

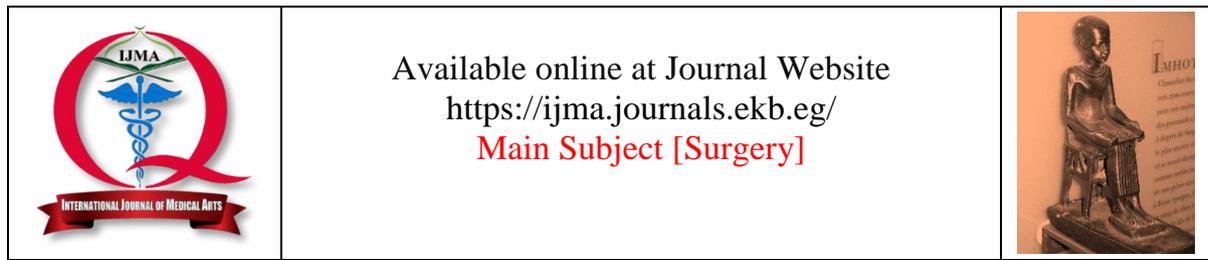
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Original Article

Comparative Study between Conventional Thyroidectomy and Subcapsular Saline Injection in Preserving Parathyroid Gland

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ABSTRACT

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Background: Since the parathyroid glands are vulnerable to damage from an accidental movement or a transient, uncontrollable force, the surgeon must exercise massive care when handling them throughout the entire surgery.

Aim of the work: The aim of this study is to compare the conventional thyroidectomy versus subcapsular saline injection in the incidence of hypocalcemia due to postoperative hypoparathyroidism.

Patients and Methods: This is a prospective randomized study included 40 patients presented by a varies of thyroid pathology who are indicated for total thyroidectomy at the general surgery outpatient clinic and admitted to the department of general surgery, Al-Azhar university hospitals in Assiut and operated from October 2022 to December 2023. These patients were randomly divided into 2 groups: Group "A" who underwent thyroidectomy with subcapsular saline injection [SCASI]. Group "B" who underwent the conventional thyroidectomy. All patients were diagnosed to have goiter on the basis of clinical symptoms and signs, serum level of thyroid hormones and thyroid stimulating hormones, Antibody detection, neck ultrasound, and FNAC of the thyroid.

Results: We compared between the two groups regarding the total Ca level all over the follow up periods, and we found that no statistically significant difference between the two groups [P > 0.05 at all follow-up periods]. However, the difference between the two groups regarding the ionized Ca was significant at the 1st week, 1st month and 6th month postoperatively [P = 0.002, 0.02, 0.03 respectively].

Conclusion: The SCASI approach may decrease the occurrence of temporary and permanent hypoparathyroidism by shielding the parathyroid glands from physical and heat damage. This approach is simple, even for inexperienced surgeons.

Keywords: Thyroidectomy; Parathyroid gland; Subcapsular saline injection.



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INTRODUCTION

One of the most often carried out surgical operations in endocrine and general surgery clinics is the thyroidectomy. When treating thyroid problems with surgery, the chosen surgical approach should assist eradicate the condition and minimize the amount of complications that arise after the procedure [1].

Surgeons can decrease risk for each patient by thoroughly studying anatomy and how to prevent each complication. An important factor in a number of thyroidectomy problems is the surgeon's experience [2].

Nowadays, the standard treatment for people with bilateral benign thyroid diseases is a total thyroidectomy. According to numerous authors, a careful surgical approach can result in low complication rates and the safe performance of complete thyroidectomies [3, 4].

Thyroidectomy complications include recurrent laryngeal nerve damage, damage to the superior laryngeal nerve's external branch, neck hematoma, infection, thyrotoxic storm, and hypoparathyroidism resulting in hypocalcemia [1].

Hypocalcemia that results from hypoparathyroidism can be either temporary or permanent. The parathyroid glands may have been directly injured, devascularized, or removed during surgery as the cause of the problem [2].

Hypoparathyroidism that is defined as transitory occurred on days 1 and 2 when serum parathormone hormone levels were less than 10 pg/ml. Permanent hypoparathyroidism was defined as serum parathormone hormone levels below 15 pg/ml at 6 months [5].

