Role of Loading Calcitriol to Control Hypocalcemia after Parathyroidectomy in Chronic Kidney Disease

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Objective: *To compare the effective calcitriol regimens in hypocalcimic hyperparathyroidism (HPT) patients who were referred to parathyroidectomy.*
Material and Method: *Retrospective study of fifty patients who underwent parathyroidectomy in Rajavithi Hospital between September 2001 and August 2009 was performed. The authors defined three regimens of calcitriol (A; fixed dose regimen, B; titrated dose regimen and C; loading dose regimen) by reviewing 41 charts of patients with chronic kidney disease. Biochemical factors available within two weeks before and after surgery were recorded and analyzed.*
Results: *Postoperative hypocalcemia was a common complication found in 82.93% (n = 34/41) of patients with chronic kidney disease, 80.61% (n = 25/31) and 90% (n = 9/10) of secondary HPT and tertiary HPT, respectively. In multiple logistic regression analysis; calcium-phosphorus product was the independent predictor of postoperative hypocalcemia requiring intravenous calcium gluconate with statistical significance at p = 0.008, ROC analysis showed calcium phosphorus products more than 53 mg^2/dl^2 represented the best compromise between sensitivity (0.71) and specificity (0.67) by area under the curve = 0.755). The amount of intravenous calcium gluconate after parathyroidectomy in the loading calcitriol regimen (initial dose 2.25-4 mcg/day) was significantly lower than that in the titrated calcitriol regimen (0.75-1.5 mcg/day) (p = 0.001).*
Conclusion: *Loading calcitriol regimen reduced hypocalcemic morbidity in postoperative parathyroidectomy in patients with chronic kidney disease.*

Keywords: *Calcitriol, Parathyroidectomy, Chronic kidney disease*

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One of the most common complications after parathyroidectomy is postoperative hypocalcemia and/or hungry bone syndrome(1-3). Calcium supplements are often required following successful parathyroidectomy (PTX) in order to prevent overt hypocalcemia. Nevertheless, transient hypocalcemia has been observed in 83% of the secondary hyperparathyroidism (2HPT) patients(4).

Hungry bone syndrome, first described in 1948 by Albright and Reifenstein(5), is characterized by severe prolonged hypocalcemia after parathyroidectomy. The abrupt withdrawal of parathyroid hormone (PTH) results in a transient marked increase in bone remineralization and a rapid shift of calcium from the circulation to bone tissue(6,7). After parathyroidectomy performed in dialysis patients with severe secondary hyperparathyroidism, acute functional changes are observable in bone cell. There are several regimens to reduce hypocalcemic symptoms. Vitamin D therapy is often used, but it does not influence bone cell activity; instead, it improves hypocalcemia mainly through the known effect on intestinal calcium absorption(8). In addition, combined oral and intravenous vitamin D and calcium supplements in the form of calcitriol (1, 25-dihydroxycholecalciferol, (1, 25-$(OH)_2D_3$), active form of vitamin D) and calcium gluconate, respectively, has been shown to ameliorate hypocalcemia.

The aim of the present study was to compare the efficacy of calcitriol administration regimens in controlling hypocalcemia in hyperparathyroidism

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patients with chronic kidney disease after successful parathyroidectomy.

Material and Method

Study design

Between September 2001 and August 2009, fifty patients underwent parathyroidectomy for symptomatic hyperparathyroidism at Rajavithi Hospital. Among them, 14 (28%) patients were excluded from the present study because of primary hyperparathyroidism (n = 9) and persistent disease after surgery (post-operative intact PTH > 300 pg/dl) (n = 5). The charts of the remaining 41 patients with chronic kidney disease stage 5 that underwent successful PTX are reviewed in detail.

Before surgery, serum levels of calcium, phosphorus, alkaline phosphatase (ALP), blood urea nitrogen (BUN) and creatinine were routinely measured using standard auto-analytical techniques. Intact PTH (1-84) was measured by the two-site immunoradiometric assay (ELSA-PTH; CIS Bio International, Gif-sur-Yvette, France) with a normal range of 10 to 65 pg/ml. All patients underwent dialysis the day before operation. Preoperative imaging of the parathyroid glands was not routinely used. Bilateral cervical exploration was performed in all patients to identify four parathyroid glands. The authors' goal was to control the level of intact PTH to the target range of 150 to 300 pg/ml, as recommended by K/DOQI guidelines[9].

