

Original Article



Balloon Dilators for Fast and Safe Flap Dissection in Transoral Endoscopic Vestibular Approach Thyroidectomy Vestibular Approach (TOETVA)

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ABSTRACT


Purpose: Creating working space while performing thyroid surgery via a transoral endoscopic thyroidectomy vestibular approach (TOETVA) can be technically challenging. We describe our experiences using a balloon dilator for easy and rapid flap dissection during TOETVA.

Methods: The medical records of patients who underwent surgery for thyroid diseases via a TOETVA were retrospectively reviewed and divided into two groups: the Routine group included patients who underwent routine flap dissection using conventional laparoscopic instruments without the use of a balloon dilator, and the Spacemaker group included patients who underwent flap dissection using a balloon dilator. The working space formation time, defined as the time from first insertion of an instrument into a trocar until the time of the completion of working space formation, and clinical outcomes were analyzed and compared between groups.

Results: A total of 39 patients (6 males and 33 females) were included in the study, with 26 patients in the Routine group and 13 patients in the Spacemaker group. There were no differences in patient demographics between groups. Flap dissection time was significantly longer in the Routine group compared to the Spacemaker group (8.0±2.8 minutes vs. 5.3±2.1 minutes, P=0.004). No excessive bleeding events or conversion to open surgery occurred during surgery in either group. There were also no postoperative bleeding events or infections in either group.

Conclusion: Balloon dilators can provide a fast, efficient, and safe flap dissection method for working space formation during thyroid surgery with TOETVA.

Keywords: Dissection; Minimally invasive surgical procedures; Surgical flaps; Thyroidectomy; Thyroid diseases

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Conflicts of Interest

No potential conflict of interest relevant to this article was reported.

Author Contributions

Conceptualization: Young Jun Chai; Data curation: Moon Young Oh, Young Jun Chai; Formal analysis: Moon Young Oh, Young Jun Chai; Project administration: Young Jun Chai; Resources: Moon Young Oh, Young Jun Chai, Jung-Man Lee; Supervision: Young Jun Chai; Writing - original draft: Moon Young Oh, Young Jun Chai; Writing - review & editing: Jung-Man Lee, Gianlorenzo Dionigi, Che-Wei Wu, Hoon Yub Kim, Hyeong Won Yu, Su-Jin Kim, June Young Choi, Kyu Eun Lee.

INTRODUCTION

Thyroid surgery via the transoral endoscopic thyroidectomy vestibular approach (TOETVA) has recently become popular worldwide because it provides excellent cosmetic outcomes while requiring minimal flap dissection area compared to other remote-access surgeries (1,2). However, the process of flap dissection for creating working space can be particularly technically challenging. Because forming working space in TOETVA involves a very small space and increased risk of bleeding, it requires the surgeon to overcome a steep learning curve and may be especially difficult for surgeons with little experience with remote-access surgeries (3).

Balloon dilators are inflatable balloons that are inserted between desired tissue planes and inflated to separate tissue layers along naturally occurring planes to create working space. The use of balloon dilators is common in various endoscopic or laparoscopic surgeries, including inguinal hernia, renal, and urologic surgeries (4-6). The use of balloons for inguinal hernia dissection has been shown to offer faster operation time, reduce the rate of conversion to open surgery, and reduce postoperative pain, without increasing postoperative complications (7,8).

Our center has recently been using a balloon dilator device (Spacemaker Plus Dissector System; Medtronic, Jacksonville, FL, USA) to create the working space during TOETVA, with satisfying results. The use of balloon dilators in TOETVA has been reported by two previous study, but these studies did not assess the outcomes or advantages of the use of balloon dilators for flap dissection (9,10).

In this study, we compared working space formation time, defined as the time from first insertion of an instrument into a trocar until the time of completion of working space formation, and clinical outcomes between patients who underwent TOETVA with and without the use of a balloon dilator for working space formation.

METHODS

1. Patient selection and ethical consideration

The medical records of patients who underwent TOETVA surgeries for thyroid disease between May 2020 and October 2021 at Seoul Metropolitan Government Seoul National University Boramae Medical Center were retrospectively reviewed.