Keeping the parathyroid gland functioning after thyroid surgery is challenging and depends on the surgeon's competence, despite the fact that several studies have proposed and investigated surgical approaches to achieve this goal [6].

Some surgical techniques that have been tested to reduce the incidence of hypoparathyroidism following total thyroidectomy include preserving the inferior thyroidal vein, autotransplantation of the parathyroid gland, and the use of gamma probe, carbon nanoparticles, or indocyanine green for parathyroid gland identification [7, 8]. It was reported that Subcapsular saline injection [SCASI] improves the blood flow to the parathyroid gland and enhances

its preservation [9]. So, the aim of this study is to compare conventional thyroidectomy versus subcapsular saline injection in the incidence of hypocalcemia due to postoperative hypoparathyroidism.

PATIENTS AND METHODS

This is a prospective randomized study included 40 patients presented by a varies of thyroid pathology who are indicated for total thyroidectomy at the general surgery outpatient clinic and admitted to the department of general surgery, Al-Azhar university hospitals in Assiut and operated from October 2022 to December 2023. These patients were randomly divided into 2 groups: Group "A" who underwent thyroidectomy with subcapsular saline injection. Group "B" who underwent the conventional thyroidectomy. All patients were diagnosed to have goiter on the basis of clinical symptoms and signs, serum level of thyroid hormones and thyroid stimulating hormones, Antibody detection, neck ultrasound, and FNAC of the thyroid. Our study was approved from the institutional review board of our university. Written informed consent was obtained from every patient upon agreement to be included.

The inclusion criteria were: [1] Age from 18 to 60 years [males or females], [2] Simple multinodular goiter, [3] Toxic goiter, and [4] Inflammatory goiter.

The exclusion criteria were: [1] Chronic debilitating disease [liver cell failure, chronic renal failure], and [2] Malignant goiter.

Data collection: All patients submitted to the following pre-operative work up; Full history taking, Complete general and local examination, and Pre-operative investigations which included the following; laboratory investigations included CBC, liver and kidney function tests, Free T3, Free T4, TSH, Serum calcium titer ionized and non-ionized, Antithyroglobulin and Anti-microsomal antibody. Radiological investigations including plain X- ray chest P-A view, and neck ultrasound. Pathological investigations included FNAC. Indirect laryngoscopy was done to assess the mobility of both vocal cords.

Surgical technique

Under general anesthesia all patients had done total thyroidectomy. The patient placed in a supine position.

Marking: The subsequent significant anatomical sites identified through superficial palpation and

delineated with a marking pen: Thyroid notch, Cricoid cartilage, Sternal notch and Superior edge of clavicles. A collar incision is utilized. The incision is made in a curved manner within a skin fold, about 1 to 3 cm or the width of two fingers above the upper edge of the clavicle and sternal notch.

Subcapsular saline injection procedure

Group "A" received an injection of 2 to 3 mL of 0.9% normal saline in the subcapsular layer of the thyroid gland at the level of the cricoid cartilage using a 5-mL syringe and a 26-gauge needle. Around 80%-90% of the superior parathyroid glands were found around the cricoid cartilage level. The distended subcapsular layer was carefully separated along the edge of the thyroid gland. The dissection was completed meticulously when the superior parathyroid glands were revealed and seen.

The lateral portion of the thyroid gland was dissected by first pushing the gland towards the center and then farther towards the center after separating the upper half of the gland. Next, a 5-mL syringe and a 26-gauge needle were used to inject 2 to 3 mL of 0.9% normal saline into the subcapsular layer of the thyroid gland at the level of the cricoid cartilage. This injection was done carefully to avoid affecting the parathyroid gland while targeting the lower pole and subcapsular area.

Group "B" received a standard total thyroidectomy procedure, which involved exposing the thyroid gland, identifying and safeguarding the parathyroid glands, identifying and safeguarding the nerve connected to the vocal cord, and removing the thyroid gland.

Post-operative follow-up: The patient was discharged from the hospital within a maximum of two days after the operation. After that, the patient continued to receive follow-up care at the general surgery clinic at Al-Azhar Assiut University Hospital as an outpatient. Evaluation of serum calcium and ionized calcium levels measured on the first and seventh day after surgery, as well as after one month and six months after the operation. The initial outpatient appointment occurred one week after the operation to remove stitches. The purpose of this visit was to monitor the progress of wound healing and check that the patients were adhering to their medical treatment, particularly the oral administration of calcium, calcitriol, and eltroxine replacement therapy. The second appointment occurred 2 weeks after the operation, followed by monthly visits for a duration of 6 months to monitor and observe symptoms of hypocalcemia. The collection

of blood samples [measuring total and ionized calcium levels] occurred 6 months after the surgery.

