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The effectiveness of a novel modified retracting arm for transaxillary endoscopic thyroid surgery to minimize complications: A randomized controlled study

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Highlights

- A novel modified retracting arm for transaxillary endoscopic thyroid surgery was designed.
- The modified hook better exposed and protected the recurrent laryngeal nerve and parathyroid glands.
- The modified retracting arm achieved better visual analog scale and cosmetic scores.

Abstract

Objective: To evaluate the safety of a novel modified retracting arm for endoscopic thyroidectomy by gasless unilateral axillary approach (ETGUA) and its effectiveness in minimizing complications. **Methods:** A novel retracting arm, which comprises a suspension part, a retracting arm, and a suction tube, was designed for ETGUA. The thyroid pull hook used in this study is an approved medical device: Su Xu, 20210063 (https://scjgj.xz.gov.cn/).The cohort of this randomized controlled study included 84 patients with unilateral thyroid cancer who underwent ETGUA at Xuzhou Central Hospital from February 2021 to March 2023. The patients (n = 42/group) were randomly assigned to a control group (conventional endoscopic retracting arm) or an experimental group (modified endoscopic thyroid retracting arm). Clinical indicators, complication rates, neck pain scores, and cosmetic scores were compared between the two groups. **Results:** There were no significant differences in hospitalization time, surgical duration, intraoperative blood loss, postoperative drainage volume, hypoparathyroidism, or postoperative hematoma between the groups. However, there were significant differences in the incidences of transient recurrent laryngeal nerve injury ($x2 = 6.65$, $p = 0.02$) and transient superior laryngeal nerve injury ($x2 = 4.49$, $p = 0.03$), as well as visual analog scale scores on postoperative day (POD) 1 and 7 ($tPOD1 = 12.66$; $tPOD7 = 10.54$; both, $p < 0.001$), and cosmetic scores ($t = -15.27$, $p < 0.05$). **Conclusion:** The modified retracting arm was safe and effective for ETGUA.

Keywords: Endoscopic thyroidectomy by gasless unilateral axillary approach; modified retracting arm; surgical complications

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Introduction

Papillary thyroid carcinoma is the most frequent type of thyroid cancer, accounting for 70%–80% of all cases [1]. Thyroid tumors occur more commonly in female and younger patients. Traditionally, thyroid tumors are removed by an open surgery via a neck incision [2]. However, with the development of minimally invasive techniques, endoscopic thyroidectomy by gasless unilateral axillary approach (ETGUA) has become more popular [3]. ETGUA not only makes full use of the folds of the axillary skin to hide the surgical scar, but also avoids the use of CO_2 gas during surgery to prevent complications associated with CO_2 accumulation [4-7]. However, ETGUA requires the use of a dedicated retracting arm for adequate exposure of thyroid tumors. Conventional retracting arms have a rectangle head approximately 6 cm wide, which leads to a large incision. To reduce postoperative scarring, a structurally simple and easy-to-use modified endoscopic retracting arm was designed and achieved satisfactory results for the resection of thyroid tumors in 42 cases.

Methods

Study approval and patient consent

The study protocol was approved by the Institutional Review Committee of Xuzhou Central Hospital (approval no. XZXY-LJ-20191212-069) and conducted in accordance with the ethical principles for medical research involving human subjects described in the Declaration of Helsinki. Prior to inclusion in this study, informed consent was obtained from all participants. The thyroid pull hook used in this study is an approved medical device (Su Xu, 20210063).

Instrument design

The novel modified endoscopic thyroid retracting arm for the transaxillary approach comprises a suspension part (**Figure 1A**, **Notes 1–3**), a retracting arm (**Figure 1A**, **Notes 4–7**, **9**), and a suction tube (**Figure 1A**, **Note 8**). The suspension part has multiple hooks on both sides. The primary hook (**Figure 1A**, **Note 1**) is used to hang the whole retracting arm on the surgical scaffold, and the height can be adjusted as needed. The main retracting arm is U-shaped, consisting of a vertical part (see **Figure 1A**, **Note 7**), a horizontal part (**Figure 1A**, **Note 6**), and a connecting part (**Figure 1A**, **Note 9**). There are three suspension holes (**Figure 1A**, **Note 3**) on the connecting part to fix the secondary hook of the suspension part (**Figure 2B**). The horizontal part, which is parallel to the connecting part, has a dissection part (**Figure 1A**, **Note 4**) at the distal end with racket-shaped hollowed-out areas (**Figure 1A**, **Note 5**). The suction tube is attached to the other side of the retracting arm, with the distal end bent at 45 ° toward the suspension part. Images of a conventional retracting arm are included for comparison in **Figure 1B**.

