

Comparative Study between Using Surgical Loupe and Direct Vision to Enhance Preservation of Parathyroid Glands and Minimize the Risk of its Injury during Total Thyroidectomy

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Background: Total thyroidectomy is now widely accepted as the gold standard for the management of thyroid carcinoma and benign thyroid disease due to suspicion of malignancy, symptoms of local compression, and the patient's desire for rapid and definitive treatment. Damage of the parathyroid glands and injury of RLN are the most dangerous complications during total thyroidectomy.

Objective: Is to evaluate the impact of loupe magnification on incidental parathyroid gland removal and hypocalcemia after total thyroidectomy.

Patients and Methods: In the present study, 60 patients who underwent total thyroidectomy, were classified into group A (Surgery with x 3 magnification= 30) or group B (surgery with direct vision= 30).

Results: 12 patients (20%) had a toxic goiter and 48 patients (80%) had multinodular goiter. The mean age was 43.93 ± 9.51 years in group A vs. 41.30 ± 10.29 years in group B, the mean operative time was 93.67 ± 5.34 min in group A vs. 97.07 ± 5.39 min in group B, The mean intraoperative bleeding was 164.76 ± 16.08 ml in group A vs. 176.04 ± 22.32 ml in group B. Only 8 cases of transient hypocalcemia which occurred were resolved within 7 days by oral calcium supplementation, the cases with transient hypocalcemia were 1(3.3%) in group A vs. 7 (35%) in group B.

Conclusion: The use of loupe magnification for the identification of parathyroid glands and RLN reduced the rate of temporary hypocalcemia after thyroid surgery and significantly reduced the postoperative complications without increasing the operating time.

Introduction

Thyroid surgery is one of the most frequently performed surgical procedures. Total thyroidectomy is now widely accepted as the gold standard for the management of thyroid carcinoma and benign thyroid disease due to suspicion of malignant, symptoms of local compression, and patient's desire for rapid and definitive treatment.¹

Despite the expertise of surgeons, postsurgical hypocalcemia remains a prevalent complication in patients undergoing total thyroidectomy and/or central lymph node dissection, causing high postoperative morbidity and compromising the quality of life, and increasing costs to the health system.²

By definition, transient hypocalcemia resolves within 6 months after total thyroidectomy, its incidence range from 0.3% to 49%. Permanent hypocalcemia persists after 6 months, with an incidence ranging from 0% to 13%.³

Therefore, hypocalcemia is one of the main outcomes for auditing and patient consent. Inpatient admission and close monitoring of postoperative

serum calcium levels have been proposed to prevent postoperative symptoms related to hypocalcemia.⁴

Symptoms depend on the degree and rapidity of hypocalcemia onset, ranging from mild paresthesia and tingling to more severe cramps, tetany, seizure, laryngospasm, congestive heart failure, and arrhythmias due to prolonged QT interval.⁵

The hungry bone syndrome could also occur after total thyroidectomy for Graves' disease as the patient recovers from the thyrotoxic effect on bone metabolism.⁶

To manage postoperative hypocalcemia, most practitioners obtain serial serum calcium measurements and respond appropriately to low levels. Oral supplementation is started with elemental calcium with or without calcitriol for immediate management of postoperative hypocalcemia.⁷

Aim of the work

The purpose of the present study was to evaluate whether the use of a loupe for operative field magnification could improve the outcome of total thyroidectomy in comparison with the conventional technique concerning the identification of the

parathyroids.

Patients and methods

Type of study: Comparative prospective randomized study.

Study setting: Ain Shams University Hospitals and National Institute of Diabetes and Endocrinology.

Study period: From June 2020 to August 2021.

Study population

Inclusion Criteria: All patients with benign thyroid masses undergoing total thyroidectomy.

Exclusion criteria: All patients with malignant thyroid masses. Patients unfit for surgery. Patients who had received irradiation to the lower neck or upper chest, and patients who refused consent.