Statistical analysis: Standard deviations and means were used to express continuous variables. We used percentages and numbers to represent categorical variables. The groups that underwent SCASI and those who did not were compared using the independent t test for continuous parametric variables and the Mann Whitney U test for continuous non-parametric variables. In order to examine nonparametric paired continuous variables, the Freidman and Wilcoxon tests were employed. When comparing the two groups on the categorical variables, Pearson's chi-square test was utilized. At P values of <.05., differences were deemed significant. The statistical analyses were carried out using SPSS for Windows [version 26.0.0, IBM].

RESULTS

In this study, the mean age of the studied patients was 40.5 ± 10.4 , with a range of 20 – 57 years. Most of the patients were female [92.5%]. The two studied groups were matched for Age and gender with no statistically significant difference between them [P value > 0.05]. As regards the type of goiter, the most common type in our study was the MNG [77.5%], in which 15 MNG patients [75%] were in SCASI group and 16 [80%] in non SCASI group with no significant difference between the two groups [P = 0.5]. In terms of the patients' comorbidities, 12.5% of them were diabetic, 17.5% were hypertensive, and 5% were both diabetic and hypertensive. According to the surgical history, 16 cases [40%] of them had past surgical history, 5 patients in SCASI group and 11 patients in non SCASI group [P value = 0.05] [Table 1].

In Table 2, we compared between the two groups regarding their thyroid profile, and we found that the two groups were relatively similar in the level of TSH, FT3, and FT4 [P value = 0.8, 0.1, 0.9 respectively].

In SCASI group, we reported a significant reduction in the Ca level from 9.1 [8.4-9.5] at the baseline to 8.6 [8-9] at 1st month postoperative [P = 0.001], however at 6th month Ca level return to its baseline level [P=0.2]. Also, the ionized Ca was significantly reduced from 1.3 [1.1-1.3] at the baseline to 1.1 [0.9-1.2] at 1st month postoperative and to 1.2 [1.1-1.3] at 6 months post-operative [P value = 0.001, and 0.009 respectively] [Table 3].

In non-SCASI group, we reported a significant reduction in the Ca level from 9.2 [8.8-9.3] at the

baseline to 8.4 [8.1-8.7] at 1st month postoperative [P = 0.001], and to 8.9 [8.5-9] at 6th month postoperative [P=0.001]. The ionized Ca was significantly reduced from 1.2 [1-1.3] at the baseline to 0.9 [0.8-1.2] at 1st month postoperative and to 1 [0.9-1.2] at 6 months postoperative [P = 0.001 for both] [Table 4].

We compared between the two groups regarding the total Ca level all over the follow up periods, and we found that no statistically significant difference between the two groups [P > 0.05 at all follow-

up periods]. However, the difference between the two groups regarding the ionized Ca was significant at the 1st week, 1st month and 6th month postoperatively [P = 0.002, 0.02, 0.03 respectively] [Table 5].

There were no statistically significant differences among both groups as regards post-operative hypercalcaemic manifestation and Severity of hypocalcaemia manifestation. Also, there was no significant difference among both groups regarding post-operative voice and bleeding.

Table [1]: Clinical data of the studied patients

Variables		Total	SCASI [n=20]	Non- SCASI [N=20]	P value ^a
Age [years]	Mean ± SD	40.5 ± 10.4	41.5 ± 10.7	39.4 ± 10.3	0.5 ^a
	Range	20 - 57	20 - 57	23 - 57	
Gender. N [%]	Male	3 [7.5%]	2 [10%]	1 [5%]	0.5 ^b
	Female	37 [92.5%]	18 [90%]	19 [95%]	
Diagnosis. N [%]	MNG	31 [77.5%]	15 [75%]	16 [80%]	0.5 ^c
	SNG	3 [7.5%]	1 [5%]	2 [10%]	
	Secondary toxic	4 [10%]	2 [10%]	2 [10%]	
	Primary toxic	2 [5%]	2 [10%]	0 [0%]	
Medical history. N [%]	DM	5 [12.5%]	1 [5%]	4 [20%]	0.11 ^c
	HTN	7 [17.5%]	5 [25%]	2 [10%]	
	DM and HTN	2 [5%]	2 [10%]	0 [0%]	
Surgical history. N [%]	Yes	16 [40%]	5 [25%]	11 [55%]	0.05 ^{c*}
	No	24 [60%]	15 [75%]	9 [45%]	

a: Independent t test. b: Fisher exact test. c: Chi square test. *: Significant P value

