



Initial Experience of Endoscopic Thyroidectomy Using Bilateral Axillary Breast and Transoral Vestibular Approach in Georgia

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Purpose: Remote access thyroid surgery using a bilateral axillary breast approach (BABA) or a transoral endoscopic thyroidectomy vestibular approach (TOETVA) are increasingly performed worldwide. In the Caucasus, these methods were first applied in the Republic of Georgia. This study compares these two methods of endoscopic thyroid surgery performed on patients in a tertiary hospital in Tbilisi, Georgia.

Methods: Between December 2015 and January 2018, 41 patients underwent endoscopic thyroid surgery at the Aversi Clinic, including 32 who underwent BABA endoscopic thyroidectomy for benign nodules and nine who underwent TOETVA for thyroid cancers. Patients' medical records were retrospectively reviewed.

Results: Tumors were significantly larger (2.38 ± 0.38 cm versus 1.70 ± 0.31 cm, p value < 0.001), operation time was significantly longer (177.66 ± 21.02 min versus 116.66 ± 5.59 min, p value < 0.001), and blood loss was significantly greater (149.07 ± 28.10 ml versus 102.22 ± 8.33 ml, p value < 0.001) in patients who underwent BABA than TOETVA. There were no significant differences in postoperative complications between the two groups.

Conclusion: Remote access thyroid surgery, either BABA or TOETVA, was successfully started, without harmful complications, at the Aversi Clinic in Tbilisi, Georgia. BABA is suitable for large sized benign nodules and TOETVA for thyroid cancers with central lymph node dissection.

Keywords: Thyroid nodule, Thyroid neoplasms, Minimally invasive surgical procedures, Natural orifice endoscopic surgery, Thyroidectomy

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INTRODUCTION

Thyroid cancer has one of the highest incidences of solid organ malignancies, and the highest incidence of malignancies of the endocrine system.¹ Worldwide, about 567,000 patients

are diagnosed with thyroid cancer annually, with thyroid cancer ranked the ninth most common cancer and the fifth most prevalent cancer among women.² Since the early 1980s, the incidence of thyroid cancer, especially papillary thyroid carcinoma, has gradually increased in many countries.^{3,4} In Eastern Europe,

the incidence rate of thyroid cancer in 2018 was 9.7 per 100,000 in women and 2.4 per 100,000 in men.²

The recommended treatment for thyroid cancer is surgical removal of the thyroid gland.¹ The standard method of open thyroidectomy with anterior neck incision is called the “Kocher method”. However, the open thyroid surgery method has the disadvantage of leaving a permanent scar on the anterior neck, which can have an unfavorable effect on patient quality of life.^{5,6} Women most frequently diagnosed with thyroid cancer are aged in their 30s and 40s, making cosmetic outcomes very important to their daily lives.⁵ These cosmetic concerns have led to the development of new surgical methods that do not leave visible surgical scars on the neck.⁷

One of the most utilized methods of remote access thyroid surgery is the bilateral axillary breast approach (BABA).⁸ Thyroidectomy via the bilateral axillary breast approach (BABA) employs an endoscopic instrument to place trocars in both the breast and axillary region. This method has shown favorable cosmetic outcomes, as well as surgical and oncologic safety.⁹ However, the BABA method still leaves scars on the breasts and axillary areas, and requires a wide area for subcutaneous flap dissection. A new natural orifice thyroid surgery technique, called the transoral endoscopic thyroidectomy vestibular approach (TOETVA), was introduced in 2016, mostly to treat benign thyroid nodules.¹⁰⁻¹² The transoral endoscopic thyroidectomy vestibular approach (TOETVA) is a surgical procedure that involves inserting a trocar into the mouth for thyroidectomy. Subsequently, TOETVA has been used to treat thyroid cancer.^{10,13-15} This method has shown surgical and oncologic safety, as well as favorable cosmetic outcomes, with a reduced area of subcutaneous flap dissection compared with the BABA method.¹⁰

The Republic of Georgia is located in the Caucasus region of Eastern Europe. The Aversi Clinic in Tbilisi, the capital of Georgia, started performing endoscopic BABA in 2015 and TOETVA in 2018, making it the first center in the Caucasus to perform these operations. The present study compares the outcomes in patients who underwent endoscopic thyroid surgery using these two methods.

