OR, 6.00 [95% CI,

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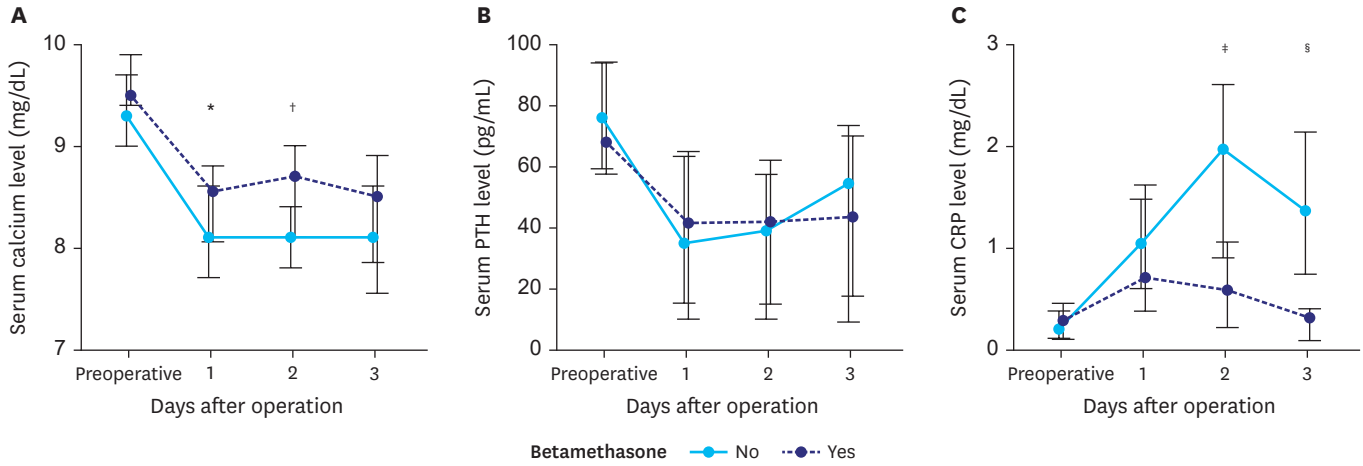

Fig. 1. (A) Changes in serum calcium levels in patients receiving betamethasone or not. In the betamethasone group, serum calcium levels were significantly higher on postoperative day 1 (*P=0.001) and day 2 (†P<0.001). (B) Changes in serum PTH levels in patients receiving betamethasone. No significant difference was observed between the 2 study groups. (C) Changes in serum CRP levels in patients receiving betamethasone or not. In the betamethasone group, CRP levels were significantly lower on postoperative day 2 (‡P≤0.015) and day 3 (§P<0.008).
PTH = parathyroid hormone; CRP = C-reactive protein.

Table 2. Predictors of SHC

Characteristics	SHC (n=18)	No SHC (n=83)	Univariate OR (95% CI)	P	Multivariate OR (95% CI)	P
Sex, female	14 (77.8)	60 (72.3)	1.34 (0.40–5.50)	0.634	0.65 (0.14–2.90)	0.573
BMI >30 kg/m^2	3 (16.7)	23 (27.7)	0.52 (0.14–1.97)	0.333	1.34 (0.24–7.31)	0.738
Age >50 yr	11 (61.1)	57 (68.7)	1.32 (0.15–1.48)	0.537	1.31 (0.23–7.41)	0.763
Co-morbidities	14 (77.8)	67 (80.7)	0.83 (0.24–2.88)	0.777	2.65 (0.28–24.90)	0.394
Preoperative diagnosis						
Multinodular goitre	14 (77.8)	64 (77.1)	Reference		Reference	
Other	4 (22.2)	19 (22.9)	0.96 (0.28–3.27)	0.951	3.39 (0.47–24.36)	0.224
ASA						
I	8 (44.4)	11 (13.3)	Reference		Reference	
> I	10 (55.6)	72 (86.7)	0.19 (0.06–0.59)	**0.002**	0.21 (0.04–1.18)	0.077
Betamethasone	4 (22.2)	50 (60.2)	0.19 (0.06–0.62)	**0.006**	0.09 (0.01–0.52)	**0.007**
Final pathology						
Benign	16 (88.9)	72 (86.7)	Reference		Reference	
Malignant	2 (11.1)	11 (13.3)	0.82 (0.16–4.05)	0.806	0.48 (0.05–4.07)	0.499
Parathyroid present in the final specimen	10 (55.6)	31 (37.3)	2.10 (0.75–5.88)	0.156	1.57 (0.35–6.89)	0.553
PGRIS						
≥3	13 (72.2)	78 (94.0)	Reference		Reference	
<3	5 (27.8)	5 (6.0)	6.00 (1.52–23.65)	**0.005**	8.41 (1.05–67.23)	**0.045**