Sampling method: Patients clinically diagnosed benign thyroid masses who presented to the Department of General Surgery at Ain Shams University Hospitals and National Institute of Diabetes and Endocrine diseases.

Sample Size: 60 cases.

Patients were randomly classified into 2 groups:

Group A: constituted 30 patients and underwent surgery with a loupe.

Group B: constituted 30 patients and underwent surgery without a loupe.

Ethical considerations: Detailed explanation of the procedure to the patient. Written consent had been taken from the patients according to ethical committee considerations. All patients signed a consent reviewing the tests, medications, and procedures including all complications and test results (Informed Consent).

Study Tools: The patients with thyroid swellings were evaluated in the following order:

History, physical examination, investigations preoperative and postoperative serum calcium levels, neck ultrasound were done for every patient. Neck CT scan for patients when there was a doubt of retrosternal extension, indirect laryngoscopy was done preoperatively for every patient for vocal cords assessment and patients with solitary thyroid nodules were submitted to (FNAC) fine-needle aspiration cytology.

Study procedures: The surgical loupe used in this study had magnifications power x3.

Written consent was obtained from all patients after they were informed about the trial and received information about its technique and potential

advantages and disadvantages.

The following parameters were compared between both groups:

1. Duration of surgery was documented in all cases.
2. Postoperative hypocalcemia signs and symptoms and investigations at day 1, day3, and day 7.
3. Follow up of all cases postoperatively at the general surgery department.

Statistical Analysis: Data were collected tabulated and statistically analyzed.

Statistical Package: The software used was the statistical package for the social sciences (SPSS).

Results

Data were coded and entered using the statistical package for the Social Sciences (SPSS) version 26 (IBM Corp., Armonk, NY, USA). Data were summarized using mean and standard deviation for quantitative variables and frequencies (Number of cases) and relative frequencies (percentages) for categorical variables. Comparisons between groups were done using unpaired t test (Chan, 2003a).⁸ For comparing categorical data, Chi square (χ^2) test was performed. Exact test was used instead when the expected frequency is less than 5 (Chan, 2003b).⁹ P-values less than 0.05 were considered statistically significant.

There was a statistical difference between the two groups regarding operation time, intraoperative bleeding, and hypocalcemia. While there was no statistical difference between the two groups regarding age, sex, perioperative diagnosis, postoperative bleeding, and RLN injury.

The mean age was 43.93 ± 9.51 years in group A vs. 41.30 ± 10.29 years in group B as shown in **(Table 1)**.

Regarding gender, male patients 5 (16.7%) and females 25 (83.3%) in group A vs male patients 4 (13.3%) and females 26 (86.7%) in group B, a shown in **(Table 2)**

Regarding perioperative diagnosis, patients with multinodular goiter (MNG) were 25 (83.3%) in group A vs 23 (76.7%) in group B, while patients with toxic goiter were 5 (16.7%) in group A Vs 7 (23.3%) in group B. as shown in **(Table 3)**

Regarding operation time, The mean was 93.67 ± 5.34 min in group A vs. 97.07 ± 5.39 min in group B; this difference was highly significant ($P = 0.017$) as shown in **(Table 4)**

Concerning intraoperative bleeding, the mean was

164.76 ±16.08 ml in group A vs. 176.04 ± 22.32 ml in group B; this difference was significant (P = 0.03)

Regarding postoperative bleeding, The mean was 76.67 ± 24.51ml in group A vs. 83.00 ± 26.02 ml in group B; (P = 0.336) as shown in **(Table 6)**.

There was no case recorded with permanent hypocalcemia, while there were 8 cases (13.3%) with transient hypocalcemia. (Reference range 8.6–10.2 mg/dL), The cases with transient hypocalcemia were 1(3.3%) in group A vs. 7 (35%) in group B; this difference was highly significant (P = 0.005). Of 8 hypocalcemic patients following surgery the peak of hypocalcemia was on the 1st postoperative day

for 8 patients (100%), on the 3rd postoperative day for 6 patients (40%), on the 7th postoperative day, the serum calcium level was normal. As shown in **(Table 7)**.