MATERIALS AND METHODS

Between December 2015 and January 2018, 41 patients underwent endoscopic thyroid surgery at the Georgia Aversi Clinic. Of these 41 patients, 32 underwent BABA endoscopic surgery and nine underwent TOETVA. For benign thyroid nodules that do not need central node dissection, the BABA approach is recommended, and for thyroid cancers that need central node dissection, the TOETVA approach is recommended.



Fig. 1. Trocar insertion of BABA for endoscopic thyroidectomy.

Description of the BABA technique

The patient was placed in a supine position with neck extension, under general anesthesia and orotracheal intubation. The intended flap area was drawn with a surgical marker and a 1:200,000 solution of epinephrine in saline was injected subcutaneously into this area. Bilateral circumareolar and axillary incisions were created and blunt dissection was performed with a vascular tunneller. Trocars were inserted into both the breast and axillary region (Fig. 1). The subcutaneous flap was completed using the energy device while maintaining CO₂ at 5 to 7 mmHg. Monopolar electrocautery was used for midline division and lateral dissection. The isthmus was divided by the energy device (Fig. 2A). After isolation of the thyroid gland and strap muscle, the latter was laterally retracted with a snake retractor (Fig. 2B). The recurrent laryngeal nerve (RLN) and inferior parathyroid gland were identified by careful dissection of the inferolateral side of the thyroid gland (Fig. 2C). The thyroid gland was separated from the trachea while dissecting upward, allowing the dissection of Berry's ligament. The upper thyroid pole was dissected with the energy device (Fig. 2D), and the specimen was removed using an endo-plastic bag. The midline of the strap muscle and the skin incisions were closed with absorbable sutures.

Description of the TOETVA technique

The patient was placed in a supine position with neck extension, under general anesthesia and orotracheal intubation, and the head was firmly fixed to prevent its rotation during surgery. The surgeon was positioned at the patient's headside. The oral cavity was disinfected using 0.05% chlorhexidine solution. The borders of the flap were set by delineating the thyroid cartilage as the upper border, the suprasternal notch as the lower border,

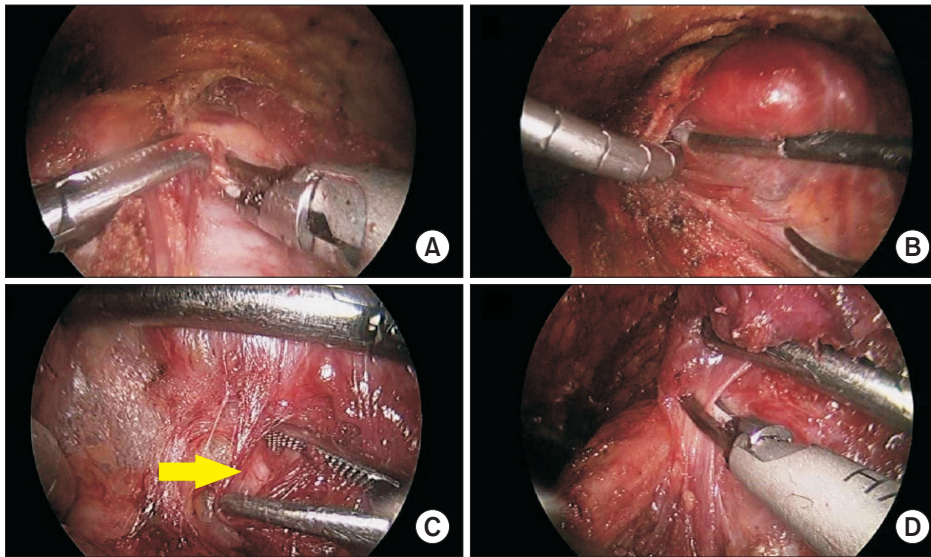


Fig. 2. Endoscopic view of BABA right lobectomy. (A) Isthmus division, (B) Thyroid mobilization with strap muscle retraction, (C) Recurrent laryngeal nerve identification (yellow arrow points to the recurrent laryngeal nerve), (D) Superior pole ligation.