Table [2]: Thyroid profile of the studied patients

Variables	Total	SCASI [n=20]	Non-SCASI [N=20]	P value
TSH. mIU/L	1.1 ± 0.5	1.4 ± 0.6	1.1 ± 0.5	0.8
FT3. mIU/L	2.7 ± 0.4	2.5 ± 0.5	2.8 ± 0.4	0.1
FT4. mIU/L	1.1 ± 0.1	1.2 ± 0.24	1.2 ± 0.2	0.9

Table [3]: Comparison between Ca levels all over the follow up periods in SCASI group

	Preop.	1 st day postop	1 st week postop	1 st month postop	6 th month postop	P ^a	P ^b
Total Ca [Mg/dl]	9.1 [8.4-9.5]	8.5 [8-8.8]	8.3 [7.8-8.6]	8.6 [8-9]	9.2 [8.4-9.5]	0.001*	P1= 0.001* P2= 0.001* P3= 0.001* P4= 0.2
Ionized Ca [Mg/dl]	1.3 [1.1-1.3]	1 [0.9-1.3]	1.1[0.9-1.2]	1.1 [0.9-1.2]	1.2 [1.1-1.3]	0.001*	P1=0.001* P2=0.001* P3=0.001* P4=0.009*

a: Freidman test. b: Wilcoxon test. P1: Comparison between the preoperative Ca level and 1st day postoperative. P2: Comparison between the preoperative Ca level and 1st week postoperative. P3: Comparison between the preoperative Ca level and 1st month postoperative. P4: Comparison between the preoperative Ca level and the 6th month postoperative.

Table [4]: Comparison between total Ca level all over the follow up periods in non-SCASI group

	Preop	1 st day postop	1 st week postop	1 st month postop	6 th month postop	P ^a	P ^b
Total Ca [Mg/dl]	9.2 [8.8-9.3]	8.4 [8-8.6]	8.2 [7.8-8.4]	8.4 [8.1-8.7]	8.9 [8.5-9]	0.001*	P1= 0.001* P2= 0.001* P3= 0.001* P4= 0.001*
Ionized Ca [Mg/dl]	1.2 [1-1.3]	0.9 [0.8-1.1]	0.8 [0.7-1.1]	0.9[0.8-1.2]	1 [0.9-1.2]	0.001*	P1= 0.001* P2= 0.001* P3= 0.001* P4= 0.001*

a: Freidman test. b: Wilcoxon test.

Table [5]: Comparison between total Ca level all over the follow up periods in non-SCASI group

Variables	SCASI [n=20]	Non-SCASI [N=20]	P value ^a
Total Ca level [Mg/dl]			
Preoperative	9.1 [8.4-9.5]	9.2 [8.8-9.3]	0.8
1 st day postoperative	8.5 [8-8.8]	8.4 [8-8.6]	0.3
1 st week postoperative	8.3 [7.8-8.6]	8.2 [7.8-8.4]	0.2
1 st month postoperative	8.6 [8-9]	8.4 [8.1-8.7]	0.1
6 th month postoperative	9.2 [8.4-9.5]	8.9 [8.5-9]	0.2
Ionized Ca [Mg/dl]			
Preoperative	1.3 [1.1-1.3]	1.2 [1-1.3]	0.6
1 st day postoperative	1 [0.9-1.3]	0.9 [0.8-1.1]	0.06
1 st week postoperative	1.1 [0.9-1.2]	0.8 [0.7-1.1]	0.002*
1 st month postoperative	1.2 [1-1.3]	0.9 [0.8-1.2]	0.02*
6 th month postoperative	1.2 [1.1-1.3]	1 [0.9-1.2]	0.03*

a: Mann Whitney U test; *: significant.

