

Evaluation of Safety, Efficacy, and Feasibility of High Cervical Mini-Incision Thyroidectomy in Comparison with Conventional Technique: A Randomized Clinical Trial

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ABSTRACT

Background: Conventional thyroidectomy usually requires a long collar incision to provide exposure to the thyroid gland. Thyroidectomy with less postoperative pain and better aesthetic outcome was and still the desired goal for thyroid surgeons. This study aimed to assess the safety, feasibility, and efficacy of high cervical mini-incision thyroidectomy compared to the conventional technique regarding postoperative pain, cosmesis, operative time, and postoperative complications.

Methods: It was a randomized controlled study done between January 2019 and June 2022 on 118 selected patients with small sized benign thyroid diseases. Patients were randomly divided into two equal groups of 59 patients each. Patients in group A were subjected to high cervical mini-incision thyroidectomy, while those in group B were subjected to the standard technique. The new approach was different from the standard one in that it provided mobile access to the thyroid gland through a small wound (2.5-3) cm with extended subplatysmal flaps dissection.

Results: Patients in group A reported less postoperative pain and were more pleased with the aesthetic outcome than those in group B. The less invasive technique also showed less intraoperative blood loss with no significant difference regarding operative time, hospital stays, and postoperative complications.

Conclusion: High cervical mini-incision thyroidectomy is a feasible, safe option performed by experienced surgeons for selected patients. It showed excellent cosmetic outcomes and less postoperative pain with the shorter skin incision.

Introduction

Thyroidectomy is globally the most common endocrine surgical procedure. Theodor Kocher won the 1909 Nobel Prize for developing the standard technique of thyroidectomy. This technique usually requires a 6-10 cm long collar skin incision [1]. Today in the early 21st century, the state of the art in thyroid surgery concentrates on techniques that minimize postoperative pain and improve cosmetic outcomes. To achieve these goals, thyroid surgeons sought to develop minimally invasive thyroidectomy (MIT) [2].

MIT can be done through different techniques including totally endoscopic thyroidectomy with or without CO₂ insufflation [3], video-assisted thyroidectomy (VAT) with cervical and extra-cervical approaches [4]. These innovative procedures come with their difficulties, such as additional costs of specialized endoscopic instruments, increased operative time, furthermore the danger of gas embolism or hypercapnia [5]. The open non-endoscopic MIT is an alternative approach that uses less expensive equipment instead while maintaining cosmesis as a top priority [6].

Ferzli et al.[7] first reported MIT with a 2.5 cm cervical incision. In 2005, Sofferman technique was introduced to decrease incision length to < 6 cm by division of strap muscles [8]. In this study, we reported our experience with high cervical mini-incision thyroidectomy with extended subplatysmal flaps through ≤ 3 cm

Patients and methods

Study design and selection criteria

Between January 2019 and June 2022, in the head and neck surgery department, Kafrelsheikh university hospital, Egypt, 118 patients with small sized benign thyroid diseases were included in the study and organized into two parallel equal groups; group A included 59 patients were subjected to thyroidectomy via high cervical minimal incision, while group B included 59 patients were subjected to conventional thyroidectomy.

Keywords: minimally invasive; thyroidectomy; head and neck surgery; complications; cosmesis

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We exclude patients with malignant thyroid diseases proved by fine needle aspiration cytology (FNAC), patients with a thyroid volume more than 50 ml or any thyroid nodule exceeding 30 mm assessed by preoperative ultrasonography (US),

retrosternal goiter, thyroiditis proved by positive thyroid autoantibodies, previous surgery or radiotherapy to the neck, and vocal cord (VC) movement disorders proved by indirect laryngoscopy (Figure 1).