Regarding hypocalcemia manifestations, there was only 1 (3.3%) case with muscle spasms in group B, and 1 (3.3%) case with circumoral numbness in group A vs 4 cases (13.3%) in group B. there were no other manifestations as shown in **(Table 9)**.

Regarding RLN injury, there was no case with vocal cord paralysis in both groups, but there were 3 (10%) cases with a change of voice in each group as shown in **(Table 10)**.

Table 1: Distribution of the studied cases according to age in both groups Comparisons between groups were done using unpaired t test (Chan, 2003a)

| | Type | | | | P-value |
|-----|-------|--------------------|--------|--------------------|---------|
| | Loupe | | Direct | | |
| | Mean | Standard Deviation | Mean | Standard Deviation | |
| Age | 43.93 | 9.51 | 41.30 | 10.29 | 0.308 |

Table 2: Distribution of the studied cases according to gender in both groups for comparing categorical data, Chi square (χ²) test was performed

| | | Type | | | | P-value |
|--------|---|-------|-------|--------|-------|---------|
| | | Loupe | | Direct | | |
| | | Count | % | Count | % | |
| Gender | M | 5 | 16.7% | 4 | 13.3% | 1 |
| | F | 25 | 83.3% | 26 | 86.7% | |

Table 3: Distribution of the studied cases according to perioperative diagnosis in both groups. For comparing categorical data, Chi square (χ²) test was performed

| | | Type | | | | P-value |
|-------------------------|--------------|-------|-------|--------|-------|---------|
| | | Loupe | | Direct | | |
| | | Count | % | Count | % | |
| Perioperative Diagnosis | Toxic Goiter | 5 | 16.7% | 7 | 23.3% | 0.519 |
| | MNG | 25 | 83.3% | 23 | 76.7% | |

Table 4: Distribution of the studied cases according to operation time in both groups. Comparisons between groups were done using unpaired t test (Chan, 2003a)

| | Type | | | | P-value |
|----------------|-------|--------------------|--------|--------------------|---------|
| | Loupe | | Direct | | |
| | Mean | Standard Deviation | Mean | Standard Deviation | |
| Operation time | 93.67 | 5.34 | 97.07 | 5.39 | 0.017 |

Table 5: Distribution of the studied cases according to Intraoperative bleeding in both groups. Comparisons between groups were done using unpaired t test (Chan, 2003a)

| | Type | | | | P-value |
|-------------------------|--------|--------------------|--------|--------------------|---------|
| | Loupe | | Direct | | |
| | Mean | Standard Deviation | Mean | Standard Deviation | |
| Intraoperative bleeding | 164.76 | 16.08 | 176.04 | 22.32 | 0.030 |

Table 6: Distribution of the studied cases according to postoperative bleeding in both groups. Comparisons between groups were done using unpaired t test (Chan, 2003a)

| | Type | | | | P-value |
|------------------------|-------|--------------------|--------|--------------------|---------|
| | Loupe | | Direct | | |
| | Mean | Standard Deviation | Mean | Standard Deviation | |
| Postoperative bleeding | 76.67 | 24.51 | 83.00 | 26.02 | 0.336 |

Table 7: Distribution of the studied cases according to hypocalcemia in both groups. For comparing categorical data, Chi square (χ^2) test was performed

| | | Type | | | | P-value |
|------------------------|-----|-------|-------|--------|-----|---------|
| | | Loupe | | Direct | | |
| | | Count | % | Count | % | |
| Transient hypocalcemia | Yes | 1 | 3.3% | 7 | 35% | 0.005 |
| | No | 29 | 96.7% | 13 | 65% | |