All patients were preoperatively counseled about the various approaches for thyroid surgery used in our institution, including the conventional transcervical approach, TOETVA, and robotic bilateral axillo-breast and transoral approaches. Indications for TOETVA included thyroid nodules less than 4 cm without lateral neck lymph node metastasis or extensive central lymph node metastasis on ultrasonography or computed tomography. Patients who met the indications for TOETVA were given detailed explanations about the advantages and disadvantages of the approach including complications specific to TOETVA such as chin numbness, subcutaneous emphysema, and CO₂ embolism. The patient then selected their desired approach.

Patients who underwent TOETVA were divided into two groups: the Routine group, which included patients who underwent routine flap dissection using conventional laparoscopic

instruments without the use of a balloon dilator, and the Spacemaker group, which included patients who underwent flap dissection using a balloon dilator.

The study was conducted in full accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the Institutional Review Board of the Seoul Metropolitan Government Seoul National University Boramae Medical Center (IRB number:10-2021-128). Individual consent for this retrospective analysis was waived.

2. Preoperative preparation

Preoperative ultrasound and computed tomography were performed for the evaluation of tumor and lymph node status, and indirect laryngoscopy was performed for the evaluation of the vocal cords. A prophylactic antibiotic (flomoxef 500 mg) was administered intravenously before the induction of anesthesia.

3. Anesthesia, patient positioning, and intraoperative neuromonitoring

Anesthesia was induced with a 30 mg bolus injection of lidocaine, followed by a 1.5 mg/kg injection of propofol. For anesthesia maintenance, target-controlled infusions of propofol and remifentanyl were administered using infusion pumps. After loss of consciousness, rocuronium (0.6 mg/kg) was injected for muscle relaxation. The patient was positioned for surgery by placing a surgical pillow underneath their neck before intubation to prevent unintentional tube displacement during positioning (11). Endotracheal intubation was performed using electromyographic endotracheal tubes (Medtronic) for intraoperative neuromonitoring. The surface-electrodes on the tube were located at the level of the vocal cords and the tube was fixed in place. Neostigmine (2 mg) and glycopyrrolate (0.4 mg) were then co-administered for neuromuscular blockade reversal.

Intraoperative neuromonitoring was performed in accordance with the International Neural Monitoring Study Group guidelines (12) using the nerve integrity monitoring (NIM)-response 3.0 system (Medtronic). Stimulation duration was set at 100 ms, and stimulus current was set at 1 mA with a frequency of 4 Hz. The cutoff value for nerve responses or event threshold was set at 100 μ V.

4. Incisions and midline widening

Three linear incisions (one 10 mm midline and two 5 mm bilateral) were made in the lower oral vestibule. The midline incision was made 1 cm above the lower labial frenulum for better mobility, and the lateral incisions were made 1 cm medial to each lateral labial commissures to appropriately distance the trocars away from the mental nerves. Hydrodissection was performed by injecting 10 mL of diluted epinephrine–saline solution (1:200,000), using a spinal needle, through the incisions down the subplatysmal plane. Blunt tunneling of the midline of the same plane was performed using an 8 mm-tipped vascular surgical tunneler. The midline was further widened by dilating the initial tract in the subplatysmal plane using Hegar cervical dilators with gradually increasing sizes (10–18 mm).

5. Routine group: working space formation using conventional laparoscopic instruments

In the Routine group, flap dissection was performed using conventional laparoscopic instruments. After midline widening, a 10-mm trocar was inserted and low pressure CO₂ (5 mmHg) was insufflated with a high flow rate. Two 5-mm trocars were placed through each of the bilateral incisions into the working space. A 10-mm 30° scope was inserted into the

midline trocar for visualization. Conventional laparoscopic instruments, including grasper forceps, an electrocautery hook, and bipolar energy device (LigaSure; Medtronic), were inserted through the lateral trocars for flap dissection.