Fig. 3. Trocar insertion of TOETVA.

and the anterior borders of both sternocleidomastoid muscles as the lateral borders. Three trocar insertion sites were used (Fig. 3). An 11 mm incision for the camera port was created between the lower lip and the frenulum. Using a Verress needle, a 1:200,000 solution of epinephrine in saline was injected subcutaneously between the mentalis muscle and the periosteum of the mandible tip, followed by blunt dissection of the subplatysmal flap with a small tunneller. A trocar 11 mm in diameter was inserted through the sub-mentalis area and a 10 mm 30° laparoscope was inserted to check the proper layer of the initial flap. The area was insufflated with CO₂ gas at 6 mmHg pressure and at a flow rate of 15 L/hour. Two 5 mm trocars for endoscopic instruments were inserted, far lateral from both incisions and close to the border of

the lip to prevent mental nerve injury, as previously described.¹³ The strap muscles were divided by endoscopic electrocautery, and the isthmus was dissected with an energy device (Fig. 4A). The thyroid gland was rotated in the opposite direction, and soft tissue between the thyroid and strap muscle was dissected. To enlarge the space between the thyroid and the strap muscle, 3-0 silk sutures were applied from outside of the skin (Fig. 4B). After dissection and ligation of the middle thyroid vein, the superior pole of the thyroid gland was identified by clearing the cricothyroid space. The superior thyroid vessels were ligated with the energy device with pull-out of the superior pole from its bed (Fig. 4C). The thyroid gland was fully rotated medially, and the RLN was identified in the tracheo-esophageal groove (Fig. 4D). The superior parathyroid could generally be saved during upper pole dissection, and the inferior parathyroid could be preserved during clearing of the tissue around the RLN. The rest of the tissue around Berry's ligament was subsequently removed, completing thyroid lobectomy. In patients with papillary thyroid carcinoma, central node dissection can be easily performed during the lobectomy due to the cranio-caudal endoscopic view. Either prophylactic or therapeutic central node dissection was used for all papillary thyroid carcinoma patients undergoing TOETVA. The specimen was removed through the 11 mm incision site using an endo-plastic bag. The oral vestibule surgical wound was closed using absorbable sutures.

Intraoperative neuro-monitoring

For endoscopic thyroid surgery, neuromonitoring with NIM-3 equipment was used (Medtronic Xomed, Jacksonville, FL, USA). In patients undergoing BABA, the probe cable was connected to the endoscopic electrocautery. In patients undergoing TOETVA,

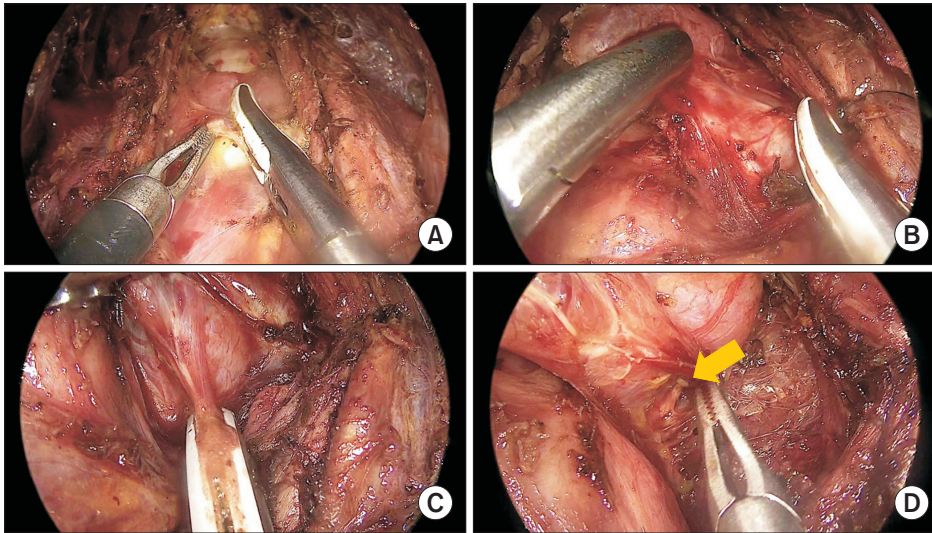


Fig. 4. Endoscopic view of right lobectomy by TOETVA. (A) Isthmus division, (B) Thyroid mobilization with hanging suture of the strap muscle, (C) Superior pole ligation, (D) Recurrent laryngeal nerve identification (yellow arrow points to the recurrent laryngeal nerve).

a long probe was connected to the Medtronic device. All 38 patients underwent surgery using intraoperative neuromonitoring.