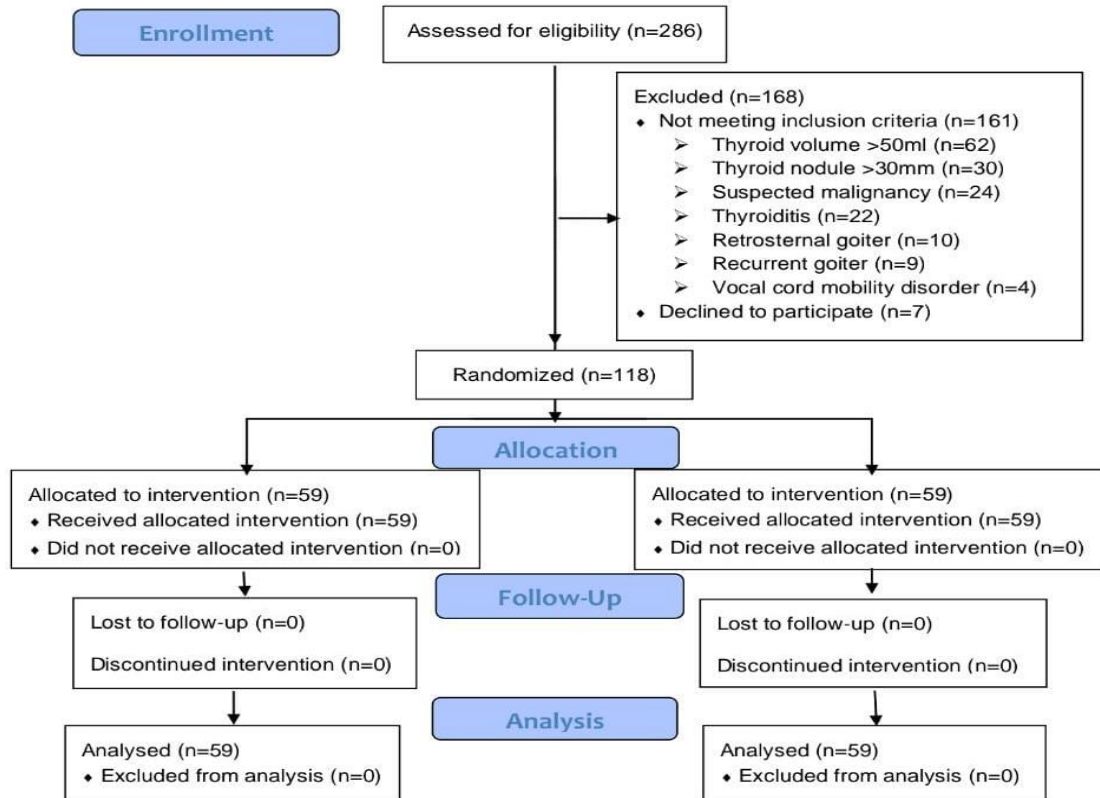


Figure 1: Consort flow diagram.

Ethical approval was obtained from the Kafrelsheikh University ethics committee. The methods used in the study complied with the Declaration of Helsinki guidelines and were disclosed in accordance with the CONSORT guidelines. This study has been registered on www.clinicaltrials.gov. All patients provided their informed written consent before participation in the study after explaining the benefits and risks of each procedure.

Sample size calculation

The sample size was calculated using the comparison of postoperative pain and cosmesis between MIT and conventional techniques. According to the previous publications [9], the mean±SD of postoperative pain score in the MIT group was 5.8±1.07, while in the conventional group, it was 6.91±0.84. Similarly, it was reported that cosmesis in the MIT group was 9.93±3.75, while in the conventional group, it was 21.43±4.23. The minimal clinically important difference was one unit for pain and 2.2 units for cosmesis (1/2 the SD of the conventional group). Based on these results, the minimum appropriate sample size was 19 and 59 cases for each group respectively to detect the suggested minimal clinically important difference with 80% power at α=0.05 level using Student's t-test for independent samples. Because the postoperative cosmesis-based sample size was the larger one, we decided to include 59 cases in each group. The sample size was calculated using

PS Power and Sample Size Calculations software, version 3.0.11 for MS Windows (William D. Dupont and Walton D., Vanderbilt University, Nashville, Tennessee, USA).

