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Original Article

A Randomized Controlled Trial of Transoral Endoscopic Thyroidectomy Vestibular Approach (TOETVA) Versus Open Thyroidectomy: A Comparative Study of Efficacy and Complications.

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ABSTRACT

Background: Minimally invasive thyroid surgery has evolved significantly, offering improved cosmetic and clinical outcomes[1]. Transoral Endoscopic Thyroidectomy Vestibular Approach (TOETVA) is a scar-free alternative to conventional open thyroidectomy (OT)[2]. This study aims to compare the safety and clinical outcomes of TOETVA and OT in patients with benign thyroid nodules, incorporating data from a randomized controlled trial (RCT).

Methods: A single-blind randomized controlled trial was conducted on patients with thyroid nodules ≤8 cm. Patients were randomized to undergo either TOETVA or conventional thyroidectomy. Postoperative pain had been evaluated using VAS on days 1 and 2. A 3-month follow-up was performed to evaluate complications, including recurrent laryngeal nerve (RLN) palsy, bleeding, and infection.

Results: Seventy patients were randomized to undergo either TOETVA or conventional thyroidectomy. The baseline characteristics, including age and thyroid nodule size, were comparable between groups. The mean operative time was longer in the TOETVA group (99 vs. 75 minutes, $P < 0.001$) and the pain score on the second postoperative day (0.74 vs. 1.86, $P < 0.001$). At the 3-month follow-up, complications in the TOETVA group included one case of transient RLN palsy, one case of mental nerve injury, and one case of subcutaneous emphysema. No complications were reported in the OT group.

Conclusion: TOETVA is associated with reduced postoperative pain and improved cosmetic outcomes compared to conventional thyroidectomy in the management of benign thyroid nodules.

Keywords: Benign thyroid nodules; Open thyroidectomy; Minimally invasive surgery; Transoral endoscopic thyroidectomy vestibular approach (TOETVA)

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Introduction

The pursuit of improved surgical outcomes through minimally invasive techniques has led to the development of Transoral Endoscopic Thyroidectomy Vestibular Approach (TOETVA), which offers potential advantages over conventional open thyroidectomy. Despite nearly a decade since its introduction, TOETVA is still performed only in a few specialized centers using various techniques.

Although the feasibility of TOETVA has been well-documented, most available studies are retrospective. TOETVA has demonstrated superior cosmetic outcomes and reduced postoperative pain compared to OT[3]. However, no prospective randomized trials have directly compared TOETVA with OT. Therefore, a well-designed prospective randomized trial is necessary to eliminate the selection bias inherent in retrospective studies. This study aims to compare the surgical outcomes of TOETVA and OT in patients with benign thyroid nodules.

This is the largest prospective randomized controlled trial (RCT) directly comparing TOETVA with OT conducted in the southeastern region of Thailand.

Methods

Study Design

A single-blind, randomized clinical trial comparing TOETVA with OT was conducted at Mahasarakham Hospital. The study was approved by the Ethics Committee of Mahasarakham Hospital (approval number MSKH_REC 67-01-121), and written informed consent was obtained from all participants before enrollment in the study.

The study population included patients with unilateral, atypical thyroid nodules or follicular lesions requiring hemithyroidectomy for further histological diagnosis. Patients with small solitary toxic thyroid nodules were also eligible for participation.

Inclusion criteria included patients with thyroid nodules smaller than 8 cm and at least one of the following: failure or recurrence after two years of anti-thyroid medication, presence of local compressive symptoms, or side effects from anti-thyroid medication.

Exclusion criteria were patients who were unfit for surgery, had a history of neck surgery or radiation, could not tolerate general anesthesia, had suspected thyroid cancer, or were diagnosed with Graves' disease. A total of 70 patients were randomized equally into two groups: 35 in the open thyroidectomy (OT) group and 35 in the transoral endoscopic thyroidectomy vestibular approach (TOETVA) group.

Study Protocol

All patients achieved euthyroid status before surgery and received antibiotic prophylaxis 30 minutes preoperatively. Patients in both groups

began oral intake on the first postoperative day. All patients were given intravenous morphine for pain control if their visual analog score was ≥ 4. Pre- and postoperative laryngoscopic evaluations were conducted to assess vocal cord mobility. Recurrent laryngeal nerve (RLN) injury was defined as unilateral or bilateral postoperative vocal cord mobility impairment confirmed via direct laryngoscopy. Permanent RLN injury was characterized by persistent vocal cord dysfunction lasting more than 12 months following surgery. A standardized surveillance protocol was implemented. Clinical, biochemical, and functional assessments were conducted at predetermined intervals (2 weeks, 3 months, 6 months, and annually). Each follow-up included clinical evaluation (surgical site bleeding, infection, and laryngeal dysfunction), biochemical testing (serum calcium, phosphorus, magnesium, TSH, and free T4), and vocal cord function assessment (repeat laryngoscopy in cases of persistent or new-onset dysphonia). Data were prospectively recorded to evaluate both transient and permanent postoperative complications.