Data are presented as number (percentage), unless otherwise specified. Bold numbers are statistically significant values.
SHC = symptomatic hypocalcaemia; OR = odds ratio; CI = confidence interval; BMI = body mass index; ASA = American Society of Anaesthesiology; PGRIS = parathyroid glands remaining in situ.

1.52–23.65]; P=0.005). After logistic regression analysis, betamethasone treatment (OR, 0.09 [95% CI, 0.01–0.52]; P=0.007) and PGRIS score <3 (OR, 8.41 [95% CI, 1.05–67.23]; P=0.045) were the only significant factors related to the development of SHC.

3. Other complications

Other postoperative complications within a 30-day follow-up are reported in **Table 3**. Postoperative NRS score for pain was 2 (1–4). During recovery, dysphonia occurred in 50 (48.1) pts and persisted in 33 (31.7) pts at the 30-day follow-up. RLN palsy was documented in 5 (4.8) pts with laryngoscopic examination. Sore throat was present in 26 (25.0) pts; dysphagia occurred in 9 (8.6) pts. No statistically significant difference was observed between the 2 study groups. No surgical site infections occurred during follow-up.

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Table 3. Complications in the study groups

Variables	Total (n=101)	Beta group (n=54)	No beta group (n=47)	P
Dysphonia				
At hospital discharge	48 (47.5)	28 (51.8)	20 (42.5)	0.353
At 30-day follow-up	32 (31.7)	18 (33.3)	14 (29.8)	0.707
RLN palsy	5 (4.9)	2 (3.7)	3 (6.4)	0.535
Sore throat	25 (24.7)	15 (27.8)	10 (21.3)	0.453
Dysphagia	9 (8.9)	4 (7.4)	5 (10.6)	0.575
Pain, NSR score	2 (1–4)	2 (1–5)	2.5 (0–4)	0.352

Data are presented as number (percentage) or median (interquartile range).
Beta = betamethasone; RLN = recurrent laryngeal nerve; NRS = numeric rating scale.

DISCUSSION

The perioperative use of glucocorticoids is increasing because of their various advantages. In particular, there is substantial evidence in the literature regarding the beneficial effects of glucocorticoids in reducing postoperative nausea and vomiting (6). However, concern about the side effects of glucocorticoids, related to a possible immunosuppression, which may increase postoperative complications such as infections and altered wound healing, is limiting their widespread use. Two recent meta-analyses supported the safety of glucocorticoids in surgical patients, although they underscored some bias present in the literature, which should caution about the reported results (7,8). Although the vast majority of the studies reports the use of a single dose of glucocorticoid, namely dexamethasone, administered before surgery, we decided to use betamethasone in the postoperative period. Our choice to use a glucocorticoid after surgery is supported by studies, which showed that glucocorticoids suppress immune response if administered when inflammation is not present but stimulate immunity during inflammatory response (9,10). The anti-inflammatory action of glucocorticoids in the postoperative period is largely documented (4) and supported by our data, which show a significant decrease of CRP level in the beta-group after surgery. The absence of any surgical site infection in our study confirms the safety of glucocorticoids, despite their anti-inflammatory action.

Post-thyroidectomy HC may recognize different causes, such as parathyroid removal and surgical trauma, leading to devascularization and damage of the parathyroid glands (1); an additional etiology includes an increase of calcitonin release due to thyroid gland handling during surgery (11); other mechanisms are postoperative alkalosis-induced HC resulting from hyperventilation, due to postoperative pain, and dilution HC (12).