Randomization

Randomization was done using (Research Randomizer Version 4.0 at <https://www.randomizer.org>). Each patient has chosen an unlabeled red or blue sealed envelope. Each color's code was known only to the medical team not to the patients. Blue color represented group A, and red color represented group B.

Preoperative assessment and preparation

All patients were subjected to thorough history taking, full clinical examination, and routine laboratory investigations, including total and direct serum calcium (Ca), hormonal assay as thyroid stimulating hormone (TSH), free triiodothyronine (T3), free thyroxine (T4), and thyroid antibodies, US of the neck, US-guided FNAC when indicated, and VC assessment by indirect laryngoscope.

Operative technique

In the operating room, all patients of both groups were subjected to general anesthesia, followed by positioning of the neck in an extended position. All procedures in both groups were performed by the same experienced surgical team. In group A, the procedure started with a little incision of 2.5 cm at the level of the cricoid cartilage as higher incision provided easy access to the superior pole of the gland (Figure 2). To accommodate this smaller

incision, we used pediatric-sized instruments, and an operating headlight was used by the surgeon and the first assistant. Subplatysmal flaps were raised superiorly to thyroid cartilage, inferiorly to the manubrium sterni, and laterally to the lateral edge of sternomastoid muscles on both sides. Extended subplatysmal space acts as mobile access as it allows moving the skin incision all over the gland. The strap muscles on each side were retracted and in some cases were partially divided. The middle thyroid vein was secured when found using suture ligation.

The upper pole was explored, to protect the external laryngeal nerve, we did not depend on direct visualization of the nerve as in 1/3 of cases it may be high and cannot be seen in the operative field. So, we usually did selective ligation of the superior thyroid vessels, the preferred method (avoid mass ligation) or ligation too near to the thyroid tissue. The lobe was then delivered through the surgical wound. The recurrent laryngeal nerve (RLN) was dissected in the tracheoesophageal groove, and gently unroofed from surrounding tissue until direct visualization occurred (**Figure 3**). Strictly pericapsular dissection with selective ligation of inferior thyroid artery terminal branches allowed parathyroid gland visibility and preservation.

The Berry's ligament was ligated and cut, followed by dissection of the undersurface of the gland toward the isthmus. For total thyroidectomy, the first dissected lobe was removed through the wound then the opposite side was similarly

dissected and removed. Hemostasis was assured, and using a closed suction drain was optional. The strap muscles were then approximated, followed by closure of the wound in layers. The wound length was once again measured just before skin closure with a running, absorbable, 5-0 subcuticular suture.

Conventional thyroidectomy was performed in group B via transverse cervical incision between sternocleidomastoid muscles on both sides two fingers above the suprasternal notch. Subplatysmal flaps were extended superiorly up to the level of thyroid cartilage and inferiorly to the suprasternal notch. Then, the gland was removed in a fashion like that reported in group A.

After excision of the thyroid gland, both volume and weight of the postoperative specimen were recorded before it was sent for histopathological analysis. The operative time (OT) was recorded from the initiation of the incision to the end of the skin closure, and the estimated blood loss (EBL) was measured using (gauze visual analog) scale according to the saturation of the different sizes of gauze material used during surgery. Total and ionized serum Ca levels were measured 12 and 72 hours postoperatively.

The postoperative pain was assessed on a (0-10) point Visual Analogue Scale (VAS) 8 hours postoperatively and the cosmetic results of the scar were assessed by the patient and observer scar assessment scale (POSAS) at the first week, six weeks, six months, and one year postoperatively (**Figure 4**).



Figure 2: A 2.5 cm skin incision in the mini-incision thyroidectomy group.