Operation technique

The technique of TOETVA used in this study has been previously described in detail. Patients were placed in the supine position with neck extension under general anesthesia administered via nasotracheal intubation. The surgeon stood at the head of the patient, with assistants stationed bilaterally. The oral cavity was disinfected with 0.05% chlorhexidine (Hibitane) solution. A 30-mL solution of 1 mg epinephrine diluted in 500 mL of normal saline solution was injected into the lower oral vestibule and anterior neck region for hydrodissection and hemostasis.

A 10-mm midline incision was made in the lower vestibule. The working space was then created from the mandible to the anterior neck using electrocautery and blunt dissection with Kelly forceps. A 10-mm blunt-tipped trocar was inserted for a 30° 10-mm endoscope, and carbon dioxide insufflation was maintained at 6 mmHg. Two additional 5-mm trocars were placed bilaterally in the lateral lower vestibule, directed toward the anterior neck.

The working space was established beneath the platysma muscle, with the larynx as the superior boundary, the suprasternal notch as the inferior boundary, and the anterior borders of the sternocleidomastoid (SCM) muscles as the lateral boundaries. The strap muscles were divided along the midline for better exposure and were retracted laterally using external hanging sutures. The thyroid isthmus was divided and removed. The bird's-eye view shows the thyroid gland and carotid artery (Figures 1 and 2).

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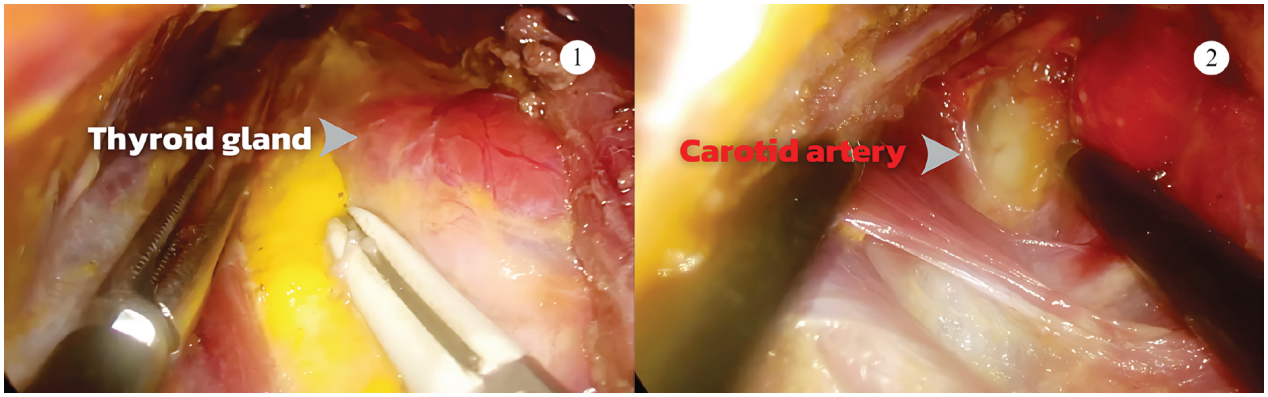

Figure 1 and 2 Bird's-eye view of the thyroid gland and carotid artery.

An ultrasonic surgical device was used for tissue dissection and vessel ligation. The middle thyroid vein, superior thyroid artery, and accompanying veins were ligated near the thyroid gland. The upper pole of the gland was dissected, and the recurrent laryngeal nerve (RLN) was identified at its entry point into the larynx (Figure 3). The inferior thyroid artery and vein were ligated adjacent to the thyroid gland, and Berry's ligament was completely divided. The parathyroid glands were identified and preserved (Figure 4).