6. Spacemaker group: working space formation using the Spacemaker balloon

In the Spacemaker group, flap dissection was performed by using the Spacemaker balloon device, which is comprised of a blunt tip trocar, a dissector cannula (10 mm in diameter) with a furled elastic round dissection balloon at the tip, and a manual rubber bulb air pump. After midline widening, the Spacemaker trocar was inserted through the midline incision and the dissector cannula was inserted into the trocar. Once the balloon on the tip of the dissector cannula was placed in the subplatysmal plane, a 10-mm 30° scope was inserted through the trocar and dissector cannula into the balloon. The balloon was inflated to separate the tissue layers along the naturally occurring planes and ultimately to form working space (**Fig. 1**). To do so, the surgical first assistant fully inflated the dissection balloon (114.3 mm in diameter) by manually pumping the rubber bulb pump (delivering 20–30 cc per pump, up to a maximum of 10 pumps). The balloon inflation procedure was done with the camera in place within the balloon, so that the process of working space formation could be observed from inside the balloon real-time. The operator also manually palpated the patient's neck during this process to monitor for excessive dilation (**Supplementary Video 1**). After withdrawal of the Spacemaker balloon and trocar, one 10 mm midline and two 5 mm bilateral trocars were inserted. Further dissection was performed with conventional laparoscopic instruments for complete working space formation.

7. Surgical procedures after working space formation

TOETVA procedures after working space formation have been described in detail in previous studies (1,3,13). In brief, after creating the working space, the midline of the strap muscles was divided. The isthmus was then transected and the lateral side of the thyroid was separated from the strap muscles. The thyroid gland was then meticulously dissected in the craniocaudal direction. Intraoperative nerve monitoring was used to confirm the functional integrity of the external branch of the superior laryngeal nerve and the recurrent laryngeal nerve (RLN). Central lymph node dissection was performed when indicated. The specimen was retrieved through the midline incision using an endobag. Oral mucosal incisions were closed using 4-0 absorbable sutures. A compressive dressing was applied to the chin and anterior neck area to prevent postoperative bleeding.

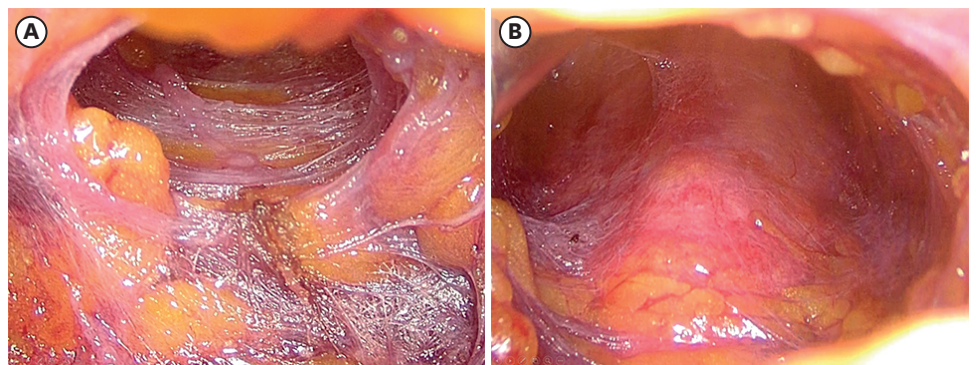


Fig. 1. Endoscopic views before (A) and after (B) Spacemaker balloon dilatation. Balloon dilators help create larger working space with enhanced visualization in a short amount of time.

8. Outcome measurement

The primary outcome was the working space formation time, defined by the time from the first insertion point of an instrument into the trocars to the time at completion of working space formation. The secondary outcomes were intraoperative adverse events such as excessive bleeding, conversion to open surgery, mental nerve or RLN injuries, and immediate postoperative complications such as bleeding or infection. Mental nerve function was evaluated postoperatively before discharge from hospital and in the outpatient clinic at 2 weeks after surgery. For those who presented with symptoms, additional mental nerve evaluation was conducted on the postoperative 3-months visit. Patients were asked whether they had paresthesia around the chin and lower lip, and an alcohol swab was brushed lightly on the skin around the chin to assess for possible sensory deficit. Potential RLN injury, indicated by vocal cord palsy, was assessed during routine laryngoscope examination at the first visit to the outpatient clinic after discharge. Postoperative bleeding was defined as active bleeding or hematoma requiring reoperation or hematoma evacuation, and postoperative infection was defined as any signs of infections requiring the use of antibiotics during the in-hospital period.