Hospital management and defining complications

All patients were hospitalized the day before surgery and were allowed to be discharged 2 or 3 days after surgery. The discharge criteria for patients were improved general condition, stable vital signs, and drain removal. Visual Analog Scale (VAS) scores were recorded daily by nurses, beginning on the first morning. The visual analog scale (VAS) is a validated, subjective measure of acute and chronic pain. RLN function was evaluated by video-assisted laryngoscopic evaluation, with RLN injury defined as impairment of cord motility. RLN injury was defined as permanent if impairment of vocal cord motility persisted more than 6 months after surgery; otherwise, it was considered transient. Hypocalcemia was defined as clinical symptoms. Blood calcium levels after surgery were generally not checked at our institution.

Data and statistics

Patients' medical records were retrospectively reviewed. Factors that were evaluated included age, gender, tumor size, tumor location, fine needle aspiration cytology, pathologic diagnosis, surgical extent, operation time, blood loss, visual pain score, hospital stay after surgery, information about radioactive iodine therapy, and complications. The amount of blood loss was estimated by measuring the amount of blood in the vacuum suction device and cotton swabs. The operation time was defined as the time from skin incision to closing the wound. Numerical variables were compared by unpaired t-tests. Because this study included a small number of patients, Fischer's exact tests were used for cross tabulation analysis. All statistical analyses were

performed using R software version 3.3.2 (www.R-project.org), with statistical significance defined as a *p* value <0.05. The study protocol was reviewed and approved by the institutional review board of Inha University Hospital.

RESULTS

During the study period, 41 patients, all women, underwent thyroid surgery, including 32 who underwent BABA endoscopic surgery and nine who underwent TOETVA. The mean ages of the two groups did not differ significantly. Of the 32 patients who underwent BABA, four had unilateral and 28 had bilateral thyroid lesions, whereas all nine patients who underwent TOETVA had unilateral thyroid lesions. All patients in the BABA group were preoperatively diagnosed with benign lesions, whereas all patients in the TOETVA group were diagnosed with malignancy or were suspicious for malignancy. At final pathologic diagnosis, all patients in the BABA group had follicular adenoma or multinodular goiter, whereas eight patients in the TOETVA group had papillary thyroid carcinoma (Table 1).

Table 2 describes the surgical variables and outcomes of each method. In the BABA group, three patients underwent lobectomy, and 29 underwent total thyroidectomy. In the TOETVA group, all nine patients underwent total thyroidectomy with central lymph node dissection. Tumors were larger in size in the BABA than in the TOETVA group (2.38 ± 0.38 cm versus 1.70 ± 0.31 cm, *p* value <0.001). Operation time was significantly longer (177.66 ± 21.02 min versus 116.66 ± 5.59 min, *p* value <0.001), and blood loss was significantly greater (149.07 ± 28.10 ml versus 102.22 ± 8.33 ml, *p* value <0.001) in the BABA than in the TOETVA group. There were no differences in VAS scores between the two groups on postoperative days 1 (3.59 ± 0.5 versus 3.44 ± 0.53) and 2 (2.59 ± 0.50 versus 2.44 ± 0.53). Mean postoperative hospital

Table 1. Clinical characteristics of patients who underwent endoscopic thyroidectomy by the BABA and TOETVA methods

Variables	BABA (N=32)	TOETVA (N=9)	p value
Age (Years, mean±sd)	35.09±11.20	31.89±9.17	0.392
Gender			
Female	32	9	NA
Tumor location			<0.001
Bilateral	28	0	
Left	1	5	
Right	3	4	
Fine needle aspiration cytology			<0.001
Benign	32	0	
Suspicious for malignancy	0	1	
Malignancy	0	8	
Pathologic diagnosis			<0.001
Follicular adenoma	4	1	
Multinodular goiter	28	0	
Papillary thyroid carcinoma	0	8	