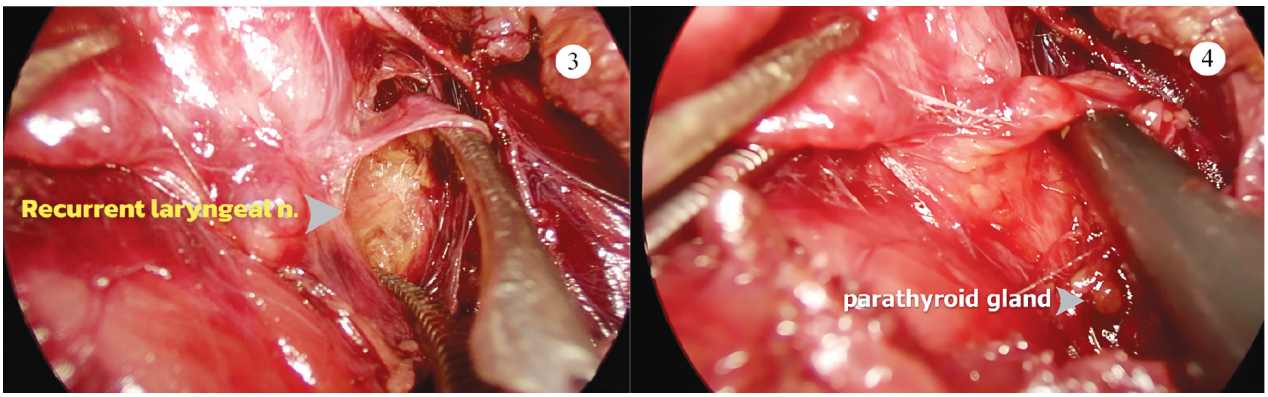

Figure 3 and 4 Fig. 3 Recurrent laryngeal nerve (RLN), Fig. 4. Parathyroid gland.

The thyroid specimen was retrieved using a specimen bag via the 10-mm vestibular incision. A drain was placed through a 5-mm port in the lateral neck. The strap muscles were sutured with absorbable material, and the oral vestibular incision was closed with absorbable sutures. A chin compression bandage was applied for 24 hours postoperatively. For OT, a 5–6 cm transverse incision was made in the anterior neck, followed by subplatysmal dissection. The strap muscles were then divided along the midline to expose the thyroid gland. The thyroid vessels were ligated near the gland using an ultrasonic device to protect the superior laryngeal nerve and parathyroid glands. The RLN and parathyroid glands were identified and preserved bilaterally. Total thyroidectomy was performed in both the TOETVA and OT groups.

Outcomes

Data recorded for each patient included age, sex, thyroid size (cm) as determined by ultrasonography (US), operative time (minutes), and length of hospital stay (days). The primary endpoints were postoperative pain at postoperative days 1, 2, and 3, as well as intraoperative and postoperative complications such as hematoma, seroma, infection, vocal cord paralysis, and hypoparathyroidism. All patients were followed according to a standardized protocol. Statistical analysis was performed using an independent sample t-test for continuous variables and Levene's test for categorical variables. A P-value < 0.05 was considered statistically significant. All statistical analyses were conducted using IBM SPSS software version 22.0 (IBM Corp., Armonk, NY, USA) for Windows. Continuous variables are presented as mean ± standard deviation (SD), while categorical variables are reported as frequencies and percentages (n, %).

Results

Between November 2022 and November 2024, a total of 76 patients were randomized to undergo either TOETVA or OT. Following randomization, three patients withdrew consent and were subsequently excluded from the study, resulting in a final cohort of 73 patients. Additionally, three participants were lost to follow-up at the three-month postoperative evaluation, leaving complete data available for 70 patients.
Patient characteristics

The clinical characteristics of patients were comparable between the two groups. Females constituted the majority in both groups. Age, ASA classification, and mean nodule size as determined by final histologic assessment were also similar between the groups. A summary of the clinical characteristics is provided in Table 1.

Table 1 Demographic data of the TOETVA and OT groups.

Characteristics	TOETVA Experiment; n = 35	OT Control; n = 35
SEX		
Male (%)	4 (11.4)	2 (5.7)
Female (%)	31 (88.6)	33 (94.3)
Age (mean ± SD)	38.71 ± 10.56	40.03 ± 13.93
Operative procedure		
Left (%)	17 (48.6)	19 (54.3)
Right (%)	18 (51.4)	16 (45.7)
ASA Classification (median, min-max)	1 (1–3)	1 (1–3)
Length of stay (days)		
2 days (%)	23 (65.7)	30 (85.7)
3 days (%)	12 (34.3)	5 (14.3)

TOETVA, Transoral Endoscopic Thyroidectomy Vestibular Approach; OT, Open thyroidectomy; SD, standard deviation; ASA, American Society of Anesthesiologist

Surgical treatment

No patients in the TOETVA group required conversion to OT. The operative time was significantly longer in the TOETVA group compared to OT ($P < 0.001$), with an average increase of 24 minutes. Estimated intraoperative blood loss was significantly lower in the TOETVA group than in the OT group.

In terms of postoperative complications, the TOETVA group had: one case of transient recurrent laryngeal nerve (RLN) palsy (resolved within 3 months); one case of transient mental nerve injury (resolved within 3 months); and one case of subcutaneous emphysema (resolved within 2 weeks). There were no cases of permanent recurrent laryngeal nerve (RLN) injury in this study. Additionally, no patients required reoperation for hematoma evacuation or treatment of infection. A summary of operative details and complication rates is presented in Tables 2 and 3.