Study design

The cohort of this randomized controlled study included 84 patients who underwent unilateral thyroid cancer surgery using the ETGUA at Xuzhou Central Hospital (Xuzhou, China) from February 2021 to March 2023. The patients were randomly assigned to an experimental group or a control group using a computer-based block randomization (block size of 20) method with sealed envelopes.

The inclusion criteria were: (1) preoperative ultrasound indicating unilateral thyroid nodules with a diameter of less than 1 cm; (2) fine-needle aspiration biopsy confirming thyroid microcarcinoma; and (3) availability of complete clinical data. The exclusion criteria were: (1) history of neck surgery; (2) tumor diameter > 1 cm; (3) distant lymph node metastasis; and (4) hepatic or renal function disorders. The primary outcome was the number of injuries to the recurrent laryngeal nerve (RLN) and superior laryngeal nerve (SLN), while the secondary outcomes were clinical indicators, among others. The sample size was calculated based on the primary outcome and adjusted according to research experience. Finally, 48 patients were included in each group. For analysis, the statisticians were not blinded to the type of surgery.

Type of surgery in the control and experimental groups

All procedures were performed by the same surgical team. Patients in the control group underwent ETGUA using a conventional retracting arm (KC-106-01; Hangzhou Kangji Medical Instrument Co, Ltd, Hangzhou, China) (**Figure 2A**). The incision was 5–6 cm long, extending beyond the axilla but not exceeding the anterior axillary line. After incising the skin and subcutaneous tissue, the second assistant exposed the surgical field with the retracting arm, and an electrocautery was used to create the working space. Depending on the depth of dissection, a different retracting arm (shallow, deep, or specialized) was used to create the working space, while a specialized retracting arm was used for left or right axillary ETGUA. The remaining steps were identical to those in the experimental

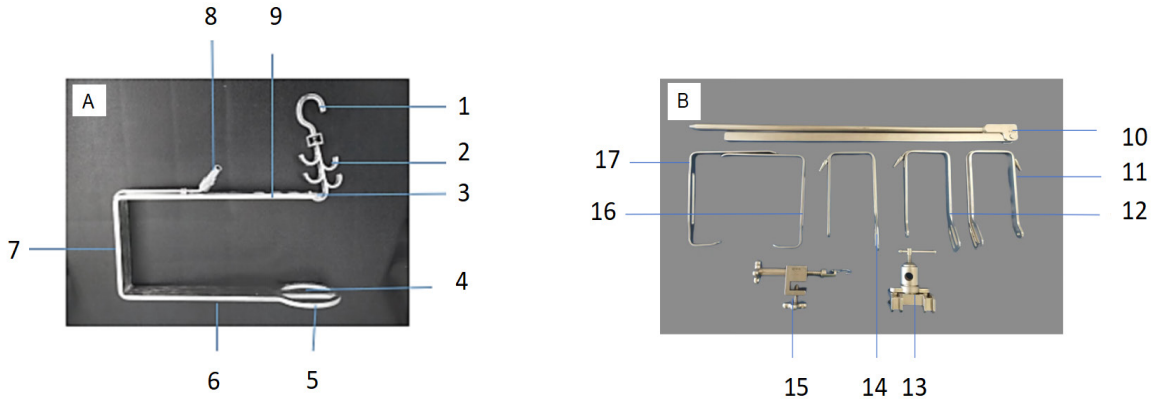

Figure 1. Design of the modified retracting arm for axillary endoscopic thyroid surgery. (A) Modified retracting arm; (B) Conventional retracting arm. Note: 1. Primary suspension hook; 2. Secondary suspension hooks; 3. Suspension hole; 4. Dissection part; 5. Hollowed-out area; 6. Horizontal part; 7. Vertical part; 8. Suction tube; 9. Connecting part; 10. Suspension bar; 11. I type retracting arm (right bending); 12. I type retracting arm (left bending); 13. Suspension device retainer; 14. Type I retracting arm (no bending); 15. Winder of suspension device; 16. Type II retracting arm 1 (simplified version); 17. Type II retracting arm 2 (simplified version).