After surgery, oral calcium carbonate and oral calcitriol was immediately supplemented. Regimens of calcitriol treatment were defined in three regimens as the following:

A; fixed dose regimen was defined by supplemented calcitriol with constant dose together with oral calcium carbonate but the amount of intravenous calcium gluconate was titrated against serum calcium.

B; titrated dose regimen was defined by supplemented calcitriol with titrated against serum calcium level (0.5-1.5mcg/d) with constant dose of oral calcium carbonate. Intravenous calcium treatment was administered when the patient's serum level of corrected total calcium fell below 7.0 mg/dl or the patient experienced severe hypocalcemic symptoms such as numbness, paresthesia, positive Chvostek's sign, carpopedal spasms, or tetany.

C; loaded dose regimen was defined by supplemented calcitriol with loading at first day of postoperation (initial starting dose of 2.25-4 mcg/d) with a constant dose of oral calcium carbonate. Intravenous calcium treatment was administered when the patient experienced conditions described in regimen B.

The authors' standard protocol was to add four to ten l0-ml ampoules of 10% calcium gluconate (360-900 mg elemental calcium) to 150 ml 0.9% saline or 5% dextrose water, infused at a rate of 20 to 40 ml/hr depending on the patient's body weight. The intravenous infusion was gradually tapered when calcium serum level was stabilized.

Postoperative length of stay was defined as the number of days from the day of operation (day 0) until hospital discharge. Patients were discharged when the corrected total calcium levels were above 7.0 mg/dl and there were no hypocalcemic symptoms.

Analysis was performed with the Statistical Package for Social Sciences version 17.0 (SPSS, Chicago, IL, USA). Comparisons between groups were performed using Fisher's exact test, Chi-squared test, or Student's t-test as appropriate. Linear regression analysis was used to examine the correlation between the length of stay and relevant markers. Receiver operating characteristic curve (ROC) analysis was used to determine the best cutoff values. Data were evaluated by ANOVA (repeated measurements) and to validate differences between mean Tukey HSD and Bonferroni test were applied for poshoc comparison. Plus-minus values were means $\pm$ SD. All p-values were two sided and were considered statistically significant at 0.05.

Results

As shown in Fig. 1, fifty patients were referred to undergo parathyroidectomy for symptomatic

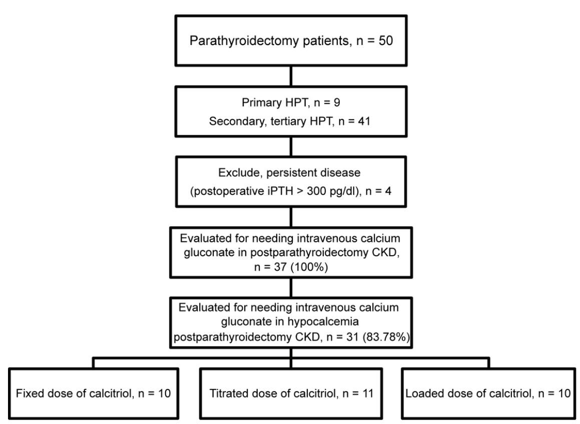

Fig. 1 Trial profile

hyperparathyroidism at Rajavithi Hospital. Among them, 14 (28%) patients were excluded from the present study because of primary hyperparathyroidism (n = 9) and persistent disease after surgery (post-operative intact PTH > 300 pg/dl) (n = 4). Charts of the remaining 37 patients with chronic kidney disease stage 5 undergoing successful PTX were reviewed in detail.

Of 50 patients, 14 patients were excluded from the present study (nine patients with primary hyperparathyroid and five patients with persistent disease (postoperative iPTH > 300pg/dl). Among the rest, 31 patients showing hypocalcemia were participated in three different calcitriol regimens.

As shown in general characteristics in Table 1, basal clinical and biochemical data were not different comparing between secondary (2HPT) and tertiary (3HPT) hyperparathyroidism patients. This was exceptional for preoperative calcium level; the averaged concentrations were 10.34 ± 1.11 mg/dl in 2HPT and 11.98 ± 0.94 mg/dl in 3HPT ($p < 0.001$).