Table 8: Distribution of the studied cases according to levels of calcium serum on 1st, 3rd, and 7th postoperative days in both groups Comparisons between groups were done using unpaired t test (Chan, 2003a)

| | Type | | | | P-value |
|--------------------------------------|-------|--------------------|--------|--------------------|---------|
| | Loupe | | Direct | | |
| | Mean | Standard Deviation | Mean | Standard Deviation | |
| 1 st day Ca level (mg/dl) | 8.91 | 0.30 | 8.88 | 0.44 | 0.757 |
| 3 rd day Ca Level (mg/dl) | 9.05 | 0.31 | 9.05 | 0.41 | 0.972 |
| 7 th day Ca level (mg/dl) | 9.09 | 0.27 | 9.13 | 0.32 | 0.577 |

Table 9: Distribution of the studied cases according to Hypocalcemia manifestations in both groups. For comparing categorical data, Chi square (χ^2) test was performed

| | | Type | | | | P-value |
|---------------------|-----|-------|--------|--------|--------|---------|
| | | Loupe | | Direct | | |
| | | Count | % | Count | % | |
| Paresthesia | No | 30 | 100.0% | 30 | 100.0% | ----- |
| Mmuscle spasms | Yes | 0 | 0.0% | 1 | 3.3% | 1 |
| | No | 30 | 100.0% | 29 | 96.7% | |
| Cramps | No | 30 | 100.0% | 30 | 100.0% | ----- |
| Tetany | No | 30 | 100.0% | 30 | 100.0% | ----- |
| Circumoral numbness | Yes | 1 | 3.3% | 4 | 13.3% | 0.353 |
| | No | 29 | 96.7% | 26 | 86.7% | |
| Seizures | No | 30 | 100.0% | 30 | 100.0% | ----- |

Table 10: Distribution of the studied cases according to RLN injury in both groups. For comparing categorical data, Chi square (χ^2) test was performed

| | | Type | | | | P-value |
|-----------------|-----|-------|-------|--------|-------|---------|
| | | Loupe | | Direct | | |
| | | Count | % | Count | % | |
| Change of voice | Yes | 3 | 10.0% | 3 | 10.0% | 1 |
| | No | 27 | 90.0% | 27 | 90.0% | |

Discussion

Total thyroidectomy and unilateral thyroid lobectomy are common surgical procedures. However, they can lead to specific complications; the most common of them are related to laryngeal nerves (Recurrent laryngeal nerve (RLN), and parathyroid glands).¹⁰

Two important risk factors of these complications are the extent of thyroidectomy and the surgeon's experience.¹¹

Therefore, a microsurgical approach in thyroid surgery by using magnifying loupes or a surgical microscope is believed to enhance the surgeon's precision. In addition, it was stated that the parathyroid glands and RLN could be identified more easily during the operation.¹²

Atti et al.¹³ reported the first microsurgical thyroidectomy in 1975. Since then, the experience of some expertized centers in the microsurgical approach of thyroidectomy has been presented in the literature. According to them, the surgical microscope is recommended in thyroid surgery due to a lower incidence of complications.^{12,14,15}

Hypocalcemia is one of the major complications of total thyroidectomy and central neck dissection due to the close anatomic relation of the thyroid gland and the parathyroid glands that regulate the calcium level in the blood through secretion of parathormone (PTH).¹⁶

Because of the short half-life of PTH, early postoperative assessment of PTH can help diagnose hypoparathyroidism before the appearance of signs of hypocalcemia.¹⁷

While hypoparathyroidism causes hypocalcemia, postoperative hypocalcemia may occur despite a normal PTH level.¹⁸

In this study, assessment of hypocalcemia was done by measuring postoperative total calcium. Measurement of PTH was done in hypocalcemic cases.

This comparative prospective randomized study aimed to investigate the impact of the magnification techniques (Loupe magnification) on the identification of parathyroid glands in total thyroidectomy compared to direct vision. The microscopic total

thyroidectomy applied here is technically very similar to traditional thyroidectomy, and each step in the procedure is performed with the traditional view with which most surgeons are familiar. The procedure differs from traditional thyroidectomy only in that it requires a microdissection technique using the loupe magnification.