Figure 3: Berry's ligament vessel ligation with visualization of the RLN

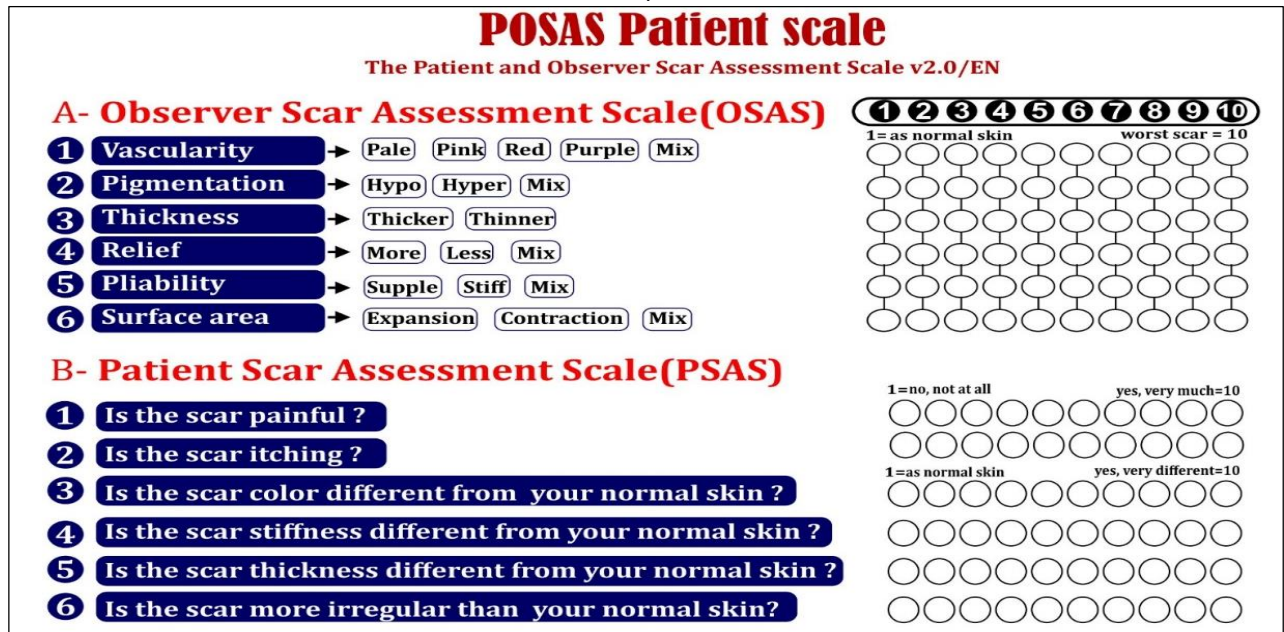


Figure 4: Patient and observer scar assessment scale (POSAS).

Statistical analysis

Data were statistically represented using mean \pm standard deviation (\pm SD), median and range, or frequencies and percentages when appropriate. The student t test for independent samples was used to compare numerical variables between the study groups. The Chi-square (χ^2) test was used to compare categorical data. Exact test was used instead when the expected frequency is less than 5. Statistical significance was defined as two-sided p values less than 0.05. All statistical analyses were performed using IBM SPSS (Statistical Package

for the Social Science; IBM Corp, Armonk, NY, USA) release 22 for Microsoft Windows.

Results

Regarding demographic data and preoperative parameters, patients in both groups were well-matched regarding age, gender, and body mass index (BMI) with significant female predominance in both groups. No significant differences were found regarding the preoperative diagnosis, thyroid volume assessed by US, and serum Ca level (Table 1).

Table 1: Demographic characteristics of patients and perioperative outcome parameters in both groups.