Postoperative hypocalcemia parathyroidectomy was defined based on the criteria of corrected serum calcium level below 8 mg/dl. The authors found that biochemical data were not different in both groups (Table 2). The present study has shown that patients who needed intravenous calcium gluconate were younger, had higher levels of preoperative serum phosphate and calcium-phosphorus products, higher incidence in hypocalcemia and longer duration of hospitalization. They showed statistical significance at p = 0.02, 0.012, 0.009, 0.046, and 0.012, respectively (Table 3).

Biochemical markers including all mentioned above (age, preoperative serum phosphate level, calcium-phosphorus products and hypocalcemia incidence) were analyzed in logistic regression model. It showed significant correlation only between

Table 1. General characteristic of patients with chronic kidney disease who underwent parathyroidectomy

	Secondary HPT (n = 30) (2HPT)	Tertiary HPT (n = 11) (3HPT)	p-value
Age (yrs)	44.30 ± 10.06	44.36 ± 10.66	0.99
BW (kg)	52.81 ± 11.13	56.83 ± 7.27	0.27
Duration RRT (yrs)	9.19 ± 3.52	9.30 ± 5.01	0.94
BUN (mg/dl)	52.50 ± 29.23	51.36 ± 28.55	0.91
GFR	11.63 ± 11.19	8.56 ± 3.45	0.38
Creatinine (mg/dl)	7.83 ± 3.12	9.17 ± 3.64	0.27
Calcium (mg/dl)	10.34 ± 1.11	11.98 ± 0.94	<0.001
Phosphate (mg/dl)	5.42 ± 2.38	5.83 ± 2.48	0.64
Ca-phosphorus (mg^2/dl^2)	55.91 ± 24.77	69.74 ± 32.07	0.15
Intact PTH (pg/dl)	1,756.01 ± 764.04	1,727.93 ± 1144.87	0.93
ALP (IU/L)	442.90 ± 279.63	385.29 ± 305.80	0.65
Sex (male)	19 (63.33%)	7 (63.64%)	0.97
Mode of renal replacement treatment			0.38
IPD	2 (6.67%)	0	
Hemodialysis	27 (90.00%)	10 (90.91%)	
CAPD	1 (3.33%)	1 (9.09%)	
KT	1 (3.33%)	1 (9.09%)	
Regimen of calcitriol therapy			0.30
Fixed	13 (43.33%)	3 (27.27%)	
Titrated	10 (33.33%)	2 (18.18%)	
Loaded	6 (20%)	5 (45.45%)	
Untreated	1 (3.33%)	1 (9.09%)	
Hypocalcemia	25 (83.33%)	10 (90.91%)	0.66
Number of glands			0.96
One gland	3 (10%)	1 (9.10%)	
Two glands	4 (13.33%)	2 (18.18%)	
Three glands	7 (23.33%)	3 (27.27%)	
Four glands with autotransplantation	16 (53.33%)	5 (45.45%)	

Table 2. General characteristics of hypocalcemic postparathyroidectomy in chronic kidney disease

	Hypocalcemic postparathyroidectomy in CKD (Ca < 8mg/dl)		p-value
	Yes (n = 35)	No (n = 6)	
Age (yrs)	43.60 ± 10.93	51.40 ± 10.09	0.12
Sex (male)	22 (62.86%)	4 (66.67%)	0.86
BW (kg)	53.46 ± 11.07	55.90 ± 6.11	0.64
Duration renal replacement (yrs)	9.29 ± 4.24	8.80 ± 1.3	0.80
BUN (mg/dl)	54.00 ± 29.81	51.80 ± 19.93	0.88
GFR	10.20 ± 9.74	9.10 ± 2.14	0.80
Creatinine (mg/dl)	8.48 ± 3.22	8.44 ± 2.62	0.98
Calcium (mg/dl)	10.66 ± 1.29	11.52 ± 1.18	0.17
Phosphate (mg/dl)	5.77 ± 2.45	4.66 ± 1.47	0.33
Ca-phosphorus product (mg^2/dl^2)	61.96 ± 28.69	52.63 ± 12.21	0.48
Intact PTH (pg/dl)	1,805.62 ± 865.05	1,310.63 ± 644.68	0.23
Alkaline phosphatase (IU/L)	460.09 ± 297.61	218.33 ± 92.14	0.18

Table 3. General characteristics of hypocalcemic postparathyroidectomy in chronic kidney disease who need intravenous calcium gluconate therapy