Figure 2. Two types of retracting arms were used for ETGUA. (A) Conventional retracting arm. (B) Modified retracting arm. (C) Sufficient exposure of the recurrent laryngeal nerve with the modified retracting arm. This figure was derived from Xuzhou Central Hospital. ETGUA: endoscopic thyroidectomy by gasless unilateral axillary approach.

group.

Patients in the experimental group underwent ETGUA using the modified retracting arm. With the patient in the supine position, the collateral arm was abducted to less than 90 °. An incision (-3 cm) was made at the second skin crease of the axilla. After incising the skin and subcutaneous fat tissue, dissection was performed to preserve the fascia of the pectoralis major muscle. The modified retracting arm was inserted and suspended on the anesthesia headframe without additional retracting arms (**Figure 2B**). Tissue dissection was continued, while identifying various anatomical landmarks, including the clavicle, space between the sternocleidomastoid muscle, clavicle, omohyoid muscle, fused part of the deep cervical fascia, and the upper pole plane of the thyroid gland. The dissection extended downwards to the suprasternal notch, exposing the isthmus of the thyroid gland. At the same time, the depth of the retracting arm was adjusted to identify the RLN and parathyroid gland (**Figure 2C**). In the upper pole of the thyroid, the anterior branch of the superior thyroid artery was ligated, while preserving the posterior branch of the superior thyroid artery. Finally, the central compartment lymphatic fat tissue was lifted and cleared. For right-side lesions, the lymph nodes behind the RLN were simultaneously removed. The wound was flushed with distilled water and physiological saline to confirm the absence of injuries to the RLN, parathyroid glands, trachea, and esophagus. A drainage tube was inserted, subcutaneous tissue was sutured, and the skin was closed.

Evaluation criteria

The primary outcome was the incidence of injuries to the RLN and SLN [8, 9]. Injury to the RLN was defined as postoperative hoarseness and/or vocal cord paralysis, while injury to the SLN

Table 1. Comparison of general data between the two groups

Parameters	Experimental group (n=42)	Control group (n=42)	x^2/t	p
Sex, cases (%)			0.21	0.46
Male	15 (32.5)	13 (27.5)		
Female	27 (67.5)	29 (72.5)		
Age, years	45.8±8.2	48.23±11.26	-1.11	0.27
Tumor diameter, mm	7.1±1.6	7.45±2.21	-0.68	0.497
Tumor location, n (%)			0.19	0.65
Left	19 (45.2)	17 (40.5)		
Right	23 (54.8)	25 (59.5)		

Table 2. Comparison of secondary outcomes between the two groups

Parameters	Experimental group (n=42)	Control group (n=42)	t	p
Hospital stays, days	6.4±1.2	6.8±1.5	-1.31	0.19
Surgical duration, min	98.3±16.2	96.2±17.9	0.57	0.57
Intraoperative blood loss, mL	19.2±12.7	16.1±11.3	1.18	0.24
Number of central zone lymph nodes dissected, n	4.0±2.3	5±2.7	1.83	0.07
Postoperative 48-hour drainage, mL	38.6±13.3	41.2±12.4	0.95	0.34

was defined as postoperative external laryngeal branch injury, cricothyroid muscle paralysis, decreased tone, internal laryngeal branch injury, loss of laryngeal mucosa sensation, and/or inability to swallow or choking when eating or drinking. The secondary outcomes included (1) clinical indicators (length of hospital stay, surgical duration, intraoperative blood loss, number of cleared central area lymph nodes, and drainage volume within 48 h after surgery), (2) incidence of complications (decreased parathyroid gland function, and postoperative hematoma), (3) neck pain score using the visual analog scale (VAS) on postoperative day (POD) 1 and 7 using a 10-cm ruler with the scale facing away from the patient for the patient to indicate the degree of pain, where a score of 0 indicated no symptoms and 10 indicated severe symptoms, (4) cosmetic score, which was assessed during a one-month follow-up visit to assess skin appearance, color, and texture on a scale of 0 to 10, where a lower score indicates a more ideal cosmetic effect for the corresponding dimension. The total cosmetic score was calculated to evaluate satisfaction with the surgical incision.

Statistical analysis

Statistical analysis was performed using IBM SPSS Statistics for Windows (version 21.0; IBM Corporation, Armonk, NY, USA). Continuous data were compared using the independent samples t-test and are presented as the mean ± standard deviation, while categorical data were compared using the chi-square test and are presented as numbers and percentages. A probability (p) value < 0.05 was considered statistically significant.