		Mini-incision thyroidectomy Group A (N= 59)	Conventional thyroidectomy Group B (N= 59)	P-value
Age				
Mean \pm SD		38.75 \pm 11.92	38.59 \pm 10.76	0.942
Median (Min. - Max.)		37.00 (18 -70)	38.00 (19 - 68)	
Gender				
Female	N (%)	56 (94.9%)	55 (93.2%)	1.000
Male	N (%)	3 (5.1%)	4 (6.8%)	
BMI				
Mean \pm SD		33.46 \pm 5.26	34.06 \pm 5.03	0.521
Median (Min. - Max.)		35.5 (21 - 45.1)	33.2 (20.8 - 44.5)	
Preoperative diagnosis				
Multinodular goiter (MNG)	N (%)	38 (64.5%)	41 (69.5%)	0.631
Solitary thyroid nodule	N (%)	9 (15.2%)	7 (11.9%)	
Graves	N (%)	7 (11.8%)	8 (13.5%)	
Toxic MNG	N (%)	5 (8.5%)	3 (5.1%)	
Thyroid volume by ultrasonography				
Mean \pm SD		38.14 \pm 7.88	36.20 \pm 8.35	0.198
Median (Min. - Max.)		40.00 (18 - 48)	37.00 (11 - 48)	
Preoperative Ca				
Mean \pm SD		9.351 \pm 1.156	9.366 \pm 0.410	0.924
Median (Min. - Max.)		9.500 (8.7-10.4)	9.300 (8.8-10.6)	

In group A, the incision was 2.5 cm long at the beginning of the procedure, which reached 2.72±0.14 cm at the end of the procedure representing an intraoperative stretch of approximately 8.8%. in group B, the incision was

markedly longer reached 6.5–9.1 cm (mean=7.69±0.56) (p<0.001). Over time, the scar contracted; it reached 2.53±0.15 cm in group A and 7.05±0.59 cm in group B (p<0.001) when measured six months later (Figure 5).

Table 2: Basic intraoperative parameters in both groups.

		Mini-incision thyroidectomy Group A (N= 59)	Conventional thyroidectomy Group B (N= 59)	P-value
Extent of Surgery				
Hemithyroidectomy	N(%)	9 (15.3%)	7 (11.9%)	0.789
Total thyroidectomy	N(%)	50 (84.7%)	52 (88.1%)	
Length of incision (cm)				
Mean ± SD		2.72±0.14	7.69±0.56	< .001*
Median (Min. - Max.)		2.70 (2.5–3.0)	7.600 (6.5–9.1)	
Scar length at 6 months (cm)				
Mean ± SD		2.53±0.14	7.05±0.57	< .001*
Median (Min. - Max.)		2.50 (2.2 - 2.9)	7(5.8-8.6)	
Operative time (min)				
1. Hemithyroidectomy				
Mean ± SD		57.14 ± 16.036	55.44 ± 10.944	0.805
Median (Min. - Max.)		50(42-84)	53(39-69)	
2. Total Thyroidectomy				
Mean ± SD		76.26 ± 16.905	72.88 ± 13.529	0.267
Median (Min. - Max.)		76(47-110)	73(38-100)	
EBL (Estimated blood loss) (ml)				
Mean ± SD		46.86 ± 18.775	58.14 ± 16.99	0.001*
Median (Min. - Max.)		40(15-100)	55(30-115)	
Weight of postoperative specimen (gm)				
Mean ± SD		40.00 ± 10.505	38.14 ± 10.124	0.328
Median (Min. - Max.)		40.00 (15-55)	40.00 (10-55)	
Volume of postoperative specimen (ml)				
Mean ± SD		36.78 ± 8.24	33.90 ± 8.15	0.059
Median (Min. - Max.)		40.00 (15-50)	35.00 (10-45)	
Histopathology of postoperative specimen				
adenomatous colloid hyperplasia	N(%)	47 (79.7%)	48 (81.4%)	0.818
controlled toxic goiter (CTG)	N (%)	12 (20.3%)	11 (18.6%)	

*Refers to significant difference



Figure 5: Mini-incision thyroidectomy scar six months postoperatively.

The OT was almost equivalent in both MIT and conventional groups; it was (76.26±16.90 vs

72.88±13.53) minutes for total thyroidectomy (p=0.267) and (57.14±16.03 vs 55.44±10.95) minutes for hemithyroidectomy (p=0.805) respectively. The mean volume of intraoperative (EBL) measured in group A was 46.86±18.77 ml but was considerably more in group B, having a mean of 58.14±16.99 ml (p=0.001). There was no real difference as regards the extent of surgery, volume, weight, and histopathological analysis of the postoperative specimen between the two groups (Table 2).