	Intravenous calcium gluconate treatment in CKD		p-value
	Yes (n = 16)	No (n = 23)	
Age (yrs)	39.31 ± 9.19	47.48 ± 11.19	0.02*
BW (kg)	52.02 ± 9.59	54.99 ± 11.20	0.39
Duration RRT (yrs)	9.57 ± 4.88	8.98 ± 3.23	0.67
BUN (mg/dl)	58.56 ± 25.90	50.35 ± 30.33	0.38
GFR	8.02 ± 2.82	11.48 ± 11.54	0.25
Creatinine (mg/dl)	8.99 ± 3.47	8.08 ± 2.84	0.40
Calcium (mg/dl)	10.84 ± 1.20	10.82 ± 1.39	0.79
Phosphate (mg/dl)	6.75 ± 1.92	4.85 ± 2.37	0.012*
Ca-phosphorus product (mg^2/dl^2)	73.98 ± 25.75	51.58 ± 24.73	0.009*
Intact PTH (pg/dl)	2,036.73 ± 1,155.01	1,537.24 ± 479.56	0.07
Alkaline phosphatase (IU/L)	502.50 ± 299.63	371.93 ± 280.51	0.26
Duration of hospitalization (days)	12.69 ± 6.07	8.70 ± 3.27	0.012*
Sex (male)	10 (62.50%)	16 (69.57%)	0.61
Mode of RRT			
IPD	0	2 (8.70%)	0.23
Hemodialysis	14 (87.50%)	23 (100%)	0.08
CAPD	2 (12.50%)	0	0.08
Kidney transplantation	2 (12.50%)	0	0.08
Number of glandectomy			0.75
1	1 (6.25%)	2 (8.70%)	
2	1 (6.25%)	4 (17.39%)	
3	4 (25.00%)	5 (21.74%)	
4	10 (62.50%)	12 (52.17%)	
Regimen of calcitriol	15 (93.75%)	20 (86.96%)	0.004*
Hypocalcemia	16 (100%)	18 (78.26%)	0.046*

preoperative calcium phosphorus products and requiring intravenous calcium gluconate ($R^2 = 0.167$; $p = 0.008$) (Table 4). The authors further examined the cut-off values for preoperative calcium-phosphorus

Table 4. Multiple linear regression analysis

Model		Unstandardized coefficients		Standardized coefficients	t	Sig.
		B	Std. error	Beta		
1	(Constant)	2.032	0.175		11.602	0.000
	CaxPO	-0.007	0.003	-0.409	-2.799	0.008*

a. Dependent variable: intravenous calcium gluconate, $R^2 = 0.167$

Model		Beta in	t	Sig.	Partial correlation	Collinearity statistics
						Tolerance
1	Hypocalcemia	0.283a	1.969	0.056	0.304	0.966
	Age	0.233a	1.512	0.139	0.238	0.872
	Regimen of calcitriol	0.163a	1.091	0.282	0.174	0.951
	Phosphate	-0.162a	-0.294	0.770	-0.048	0.072

a. Predictors in the model: (Constant), Calcium-phosphorus
b. Dependent variable: intravenous calcium gluconate

products. As demonstrated in Fig. 2, ROC analysis showed calcium phosphorus products to be a significant discriminator of requiring intravenous calcium gluconate (area under the curve, 0.755).

The authors explored various cut-off levels for preoperative calcium-phosphorus products and found that 53 mg^2/dl^2 represented the best compromise between sensitivity (0.71) and specificity (0.67). Finally, regimens of calcitriol treatment in postparathyroidectomy were compared and it showed difference between titrating regimen and loading regimen (ANOVA; 0.001) in requiring intravenous calcium gluconate supplement (Table 5). Loading calcitriol regimen significantly reduced the amount of intravenous calcium gluconate.