BABA = bilateral axillary breast approach, TOETVA = transoral endoscopic thyroidectomy vestibular approach.

stay was 3 days in the BABA group and 2 days in the TOETVA group. There were no significant between-group differences in postoperative complications (Table 2). Only five BABA patients and one TOETVA patient showed temporary hypocalcemia symptoms, which returned to normal within 10 days. There was no mental nerve palsy or surgical site infection in the TOETVA group.

Table 3 shows the oncologic outcomes in the eight patients

Table 3. Oncologic outcomes in patients with papillary thyroid carcinoma who underwent TOETVA

Variables	Value
Number of retrieved lymph nodes (mean±sd, numbers)	4.78±2.82 (0~10)
Number of metastatic lymph nodes (mean±sd, numbers)	1.33±0.87 (0~3)
Radioactive iodine therapy	
1st RAI dose (mean±SD, mCi)	120±0
TSH level before RAI (mean±SD, μ IU/ml)	73.22±8.56 (60~82.5)
Stimulated Tg level before RAI (mean±SD, ng/ml)	0.87±0.07 (0.76~0.95)

RAI = radioactive iodine therapy.

Table 2. Comparison of surgical variables and outcomes in patients who underwent BABA and TOETVA

Variables	BABA (N=32)	TOETVA (N=9)	p value
Surgical extent			
Lobectomy	3	0	<0.001
Total thyroidectomy	29	9	
Central node dissection	0	9	
Tumor size (cm, mean±sd)	2.38±0.38	1.70±0.31	<0.001
Operation time (min, mean±sd)	177.66±21.02	116.66±5.59	<0.001
Blood loss (ml, mean±sd)	149.07±28.10	102.22±8.33	<0.001
Visual pain score (mean±sd)			
Postoperative day 1	3.59±0.50	3.44±0.53	0.462
Postoperative day 2	2.59±0.50	2.44±0.53	0.462
Hospital stay days after surgery (mean±sd)	3.09±0.30	2.00±0.00	<0.001
Surgical complications			
Vocal cord palsy, transient	2	1	NA
Vocal cord palsy, permanent	0	0	
Hypocalcemia	5	1	
Mental nerve injury	0	0	
Surgical site infection	0	0	
Other complications	0	0	

with papillary thyroid carcinoma who underwent TOETVA. The mean number of lymph nodes was 4.78 ± 2.82 (range, 1–10), and the mean number of metastatic lymph nodes was 1.33 ± 0.87 (range, 0–3). All patients received radioactive iodine (RAI) therapy, at an initial dose of 120 mCi. Radioactive iodine (RAI) is a radiation therapy involving the administration of radioactive iodine to destroy or ablate residual healthy thyroid tissue remaining after thyroidectomy. The mean TSH level before RAI was 73.22 ± 8.56 $\mu\text{IU/ml}$ (range, 60.0–82.5 $\mu\text{IU/ml}$). The mean TSH stimulated serum thyroglobulin level (sTg) was 0.87 ± 0.07 ng/ml (range, 0.76–0.95 ng/ml), with all patients having stimulated serum thyroglobulin below 1.0 ng/ml.

DISCUSSION

The incidence of thyroid cancer has gradually increased worldwide.² One of the main reasons for increased thyroid cancer in Eastern Europe is exposure to radiation, due to geographic proximity to the Chernobyl nuclear accident area.^{16,17} Georgia and other regions in the Caucasus are also closely located to high radiation areas, resulting in an increased incidence of thyroid cancer over time, from 30 patients in 2007 to 890 in 2016.