Postoperative pain assessed using VAS was significantly less in group A having a mean of 3.51±0.73 than in group B with a mean of 5.58±1.10 (p<0.001). Cosmetic results were significantly better for patients in group A than those in group B when evaluated by both patient and physician at the first week, six weeks, six months, and one year postoperatively. Postoperative hospital stay was almost equivalent in both groups (Table 4).

Postoperative complications were almost similar across the two methods. Asymptomatic hypocalcemia was found in 4 patients (6.77%) in group A and 3 patients (5.08%) in group B, transient symptomatic hypocalcemia occurred in 2 patients (3.38%) in group A and 2 patients (3.38%) in group B, no one in both groups suffered from persistent hypocalcemia. All patients with hypocalcemia were ordered oral calcium supplementation and rechecked for their serum Ca levels after two-week therapy. All cases returned to normal serum Ca levels within three months. Temporary hoarseness of voice (HOV) was experienced by 2 patients in group A and one patient in group B; these cases were ordered to indirect laryngoscope, which showed bilateral mobile VC. All cases improved with medications within six weeks. Wound complications were found in 4 patients in each A and B groups, seroma in 2 vs 1, infection in 2 vs 1, and hypertrophic scar in 0 vs 2 respectively (Table 3).

Table 3: Postoperative outcomes among patients in both groups.

		Mini-incision thyroidectomy Group A (N= 59)	Conventional thyroidectomy Group B (N= 59)	P-value
VAS (Visual analogue scale)				
Mean ± SD		3.51 ± 0.728	5.58 ± 1.102	< .001*
Median (Min. - Max.)		3.00 (2 - 5)	6.00 (3 - 8)	
Hospital stays(h)				
Mean ± SD		24.41 ± 8.024	25.08 ± 9.85	0.683
Median (Min. - Max.)		22 (19-62)	22 (18-76)	
Postoperative Ca				
Mean ± SD		9.13 ± 0.867	8.91 ± 0.73	0.968
Median (Min. - Max.)		9.2 (6.8-10.5)	9 (6-10.1)	
Asymptomatic hypocalcemia	N(%)	4 (10.2%)	3 (8.5%)	1.000
Transient symptomatic hypocalcemia	N(%)	2 (10.2%)	2 (8.5%)	1.000
persistent hypocalcemia	N(%)	0 (0%)	0 (0%)	1.000
Transient voice change	N(%)	2 (3.4%)	1 (1.7%)	0.563
Wound Seroma	N(%)	2 (3.4%)	1(1.7%)	0.563
Wound infection	N(%)	2 (3.4%)	1(1.7%)	0.563
Hypertrophic scar	N(%)	0(0.0%)	2 (3.4%)	0.496

*refers to significant difference

Discussion

Criteria used to decide whether to use MIT or standard approaches are based on variables as thyroid gland volume, histopathology of thyroid nodules, and history of previous neck surgeries [10].

Thyroidectomy has been done for toxic or simple benign and malignant thyroid diseases [11,12]. Some authors have expressed reservations about using MIT in patients with thyroid cancer due to concerns about its oncological completeness. Other studies in the literature reported using MIT for small size well-differentiated papillary or follicular carcinoma [13]. The current study was a single-center experience to assess the clinical outcomes of high cervical mini-incision thyroidectomy for small-sized benign thyroid diseases.

The length of the skin incision for thyroidectomy was variable according to the size of the resected thyroid gland [14]. In this study, the skin incision in group A was markedly shorter than in group B.