In this study, we hypothesized that the prevalence of injury to the RLN and/or SLN would be lower in the experimental group than in the control group. The primary end point of this study was the prevalence of injury to the RLN and/or SLN. In the preliminary experiment, the prevalence of injury to the RLN and SLN in the experimental and control groups was 0.0% and 12.3% vs. 1.0% and 11.3%, respectively. At an α value of 0.05 and 1-β value of 0.80, the sample size was calculated to be 30 participants using the following formula:

$$n_1 = \frac{[u_\alpha \sqrt{p(1-p)(1+c)/c} + u_\beta \sqrt{p_1(1-p_1)+p_2(1-p_2)/c}]^2}{(p_1-p_2)^2}$$

Results

Comparison of general data

As shown in **Table 1**, there were no statistically significant differences in sex, age, tumor size, or location between the two groups (p > 0.05).

Comparison of clinical indicators

As shown in **Table 2**, there were no significant

Table 3. Incidences of SLN injury, RLN injury, postoperative hematoma, and parathyroid function decline between the two groups

Parameters	Experimental group (n=42)	Control group (n=42)	x^2	p
Superior laryngeal nerve injury, cases (%)	1 (2.4)	7 (16.7)	4.49	0.03
Recurrent laryngeal nerve injury, cases (%)	0 (0.0)	6 (14.3)	6.65	0.03
Postoperative hematoma, cases (%)	0 (0.0)	1 (2.4)	1.10	0.99
Parathyroid function decline, cases (%)	0 (0.0)	0 (0.0)	---	---

Table 4. Comparison of the VAS score on POD 1 and 7 and cosmetic score between the two groups

Parameters	Experimental Group (n=40)	Control Group (n=40)	t	p
VAS score on POD 1	3.3±1.7	7.3±1.4	12.66	<0.001
VAS score on POD 7	1.7±0.9	4.2±1.2	10.54	<0.001
Cosmetic score	2.6±1.8	8.1±1.4	-15.27	<0.001

Note: VAS: visual analog scale; POD: postoperative day.

difference in hospitalization stay, surgical duration, intraoperative blood, number of dissected central zone lymph nodes, or postoperative 48-hour drainage between the two groups ($p > 0.05$).

Comparison of postoperative complications

As shown in **Table 3**, there were significant differences in the incidences of SLN injury ($x^2 = 4.49$, $p = 0.03$) and RLN injury ($x^2 = 6.65$, $p = 0.02$) between the groups, but not in postoperative hematoma and hypoparathyroidism ($p > 0.05$). All instances of nerve injury in this study were transient and fully recovered within the 6-month follow-up period.

Comparison of postoperative VAS and cosmetic scores

As shown in **Table 4**, there were significant differences in the cosmetic score, and the VAS score on POD 1 and 7 ($t_{POD1} = 12.66$; $t_{POD7} = 10.54$; both, $p < 0.05$).

Discussion

Following the widespread use of ETGUA in clinical practice, various approaches have been developed, such as transoral, areolar, axillary, and various combinations. The advantages and disadvantages of each of these surgical approaches remain controversial. ETGUA is reported to achieve good results in terms of both surgical safety and cosmetic outcomes [10-13]. Regardless of the approach, an adequate surgical space must be established [14-17]. The traditional cavity-building model relies on the use of CO_2 at a certain pressure to maintain the surgical space. However, this approach is limited by the risks of intraoperative hypercapnia, obstruction of blood flow from the brain to the heart, unstable maintenance of the surgical space, interference of smoke, and waste of medical resources [18]. In contrast, gasless ETGUA has many advantages, including stability of the surgical space, clear visualization, flexible adjustment, less environmental pollution in the operating room, and minimal waste of resources [19]. However, gasless procedures often require specific surgical instruments, which can easily lead to medical waste and hinder widespread applications. Consequently, cavity-building instruments that are compatible with multiple gasless procedures are urgently needed to meet clinical requirements.

ETGUA is a side neck approach [20]. As compared to open surgery, ETGUA involves an axillary incision and uses the anatomical natural space of the neck to build the cavity, which is convenient, feasible, safe, and can ensure good cosmetic outcomes. Exposure of the RLN and central regional lymph nodes during ETGUA can be problematic [21, 22]. Hence, safe and effective access to the thyroid is key to ETGUA with the distal neck approach [23, 24]. In this study, a novel retracting arm, consisting of a suspension device, a main hook, and a suction tube, was developed for ETGUA. The stripping part of the pull hook is a racket type. Gently moving the pull hook can achieve surgical exposure and improved access to the tissue gap to avoid secondary damage. The hollow design of the stripping part can reduce pressure on the tissue and protect the neck muscles. The suction tube facing the joint bend allows for cleaning and dredging of the blockage. The suspension device with adjustable height can help reduce the incidence of nerve injury and postoperative pain, while improving cosmetic outcomes.