Discussion

Postoperative hypocalcemia in patients with renal hyperparathyroidism is a common problem after parathyroidectomy. Similar to the authors' finding, a previous study reported that transient hypocalcemia was observed in 83% of the patients[3]. However, postoperative hypocalcemia is not always present after surgical cure[10]. With renal hyperparathyroidism, Jofre et al[2] observed that 20% of their patients had hungry bone syndrome necessitating longer hospitalization. This postoperative hypocalcemia is defined as calcium levels of less than 8.0 mg/dl for more than eight days. In addition to biochemical values, the presence or absence of hypocalcemic symptoms has also been

Table 5. Comparison of calcitriol treatment regimens in postparathyroidectomy patients with chronic kidney disease who required intravenous calcium gluconate

Regimen of calcitriol	Regimen of calcitriol	Sig.[+]
A; Fixed (n = 11)	Titrated	0.068
	Loaded	0.321
B; Titrated (n = 13)	Fixed	0.068
	Loaded	0.001*
C; Loaded (n = 11)	Fixed	0.321
	Titrated	0.001*

[+] Both Turkey HSD and Bonferroni

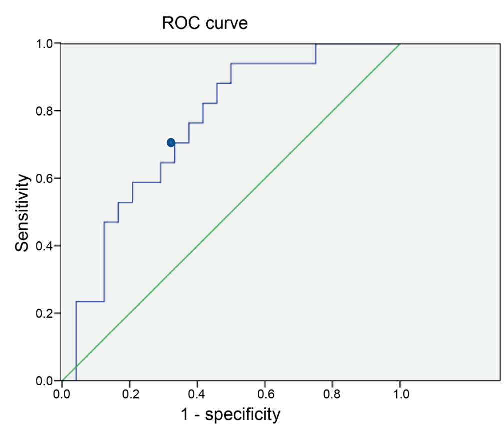

Fig. 2 Receiver operating characteristic curve (ROC) analysis, AUC = 75.5%, R^2 =0.167, p = 0.008

taken into consideration in many studies. Comparisons are further complicated by the fact that a low serum calcium level does not always indicate the development of symptoms or signs of hypocalcemia. Previous studies[11-18] have used the calcium nadir level, changes of calcium levels, duration of hypocalcemia, or dosage of required calcium supplementation as estimates of the severity of hungry bone syndrome. Factors that have been found to be related to post-operative hypocalcemia include age, preoperative PTH, alkaline phosphatase levels, subperiosteal bone resorption and the histology of the bone biopsy[1-3,7,11-16,18,19]. However, the present study hasn't found any factors relating to postoperative hypocalcemia in renal hyperparathyroidism but loaded calcitriol dose regimen was the best strategies to reduced administration of intravenous calcium gluconate after parathyroidectomy by significant (p = 0.001) as in Table 5.

The present study has found that calcium-phosphorus products, age, regimen of treatment and phosphate level were correlated with requirement of intravenous calcium gluconate administration after parathyroidectomy. Calcium-phosphorus product was the only independent factor to predict requirement of intravenous calcium supplement when the serum level was more than 53 (area under the curve 0.76, p = 0.008).

Retrospective study design is the limitation of the present study. For instance, several markers were not routinely measured during preoperative and postoperative period. Variations in calcitriol doses were found in the same regimen. Despite this fact, the present findings are still helpful for optimization of management strategies to prevent and reduce symptomatic hypocalcemia in postoperative para-thyroidectomy. It is generally agreed that aggressive calcium supplement is helpful in alleviating symptoms of hypocalcemia[1,3,9,20]. Oral calcium and active vitamin D supplements are sufficient in some patients. On the other hand, intravenous calcium administration is often necessary if severe or symptomatic hypocalcemia develops. "Need for intravenous calcium" has been used as an indicator of the magnitude of hypocalcemia. Vitamin D usually takes two days to increase intestinal uptake of calcium. Therefore, preoperative vitamin D treatment is recommended, even in patients who are hypercalcemia. As aforementioned, intravenous calcium administration remains the most straightforward strategy to restore serum calcium levels rapidly. Cozzolino et al[1] proposed an algorithm to start calcium infusion when a steep fall in calcium levels is noted. However, it might be better to prevent hypocalcemia altogether.

Conclusion

Based on the present results, loaded calcitriol dose regimen are more effective strategies to control hypocalcemia after parathyroidectomy than titrated and fixed dose regimen. The authors recommend a preventive approach by starting loading calcitriol dose regimen immediately after surgery in any patients who have preoperative calcium-phosphorus product level more than 53 to reduce administering intravenous calcium. The risks of intravenous calcium administration include damage in soft tissue, skin necrosis and complication from administered via central vein especially potential risks of catheter-related infection. Further study is required to determine the loading regimen of calcitriol to prevent calcium infusion in patients with high calcium-phosphorus products levels.