These data agreed with other studies as El Fol et al. [15]; the incisional length for MIT was 2.5-4.5 cm (mean=3.292±0.42) as compared to the standard group it was 7-9.5 cm (mean=7.7±0.57). Perigli's study on patients with Graves' disease reported that the skin incision was markedly shorter in MIT group than that in standard group (3.13±0.08 vs. 5.35±0.25) cm respectively [16]. There were no conversions to conventional thyroidectomy in the MIT group in our study. This is mainly due to that the patients were carefully selected with strict adherence to the inclusion and exclusion criteria. The same results were noted by Park et al., Noori et al., and Perigli et al. [16-18] Yazicioglu M et al. reported a 1.49% (2 patients) conversion rate to conventional thyroidectomy.[19] The OT difference in both groups did not attain significance in this study. Also, Perigli et al. [16] performed their thyroidectomies classically through a mean time of 65.8±4.8 minutes compared to 61.6±4.6 minutes for the mini

thyroidectomy. OT recorded by Noori et al. [18] in MIT was significantly longer than that of classic thyroidectomy; it was (82.2 vs 62.8) minutes for subtotal thyroidectomy and (55.6 vs 42.3) minutes for hemithyroidectomy. As opposed to that, El Folet al. [15] stated that OT for mini

thyroidectomy was 64.40±10.9 min, significantly less than that of the traditional method 92.12±9.87 min. Our results demonstrate that with experience, the new emerging facilities, and vascular sealing devices, MIT can be performed within a similar duration as the classic approach.

Table 4: Cosmetic outcome assessed by POSAS among patients in both groups.

	Mini-incision thyroidectomy Group A (N= 59)	Conventional thyroidectomy Group B (N= 59)	t	P-value
PSAS - 1 week				
Mean ± SD	14.98±2.549	28.44 ± 3.980	-21.872	< .001*
Median (Min. - Max.)	15.00(10-21)	28.00(20-36)		
PSAS - 1 months				
Mean ± SD	12.88±1.894	25.22 ± 3.270	-25.080	< .001*
Median (Min. - Max.)	13.00(9-18)	25.00(20-32)		
PSAS - 6 months				
Mean ± SD	10.37±1.473	22.86 ± 2.417	-33.897	< .001*
Median (Min. - Max.)	10.00(7-14)	23.00(18-28)		
PSAS - 1 year				
Mean ± SD	9.24±1.278	21.27 ± 2.227	-36.002	< .001*
Median (Min. - Max.)	9.00(6-12)	21.00(17-28)		
OSAS - 1 week				
Mean ± SD	12.97±1.217	24.36 ± 2.753	-29.066	< .001*
Median (Min. - Max.)	13.00(10-16)	24.00(18-33)		
OSAS - 1 months				
Mean ± SD	10.97±1.159	22.31 ± 2.087	-36.489	< .001*
Median (Min. - Max.)	11.00(8-13)	22.00(18-29)		
OSAS - 6 months				
Mean ± SD	9.22±1.115	20.51 ± 1.580	-44.839	< .001*
Median (Min. - Max.)	9.00(6-12)	20.00(17-25)		
OSAS - 1 year				
Mean ± SD	7.93±1.015	19.17 ± 1.642	-44.724	< .001*
Median (Min. - Max.)	8.00(6-10)	19.00(16-23)		

PSAS: Patients scar assessment scale; OSAS: observer scar assessment scale; *refers to significant difference.

Regarding EBL, it was significantly less in group A than in group B. This coincided with Sakr et al. [9]; the EBL in their study had a mean of 87.0±33.88 ml in the MIT group, significantly less compared to 109.3±21.44 ml in the standard group. Other previous studies showed a non-significant difference between MIT and standard techniques regarding EBL; it was (35.6±46.3 vs 38.5±48.2) ml for Govednik et al. [20] and (60.5 versus 69.6) ml for Noori et al. [18].

In the current study, postoperative pain was dramatically less in group A than in group B using 0-10 VAS. The same results were obtained by other previous studies; their 0-10 VAS scores were (3.4 vs 5.7) for Noori et al. [18] (5.79±1.07 vs 6.91±0.83) for Sakr et al. [9] and (4.3±0.6 vs 8.3±0.4) for Perigli et al. [16] respectively. Other previous studies have concluded with the same results with different methods of pain assessment. El Fol et al. [15] using 0-100 VAS reported a score of 48.40±9.70 in the MIT group compared to 63.07±9.12 in the standard group. Yazıcıoğlu M et al. [19] used a (yes or no) scale; only 6 of 132 (4.54%) reported postoperative pain in the MIT group, significantly lower than the standard group 46 of 293 (15.69%).