The inflatable posterior axillary approach for ETGUA with a pull hook can be complicated and involve the entire surgical space. At present, the pull hook used in thyroid surgery requires the use of a special frame, and different types of pull hooks must be adjusted during different steps of the procedure. The square head design of the hook with the modified retracting arm can adequately expose the surgical space. The modified retracting arm, including the suspension device, main hook, and suction tube, is easy to assemble and operate, without requiring exchange midway through the procedure, which can shorten the surgical duration and reduce the workload of the operating room nurse.

With the rear approach, the lens hook must be fully exposed to open the central area and the posterior surface of the vertebral fascia in order to transit to the tracheal esophageal ditch until the anterior tracheal gap, and access the central lymphoadipose tissue from behind [25]. At this point, the thyroid and central area lymph nodes remain on the ceiling of the cavity space, fully exposing the posterior boundary of the lymph nodes in the central area, while reducing the omission of cleaning and minimalizing lymph node dissection required with open surgery [26].

The modified retracting arm reduced the incidence of nerve injury. Recent studies have primarily focused on the ability to expose the surgical area, shorten the surgical duration, and reduce blood loss [27, 28]. As the most common complication of ETGUA, nerve injury was the primary outcome in the present study [29]. The rate of nerve injury was relatively high in the control group, which may be attributed to the type of retracting arm and the surgery team being less aware of the importance of protecting the nerves. The conventional retracting arm used in the control group had a wide rectangle dissection part, which can easily stretch the nerves. Since nerve injury is usually transient, the surgical team may be less concerned about protecting the nerve from injury. The modified retracting arm was used in the experimental group to create the surgical space and reduce the incidence of nerve injury.

The novel design of the mirror hook allows creation of a surgical space, while avoiding muscle damage and local trauma. The lateral approach with the thyroid suspension hook allows for continuous negative pressure, maintenance of field clarity to protect the parathyroid gland and SLN, and minimal exposure of the RLN to avoid injury. In addition, the dissection part of modified retracting arm is designed to be hollow to minimize damage to local tissues and reduce nerve stimulation. In this study, ETGUA was conducted with the lateral approach, and the thyroid gland was suspended to create a natural, well-exposed working space. The suction tube of the modified retracting arm helped to maintain clarity of the surgical field. These factors allowed total exposure of the nerves and reduced the risk of nerve injury.

The modified retracting arm improved cosmetic outcomes. The conventional laparoscopic retracting arm has a head width of 6 cm, which results in a longer scar in the fold from the armpit to the anterior axillary line. Although the surgical incision is relatively concealed and does not exceed the anterior axillary line, the scar is noticeable. Comparatively, the modified retracting arm has a racket-shaped design at the front end with a head width of 4 cm. Due to the elasticity and laxity of the armpit skin, the incision is limited to only 3 cm and remains concealed within the armpit, resulting a greater satisfaction with postoperative cosmetic outcomes.

The modified retracting arm has a simple design, is easy to transport, and can be reused after sterilization. The height can be adjusted as needed during the procedure to provide better exposure of the limited space for laparoscopic surgery. In addition, reducing the flap detachment time facilitates tumor dissection, especially for large nodules close to the capsule. The retracting arm also helps to separate the tissues and better protect the RLN to reduce the risks of postoperative complications and shorten the surgical duration. Additionally, the modified retracting arm leads to small concealed surgical incisions and satisfactory cosmetic outcomes.

Conclusion

The safety and efficacy of the modified laparoscopic retracting arm were confirmed for ETGUA, resulting in satisfactory cosmetic outcomes. However, the present study was limited by the relatively small sample size and short follow-up period.

Author Contributions: Mingling Wang contributed to the conception of the study; Mingling Wang and Gaolei Jia performed the experiment; Kai Wang and Haifeng Zhuang contributed significantly to analysis and manuscript preparation; Mingling Wang performed the data analyses and wrote the manuscript; Li Ma and Ping Wang helped perform the analysis with constructive discussions.

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