Table 2 Patient characteristics comparing between the Thyroidectomy Vestibular Approach (TOETVA) and Open Thyroidectomy (OT)

Method	Age (years)	Age by gender		Thyroid nodule size (cm)
		Male age (years) (n)	Female age (years) (n)	
Total (n = 70)	39.37 ± 12.29	41.33 ± 13.66 (6)	39.19 ± 12.25 (64)	6.07 ± 1.18
TOETVA (n = 35)	38.71 ± 10.56	38.00 ± 8.60 (4)	38.81 ± 10.90 (31)	6.26 ± 1.22
OT (n = 35)	40.03 ± 13.93	48.00 ± 24.04 (2)	39.55 ± 13.56 (33)	5.89 ± 1.13
P value	0.658	-	-	0.191

TOETVA, Transoral Endoscopic Thyroidectomy Vestibular Approach; OT, Open thyroidectomy

Table 3 Operative details comparing between the Thyroidectomy Vestibular Approach (TOETVA) and Open Thyroidectomy (OT)

Variable	TOETVA (n = 35)	OT Control (n = 35)	*P* value
Operative time (min)	99.94 ± 14.42	75.71 ± 8.73	< 0.001
Blood loss (ml)	23.17 ± 4.81	27.26 ± 5.54	0.002
Pain score (VAS)			
Pain score day 1	1.43 ± 0.50	3.89 ± 0.40	< 0.001
Pain score day 2	0.74 ± 0.44	1.86 ± 0.36	< 0.001
Average VAS score	1.09 ± 0.39	2.87 ± 0.35	< 0.001
Complications			
Transient RLN palsy (n)	1	0	-
Permanent RLN palsy (n)	0	0	-
Transient hypocalcemia (n)	0	0	-
Permanent hypocalcemia (n)	0	0	-
Infection (n)	0	0	-
Hematoma (n)	0	0	-
Transient Mental nerve injury (n)	1	0	-
Subcutaneous emphysema (n)	1	0	-

TOETVA, Transoral Endoscopic Thyroidectomy Vestibular Approach; OT, Open thyroidectomy; VAS, visual analog scale; RLN, recurrent laryngeal nerve

Outcome measures

Postoperative pain scores, assessed using the visual analog scale (VAS), were significantly lower in the TOETVA group compared to the OT group on both the first and second postoperative days. The mean pain scores for the TOETVA group were 1.43 on the first postoperative day and 0.74 on the second postoperative day, whereas for the OT group, the scores were 3.89 and 1.86, respectively.

Discussion

This study compares the TOETVA with OT for benign thyroid nodules. TOETVA was feasible and performed safely in all patients without conversion. However, its mean operative time was significantly longer than OT (102.96 ± 16.51 vs. 76.72 ± 11.23 minutes; $P < 0.001$), consistent with prior studies attributing the delay to working space creation and meticulous transoral dissection[8-10]. Despite this, infection rates in TOETVA were comparable to other endoscopic approaches[4-7], reinforcing its safety.

Postoperative pain scores within 72 hours were significantly lower in the TOETVA group (VAS 1.13 ± 0.41 vs. 2.94 ± 0.32; $P < 0.001$), aligning with studies indicating that avoiding a cervical incision reduces cutaneous nerve disruption and discomfort[11]. Less pain contributes to faster mobilization and recovery.

Complication rates were similar. Transient recurrent laryngeal nerve palsy occurred in 3.52% (TOETVA) and 2.78% (OT), resolving within three months. Transient hypocalcemia occurred in 1.41% (TOETVA) and 2.08% (OT), with no permanent cases. Transient mental nerve injury (2.11%) and subcutaneous emphysema (1.41%) were exclusive to TOETVA but resolved spontaneously.

Although TOETVA offers cosmetic and recovery benefits, OT remains the standard surgical approach. TOETVA in this study was performed by experienced surgeons, and patient selection was based on shared decision-making after counseling on risks and benefits.

The scarless nature of TOETVA makes it appealing, especially to younger patients. This supports TOETVA's role as a viable, cosmetic-focused alternative for appropriately selected patients. (Figure 5).

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Figure 5 Postoperative TOETVA outcomes. (A) Healed intraoral incision. (B) Absence of visible cervical scar, illustrating cosmetic advantage.

Unlike most previous studies that were retrospective in nature, this trial provides prospective randomized evidence directly comparing TOETVA with OT[2-3]. This strengthens the reliability of the findings, confirming cosmetic benefits while also demonstrating significantly lower pain[11], reduced blood loss[6,9], and comparable complication rates[4-7]

Conclusion

TOETVA is a safe, effective alternative to OT for benign thyroid disease. While it requires a longer operative time, it provides significant advantages, including reduced postoperative pain, comparable complication rates, and superior cosmetic outcomes. As surgical experience with TOETVA continues to advance, it is expected to become a widely accepted approach, particularly for patients prioritizing aesthetics and minimally invasive techniques in thyroid surgery.

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