Thyroid cancer mostly occurs in younger aged women, leading to the development of surgical approaches that do not leave scars on the visible anterior neck.^{5,6,12,18} Despite the high incidence of thyroid cancer in Eastern Europe, these methods have not yet been widely introduced in these countries, especially in the Caucasus. Our center, located in Tbilisi, the capital of Georgia, was the first in the Caucasus to introduce remote access thyroid surgery, introducing BABA endoscopic thyroid surgery in 2015. Despite the advantages of BABA endoscopic surgery,¹⁹ this method requires a wide subcutaneous flap around the anterior chest, increasing the effort required to make the flap. This results in BABA requiring a longer operation time than TOETVA, as illustrated in the present study. Furthermore, the use of endoscopic instruments makes the approach to level 6 central lymph nodes very difficult, due to the caudal-cephalic view of the camera and the inferior-to-superior direction of the endoscopic instruments. Proper central node dissection is important in patients with papillary thyroid carcinoma to improve oncologic outcomes, such as staging, and to prevent recurrence.^{20,21} The BABA approach has therefore been largely performed in a da-Vinci robotic assisted manner. Due to these limitations, only patients with benign nodules in this study underwent BABA endoscopic thyroid surgery.

TOETVA was first reported to be successful in 2015, with most of the patients having benign nodules.^{11,12} TOETVA for thyroid cancer was first performed in 2016,^{10,13–15} with oncologic outcomes similar to those of conventional open surgery.^{10,22,23} For example, the numbers of harvested lymph nodes and stimulated thyroglobulin levels before the first RAI did not differ significantly,

indicating that TOETVA was oncologically safe for thyroid cancer surgery.¹⁰ Our study showed that the mean number of lymph nodes was 4.78 ± 2.82 (range, 1–10), and the mean stimulated Tg level was 0.87 ± 0.07 ng/ml (range, 0.76–0.95 ng/ml), similar to previous results, which showed that the mean number of harvested central lymph nodes in patients who underwent robotic thyroid surgery was 4.5 ± 2.6 to 4.7 ± 3.2 , and that the mean concentration of stimulated Tg was 0.8 ± 1.9 to 1.2 ± 3.4 ng/ml.²⁴

We found that tumor size was significantly larger in the BABA than in the TOETVA (2.48 ± 0.38 cm versus 1.70 ± 0.31 cm), although both groups showed similar surgical outcomes, including postoperative pain scores, vocal cord palsy, and hypocalcemia. Operation time, however, was a mean 60 min shorter and blood loss a mean 45 ml lower in the TOETVA than in the BABA group, perhaps because TOETVA requires a smaller subcutaneous flap than BABA. In addition, the midline cephalo-caudal approach of TOETVA allows both thyroid glands to be easily seen using the same camera trocar.²⁵ Cervical lymph node dissection around levels 6 and 7 was also easier with TOETVA than with the BABA endoscopic view. These results suggest that TOETVA is safe for thyroid cancer patients, with excellent cosmetic outcomes.

To our knowledge, this study is the first to show that these two surgical methods, BABA and TOETVA, are safe and effective methods of scar-less thyroid surgery in an Eastern European country. We think that TOETVA is suitable for selective thyroid cancer surgery requiring central node dissection. However, the major limitation of this study was its inclusion of relatively few patients. In the future, we will prospectively enroll and analyze larger numbers of patients. In addition, to assess the effect of surgical method on survival and recurrence, we will extend the follow-up duration, rather than measure stimulated Tg concentration. Another limitation was the failure to measure objectively hypocalcemia. Our center does not perform routine blood tests for calcium or parathyroid hormone (PTH). We evaluate hypocalcemia by observing patients' clinical symptoms of hypocalcemia. We intend to perform a blood laboratory test for hypocalcemia in future research. The final limitation is that we compared the performances of two different surgical methods for patients with different pathologic thyroid diseases, namely BABA for thyroid nodule(s) and TOETVA for papillary thyroid carcinoma. The reason we made this type of comparison was because the main focus of our study was to judge the performance of a new surgical method at our institution. In the future, we intend to increase the number of cases and compare the performances of BABA and TOETVA for the surgery of one disease entity.

In summary, the present study shows that the Aversi Clinic in Georgia was the first to perform oncoplastic thyroid surgery using the BABA and TOETVA methods without harmful complications. BABA was suitable for large sized benign nodules, and

TOETVA was suitable for complete removal of thyroid cancers coupled with lymph node dissection.

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CONFLICT OF INTEREST

None.

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