Demography

In the present study, the sample size was 60 patients. Patients were classified into two groups; group A (30 [50%] patients; 25 [41.67%] females and 5 [8.33%] males; mean age, 43.93 years, surgery with x3 loupe magnification,) and group B (30 [50%] patients; 26 [43.33%] females, and 4 [6.67%] males; mean age, 41.30 years, surgery with no magnification). Similar studies by SABER, A et al., 2011,¹⁹ the sample size was 242 patients, they were classified into two groups; group A (surgery with loupe magnification, 121 [50%] patients, 72 [29.75%] females, and 49 [20.25%] males) and group B (surgery with no magnification, 121 [50%] patients, 78 [32.23%] females, and 43 [17.77%] males) and a study by SUFFAT, L. P. et al., 2020,²⁰ the sample size were 140, classified into two groups: group A (surgery with loupe magnification, 70 [50%] patients, 49 [35%] females, and 21 [15%] males; mean age, 52 years) and group B (surgery with no magnification, 70 [50%] patients, 52 [37.14%] females, and 18 [12.86%] males; mean age, 54 years), as each group had 50% of total sample size.

While Testini M et al., 2004.²¹ study's sample size was 97 consecutive patients, classified into two groups: group A (surgery with loupe magnification 47 [48.45%] patients, 30 [30.93%] females and 17 [17.35%] males; mean age, 44.0 years) and group B (surgery with no magnification, 50 [51.55%] patients, 39 [40.21%] females, and 11 [11.34%] males; mean age, 43.3 years). Another study by Seven H et al., 2005,²² study's sample size was 98 consecutive patients. Patients were classified into two groups; group A (surgery with loupe magnification, 58 [59.18%] patients, 51 [52.04%] females, and 7 [7.14%] males; mean age, 44.6 years) and group B (surgery with no magnification, 40 [40.82%] patients, 37 [37.76%] females, and 3 [3.06%] males; mean age, 42.3 years) and PATA, G et al., 2010,²³ study's sample size was

244 consecutive patients. Patients were classified into two groups: group A (surgery with loupe magnification, 126 [51.64%] patients, 92 [37.70%] females, and 34 [13.93%] males; mean age, 57.9 years) and group B (Surgery with no magnification, 118 [48.36%] patients, 88 [36.06%] females, and 30 [12.29%] males; mean age, 55.8 years).

Magnification power

In the present study, the loupe magnification was x3 which is close to studies by SABER, A et al., 2011,¹⁹ SUFFAT, L. P. et al., 2020,²⁰ and Testini M et al., 2004,²¹ and PATA, G et al., 2010,²³ who used loupe with magnification power x2.5; while a study by Seven H et al., 2005,²² used loupe with magnification power from x4 to x10.

Clinical diagnosis

In the present study, the patients had a bilateral benign multinodular goiter. Similar to SABER, A et al., 2011,¹⁹ and SUFFAT, L. P. et al., 2020,²⁰ conversely to other studies whose patients had benign and malignant thyroid masses. Testini M et al., 2004,²¹ Seven H et al., 2004,²² PATA, G et al., 2010,²³ and LOTFY ALI, M et al., 2017,²⁴ which may affect the time of operation and postoperative complications rate.

Operative time

In the present study, we found that there was a highly statistically significant relation in operation time between group A and group B, the mean operative time was 93.67 ± 5.34 min in group A vs. 97.07 ± 5.39 min in group B; this difference was highly significant ($P = 0.017$). This is close to studies by SUFFAT, L. P. et al., 2020,²⁰ and Testini M et al., 2004 that the mean operative time was 79.00 ± 20.9 min in group A vs. 110.00 ± 26.3 min in group B, 125 ± 4 min in group A vs. 150 ± 4 min in group B respectively, which have a significant relation that is close to our study.

While, Seven H et al., 2005 found that the mean \pm SD operating time was 98.6 ± 24.7 min (Range 38–130) in group A and 91.2 ± 32.4 min (Range 45–140) in the group B ($P > 0.05$) with no significance.