Potential conflicts of interest

None.

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บทบาทของการรักษาภาวะแคลเซียมในเลือดต่ำภายหลังการผ่าตัดต่อมพาราไทรอยด์ด้วยไวตามิน ดี ขนาดสูงในผู้ป่วยไตวายเรื้อรัง

สถิตย์ นิรมิตรมหาปัญญา, ทองคำ สุนทรเทพวรากุล, ชัยชาญ ดีโรจนวงศ์, วีระศักดิ์ ศรินนภากร, พรเอก อธิพันธ์

วัตถุประสงค์*: เพื่อศึกษาเปรียบเทียบประสิทธิภาพของการรักษาภาวะแคลเซียมในเลือดต่ำ ภายหลังการผ่าตัดต่อมพาราไทรอยด์ ด้วยไวตามิน ดี ในผู้ป่วยไตวายเรื้อรัง*

วัสดุและวิธีการ*: การศึกษาย้อนหลังผู้ป่วยที่ผ่าตัดต่อมพาราไทรอยด์ในโรงพยาบาลราชวิถี ตั้งแต่กันยายน พ.ศ. 2544 ถึง สิงหาคม พ.ศ. 2552 จำนวน 50 ราย โดยเป็นผู้ป่วยไตวายเรื้อรังจำนวน 41 ราย ศึกษาเปรียบเทียบวิธีที่ได้รับการรักษาภาวะแคลเซียมในเลือดต่ำภายหลังการผ่าตัดต่อมพาราไทรอยด์ด้วยไวตามิน ดี 3 วิธี (วิธี A: ไวตามิน ดี ขนาดคงที่, วิธี B: ไวตามิน ดี ด้วยการค่อย ๆ เพิ่มขนาด, วิธี C: ไวตามิน ดี ขนาดสูง) โดยเก็บข้อมูลทั่วไป ประวัติผู้ป่วย ผลการตรวจทางห้องปฏิบัติการ ผลการรักษา และภาวะแทรกซ้อนภายหลังการผ่าตัดต่อมพาราไทรอยด์*

ผลการรักษา*: ภาวะแคลเซียมในเลือดต่ำภายหลังการผ่าตัดต่อมพาราไทรอยด์พบถึงร้อยละ 82.93 แบ่งเป็น ร้อยละ 80.61 และร้อยละ 90 ในภาวะฮอร์โมนพาราไทรอยด์สูงชนิดทุติยภูมิและตติยภูมิตามลำดับ จากการศึกษาพบว่าระดับผลคูณของแคลเซียมฟอสฟอรัส เป็นตัวแปรอิสระที่บ่งถึงความต้องการเกลือแคลเซียมกลูโคเนตทางหลอดเลือดดำภายหลังการผ่าตัดต่อมพาราไทรอยด์ ในผู้ป่วยไตวายเรื้อรังอย่างมีนัยสำคัญทางสถิติ ($p = 0.008$) โดยพบว่าระดับผลคูณของแคลเซียมฟอสฟอรัสที่มากกว่า 53 ใช้ทำนายความต้องการเกลือแคลเซียมกลูโคเนตทางหลอดเลือดดำภายหลังการผ่าตัดต่อมพาราไทรอยด์ ที่ความไวและความจำเพาะที่ ร้อยละ 71 และร้อยละ 67 ตามลำดับ*

การศึกษาเปรียบเทียบของการรักษาด้วยไวตามิน ดี พบว่าการรักษาด้วยไวตามิน ดี ขนาดสูงลดอัตราการใช้เกลือแคลเซียมกลูโคเนตทางหลอดเลือดดำภายหลังการผ่าตัดต่อมพาราไทรอยด์ในผู้ป่วยไตวายเรื้อรัง มากกว่าการรักษาด้วยไวตามิน ดี ด้วยการค่อยๆเพิ่มขนาดอย่างมีนัยสำคัญทางสถิติ ($p = 0.001$)

สรุป*: การรักษาภาวะแคลเซียมในเลือดต่ำภายหลังการผ่าตัดต่อมพาราไทรอยด์ด้วยไวตามิน ดี ขนาดสูง สามารถลดภาวะแทรกซ้อนจากภาวะแคลเซียมในเลือดต่ำในผู้ป่วยไตวายเรื้อรัง*