Most patients in our study were discharged from

the hospital within the first day postoperatively, this could explain why thyroidectomy has been considered outpatient surgery in our institution since the beginning of the outbreak of Coronavirus (COVID-19) in Egypt in February 2020. Like our results, Perigli et al. [16] revealed that their hospital stay was 28.2±2.0 hours in the MIT group and 28.2±2.5 hours in the standard group. A significant short postoperative hospital stay was reported in MIT compared to the conventional group in the other previous studies; Noori et al. [18] had a mean hospital stay of (1.2±0.5 vs 2.3±1.5) days, while for Yazıcıoğlu M et al. [19] it was (2.5±1.0 vs 3.0±1.0) days respectively.

As regards scar assessment and patient satisfaction, POSAS was our choice, the results were significantly better in group A than in group B (table 4). The results were consistent with previous studies, which used different methods for scar assessment. Sakr et al. [9] used POSAS at day 1, 3 months, and 6 months postoperatively; the mean POSAS score in the MIT group was 9.93±3.75, 6.73±3.16 and 3.73±2.98, while in the conventional group, it was 21.43±4.23, 15.87±4.29, and 10.43±4.72 respectively. A (0-10) numerical score system (NSS) was used by El Fol, Govednik, and Perigli. Their results were 6.83±0.72, 9.56±1.0 and 8.4±0.3 for the MIT group compared to 3.92±0.75,

8.66±2.1 and 3.8±0.9 for the conventional group respectively [15,16,20].

In our study, postoperative complications were comparable between the two approaches. In the study of El Fol et al.[15], the MIT group showed 2 cases (8%) of postoperative seroma and one case of RLN neuropraxia, whereas in the standard group, wound seroma occurred in 2 patients (8%), wound hematoma in one patient and RLN neuropraxia in one patient. Yazicioglu M et al.[19] observed that the incidence of postoperative complications in the mini-incision group (132 patients) compared to the standard group (293 patients) were comparable. There were 6 cases (4.54%) versus 10 cases (3.41%) of wound infection, 9 cases (6.81%) versus 26 cases (8.87%) of wound seroma, 27 cases (20.45 %) versus 89 cases (30.37%) of HOV, 24 cases (18.18%) versus 64 cases (21.84%) of temporary hypoparathyroidism and 5 cases (3.78%) versus 12 cases (4.09%) of permanent hypoparathyroidism respectively.

Conclusion

High cervical mini-incision thyroidectomy is a feasible and reliable alternative to conventional technique without any increase in the incidence of postoperative complications. It is better than the traditional method with significantly better cosmetic results and less postoperative pain with no need for any specialized endoscopic instruments. However, it requires a competent surgeon and cannot replace the conventional technique that is required for large-sized thyroid glands.

Main novel aspects

- The study was a randomized clinical trial done that provided a single center experience of mini-incision thyroidectomy searching for better cosmetic appearance with no added cost for patients.
- Combination of high level of the cervical incision with widely extended subplatysmal flap enable the small incision to give good exposure to the thyroid gland.
- Evaluation of the cosmetic outcomes of the scar was done by both patients and physician separately using the patients and observer scar assessment scale (POSAS).

Authors' contributions

Mohammed Shaalan designed the study, shared in data collection and analysis, and writing of the manuscript. Mohamed Tolba contributed to writing, analysis, interpretation of the data, and revision. Mohamed Abdelaziz shared in data collection, analysis, and revision. Khalid Ismail contributed to the analysis, interpretation of the data, and supervision of the manuscript. Taha Esmail contributed to the writing, data collection, analysis, and revision. Reda F. Ali shared in the interpretation of the results, writing parts of the manuscript, and critical revision of the final version. All authors read and approved the final manuscript.

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Conflict of interest

All authors declared that there is no conflict of

interest.

Ethics approval

Approval was obtained from the ethics committee of Kafrelsheikh University. The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

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