Complications

Regarding the intraoperative bleeding in this study, the mean intraoperative bleeding was 164.76 ± 16.08 in group A vs. 176.04 ± 22.32 ml in group B; this difference was significant. Intraoperative blood loss was lower for group A compared to group B and the difference was significant. A study by SUFFAT, L. P. et al., 2020,²⁰ that has a significant relation that is close to our study the mean Intraoperative bleeding was 22 ± 10 ml in group A vs. 38 ± 12 ml in group B. Intraoperative blood loss was significantly lower for group A compared to group B and the difference

was significant. However, a study by Seven H et al., 2005,²² found that the mean \pm SD amount of intraoperative blood loss was 132 ± 114 ml (Range 20–380) in group A and 95 ± 103 ml (Range 15–600) in group B. Intraoperative blood loss was significantly lower for group A compared to group B and the difference was not significant.

Concerning postoperative bleeding in this study, the mean postoperative bleeding was 76.67 (Range 50–100), ± 24.51 ml in group A vs. 83.00 (Range 50–120) ± 26.02 ml in group B which is similar to a study by SUFFAT, L. P. et al., 2020,²⁰ which reported that the mean postoperative bleeding was 38 ± 25.3 ml in group A vs. 60 ± 30.1 ml in group B. postoperative blood loss was lower for group A compared to group B.

Regarding postoperative hypocalcemia in this study, there is no case recorded with permanent hypocalcemia, while there were 8 cases (13.3%) with transient hypocalcemia, The cases with transient hypocalcemia were 1 (3.3%) in group A vs. 7 (35%) in group B, which is close to a study by Testini M et al., 2004(21) who found that cases with transient hypocalcemia were 2 (4.3%) in group A vs 7 (14%) in group B and a study by Seven H et al., 2005(22) found that cases with transient hypocalcemia were 1 (1.72%) in group A vs 2 (5%) in group B. Another similar study by Cavallaro G et al., 1998,²⁵ reported cases with transient hypocalcemia were 5 (2.32%) in group A vs 12 (4.42%) in group B.

In contrast of that, other studies by SABER, A et al., 2011,¹⁹ reported that cases with transient hypocalcemia were 2 (0.8%) in group A vs 2 (0.8%) in group B., SUFFAT, L. P. et al., 2020,²⁰ study, the cases with postoperative hypocalcemia was 27 (38.6%) in group A vs. 31 (44.3%) in group B and PATA, G et al., 2010(23) who found that cases with transient hypocalcemia were 42 (33.1%) in group A vs 79 (66.9%) in group B.

Concerning postoperative recurrent laryngeal nerve (RLN) injury in this study, there are no cases recorded with RLN injury confirmed by a postoperative laryngoscope examination, while what was recorded in 6 cases (10%) with change in voice, The cases with change in voice were 3 (10%) in group A vs. 3 (10%) in group B; with no statistical significance. While, SUFFAT, L. P. et al., 2020,²⁰ found temporary RLN injury occurred in only 1 (1.4%) patient in group A and 2 (2.9%) patients in group B. In all cases, the injury affected the right RLN, as confirmed by a postoperative laryngoscope examination, other studies by SABER, A et al., 2011,¹⁹ and Cavallaro G et al., 1998,²⁵ reported cases with temporary RLN injury were 2 (1.65%) in group A vs 4 (3.3%) in group B and 3 (1.4%) in group A vs 6 (2.2%) in group B respectively.

Conclusion

In overall points of view, we can consider total thyroidectomy by loupe magnification is feasible, improves the outcome, and should be done by an experienced surgeon. Great care should be taken in patients undergoing total thyroidectomy during the dissection of the recurrent laryngeal nerve and the parathyroid glands and their minute blood vessels.

The use of loupe magnification for the identification of parathyroid glands and RLN, reducing the rate of temporary hypocalcemia after thyroid surgery. In addition, they appeared to be as safe as direct vision and it significantly reduces the postoperative complications without increasing the operating time.

Finally, to get more data and more valuable statistics, more studies on a larger number of cases (maybe multicenter) with the same method of postoperative assessment and standardization of both inclusion and exclusion criteria.

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