It is evident that surgical trauma is a major cause of post-thyroidectomy HC, so that decreasing inflammation related to trauma is a possible effective treatment to reduce this common complication. However, evidence in the literature is lacking. There is only one published randomized trial, showing a lower occurrence rate in postoperative SHC in a group of patients treated before thyroidectomy with dexamethasone and compared with a control group, although there was no statistical significance (5). A Chinese retrospective study on patients submitted thyroid surgery for papillary carcinoma showed that in the group of patients treated with intraoperative plus postoperative application of glucocorticoids, the incidence of hPT was decreased after surgery (13). Our data showed that either biochemical HC or SHC was significantly reduced in the group of patients treated with betamethasone postoperatively. Moreover, treatment with betamethasone was one of the 2 independent factors significantly related to the occurrence of SHC after surgery. The other one was PGRIS score. In the literature, unclear results are reported with respect to the number of preserved

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parathyroid glands and the occurrence of SHC (14). In the present study, we found that the removal of at least 2 parathyroid glands is a significant risk factor for SHC occurrence.

Voice dysfunction after thyroidectomy is common. RLN palsy is a well-established cause of dysphonia. However, transection of the RLN is rare (15). Surgical trauma related to the intraoperative identification and manipulation of the RLN is the main cause of its functional impairment (16). According to these observations, the perioperative use of glucocorticoids was suggested to reduce the inflammatory response to surgical trauma and preserve RLN function. In the literature, there are 3 published randomized studies, all addressing the effect on voice outcome after a single preoperative injection of 8 mg of dexamethasone (17-19). Improvement of the voice with respect to the control group only occurred 24 hours after surgery and was not sustained in the subsequent recovery period in 2 trials (18,19). The study of Feroci et al. (18), assessing voice outcome as a secondary endpoint, showed no impact of dexamethasone on this complication. Our study confirms that glucocorticoids do not affect voice outcome in the postoperative period if they are used postoperatively.

Glucocorticoids are also effective in reducing postoperative sore throat following tracheal intubation (20). The incidence of sore throat is particularly high in thyroid surgery performed under general anaesthesia (21). A randomized trial showed that preoperative dexamethasone could reduce postoperative sore throat (22). Our data do not support the efficacy of postoperative glucocorticoid infusion to prevent this common complaint after thyroid surgery.

Dysphagia after thyroidectomy is common, too (23). In the absence of RLN transection, post-thyroidectomy swallowing alterations seem to be mainly associated with surgical trauma (24,25). A retrospective study showed that perioperative dexamethasone could influence swallowing problems in early postoperative recovery after thyroidectomy (26). Our study showed a tendency towards a reduction in swallowing complaints in the beta group, without a significant difference compared to the no beta group.

Perioperative glucocorticoids have been largely used to reduce postoperative pain in a wide range of surgical procedures with limited benefits (27). With respect to thyroid surgery, trials showed a significant effect of glucocorticoids in reducing postoperative pain, even though pain was not the primary outcome in all studies (17,18,28). In another trial, where postoperative pain was set as the primary endpoint of the study, dexamethasone at 2 different preoperative doses had no analgesic or opioid sparing effect compared to placebo (29). Our study confirmed the results of this trial.

The main limitation of the present study is the retrospective analysis of the data, although they were extracted from a prospective database and matched for the presence of the parathyroid glands in the final specimens in both study groups, a well-recognized factor influencing postoperative HC. Another limitation is that our sample size is relatively small, with notably different numbers of cases in the 2 study groups. Moreover, postoperative symptomatic outcomes were all reported subjectively by the patients, without any objective measure. Indocyanine green fluorescence angiography has been shown to be a reliable intraoperative adjunct to assess the perfusion and consequent function of the residual parathyroid glands (30). To assess the efficacy of glucocorticoids in reducing postoperative functional impairment of the parathyroid glands, the use of this technique is advisable.

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CONCLUSION

In the context of the present study, our findings support the postoperative use of betamethasone to reduce the incidence of SHC after thyroid surgery. The other common complications were unaffected by the glucocorticoids used in our study. We believe that further prospective randomized trials need to be performed to address the efficacy of glucocorticoids in reducing complications after thyroid surgery.

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