DISCUSSION

Our study showed that the mean age of the studied patients was 40.5 ± 10.4 years old. This age group is considered an important risk factor for goiter as reported by **Zheng et al.** ^[10]. Also, this age group is considered an operable age with less complications than old age as reported by **Tabriz et al.** ^[11].

In our study female is more prevalent than males which agree with previous literature ^[12, 13]. The amount of thyroid hormone produced could be affected by sex steroids. One possible explanation for the reduced frequency of goiter in men compared to women in iodine-deficient locations is that testosterone reduces thyroid hypertrophy and serum-free T4 levels in iodine-deficient castrated rats ^[14].

In the present study the most common type of goiter is the MNG [73.8%] followed by secondary toxic goiter [9.5%] which agree with **Saran** ^[15], who reported that Multinodular goiter [MNG] is the most common disorder of the thyroid gland.

There is a strong correlation between diabetes mellitus and thyroid dysfunction. A number of researches have shown that both diabetes mellitus and thyroid problems are more common in those with diabetes ^[16]. An increased risk of hypertension can be associated with a number of endocrine problems; among these, thyroid disease is both common and sometimes disregarded, particularly in less severe manifestations. The underlying mechanisms are only partially known, but both overt and subclinical hypothyroidism can cause [usually moderate] hypertension ^[17]. In our study we reported five cases of DM [11.9%], seven cases of hypertension [16.7%], and two cases of DM and Hypertension [4.8%].

As regards the total Ca level, we found that the total Ca level in SCISA was 9.1 [8.4-9.5] preoperatively, which decreased to 8.6 [8-9] at the 1st month postoperative then return to 9.2 [8.4-9.5] at 6th month postoperative [P = 0.2]. However, in the non-SCISA, we found that the total Ca level decreased from 9.2 [8.8-9.3] preoperatively to 8.9 [8.5-9] at 6 months post-operative [P = 0.009]. By comparing the two groups we found no statistically significant difference between the two groups all over the follow up periods [P > 0.05] for all. These results are in agreement with **Choi et al.** ^[18], who found that the total Ca in SCISA was 8.22 ± 0.35 at 1 day postoperative and 9.8 ± 0.3 at six months post-operative. This result was comparable to that of non-SCISA at 1 day and 6 months postoperatively [P value = 0.3, and 0.2 respectively].

In terms of the ionized Ca level, it was 1.3 [1.1-1.3] at the base line in SCISA group which become 1.2 [1.1-1.3] at 6th month postoperative. However, in non-SCISA group, it was significantly decreased from 1.2 [1-1.3] at the base line to 1 [0.9-1.2] at 6th month postoperatively. The difference between the two groups of our study was significant statistically [P = 0.03]. These results also, were consistent with the findings of **Choi et al.** ^[18], who found that the level of ionized Ca in group 1 was 1.08 ± 0.07 at 1 day post-operatively in SCISA group and was 1.05 ± 0.08 in non-SCISA group at 1 day postoperatively with a statistically significant difference between the two groups. This difference between the 2 groups regarding the ionized Ca level in the study of **Choi et al.** ^[18], was disappeared [P value = 0.2].

Another study was done by **Yu et al.** ^[19], who evaluated the application of a novel method, subcapsular saline injection, to save the parathyroid gland during bilateral axillo-breast approach

[BABA] robotic total thyroidectomy in 81 patients. They found that the total Ca level at one day postoperative was 8.26 ± 0.46 in SCISA group and was 8.11 ± 0.49 in non-SCISA with no significant difference between the two groups [$P = 0.3$]. They also, found no difference between the two groups at the 9th month postoperative. According to the ionized Ca in the study of **Yu et al.** [19], found that no difference between the two groups neither at 1 day or 9 months postoperatively, which is similar to our findings.

Study limitations included the following; Except for the saline injection, the surgical methods in the non-SCASI group were the same as those in the SCASI group. Furthermore, the criteria for different surgical methods were identical for both groups. One restriction was the small sample size in each group, with $n=100$. We require a comprehensive investigation using data collected in advance to confirm our current results.

Conclusion: The SCASI approach may decrease the occurrence of temporary and permanent hypoparathyroidism by shielding the parathyroid glands from physical and heat damage. This approach is simple, even for inexperienced surgeons.

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