9. Statistical analysis

All data are presented as mean ± standard deviation for continuous variables. Student’s t-test and chi-squared test were used for statistical analysis, and two tailed values of P<0.05 were considered statistically significant. Analyses were performed using SPSS 26.0 software for Windows (IBM, Armonk, NY, USA).

RESULTS

1. Patient demographics

Thirty-nine consecutive patients (6 males and 33 females) were included in the study. The mean age was 37.5±10.3 years, and the mean body mass index was 24.7±3.6. The mean longest overall tumor diameter was 1.0±0.6. Lobectomies were performed in 38 (97.4%) patients, and total thyroidectomy was performed in one (2.6%) patient. The final diagnoses were 32 (82.1%) papillary thyroid carcinomas, six (15.4%) follicular adenomas, and one (2.6%) follicular cell carcinoma. No statistical differences were seen in patient demographics between the two groups. Patient demographics are summarized in **Table 1**.

Table 1. Patient characteristics

Characteristics	Total (n=39)	Routine group (n=26)	Spacemaker group (n=13)	P value
Sex (male:female)	6:33	4:22	2:11	1.000
Age (yr)	37.5±10.3	38.9±6.8	38.9±11.6	0.269
BMI (kg/m ²)	24.7±3.6	25.6±4.9	24.2±2.7	0.373
Longest tumor diameter (cm)	1.0±0.6	1.2±0.7	1.0±0.6	0.317
Extent of operation				0.152
Lobectomy	38 (97.4)	26 (100.0)	12 (92.3)	
Total thyroidectomy	1 (2.6)	0 (0.0)	1 (7.7)	
Diagnosis				0.472
Papillary thyroid carcinoma	32 (82.1)	20 (76.9)	12 (92.3)	
Follicular cell adenoma	6 (15.4)	5 (19.2)	1 (7.7)	
Follicular cell carcinoma	1 (2.6)	1 (3.8)	0 (0.0)	

Data are presented as number (%) or mean ± SD.
 BMI = body mass index.

2. Clinical outcomes between the routine group and the Spacemaker group

The mean flap dissection time was 8.0 ± 2.8 minutes for the Routine group and 5.3 ± 2.1 minutes for the Spacemaker group ($P=0.004$). The mean total operation time was 106.7 ± 28.9 minutes for the Routine group and 92.5 ± 30.2 minutes for the Spacemaker group ($P=0.163$). There were no cases of excessive bleeding or conversion to open surgery among any patients from either group. There were also no signs of mental nerve or RLN injuries, or immediate postoperative complications such as bleeding or infection, among any patients from either group.

DISCUSSION

TOETVA has become an attractive minimally invasive thyroidectomy approach for both surgeons and patients worldwide because it provides excellent cosmetic outcomes (14). TOETVA leaves no visible scars because the intraoral scars are unnoticeable and heal completely within 2 to 3 weeks, compared to other remote-access approaches which merely transfer scars to other parts of the body (15,16). Moreover, unlike other remote-access surgeries that require extensive flap dissection, TOETVA only requires minimal dissection (similar to conventional open thyroidectomy) and provides an exceptional magnified view of the surgical field (17). Many studies have also reported the promising safety and outcomes of TOETVA, by showing comparable complication rates to that of traditional open thyroidectomies (18-20).

Although TOETVA has many advantages compared to other thyroidectomy approaches, there are some initial difficulties faced by inexperienced surgeons including unfamiliarity with the cranio-caudal view and the use of laparoscopic instruments (21). Working space formation in TOETVA is an especially difficult procedure with a steep learning curve for inexperienced surgeons (10). Due to the limited field-of-view and small space, bleeding is difficult to control once it occurs. Moreover, there is a risk of fatal CO_2 embolism, especially in the presence of bleeding (22,23). In the present study, we developed a technique of using a balloon dilator to create the working space. Balloon dilation significantly reduced the time taken to form the working space, with enhanced visualization and little risk of bleeding.

Balloon dilatation for working space formation has been performed and reported in various endoscopic and laparoscopic surgeries (4-6). Balloon dilators are especially popular for laparoscopic totally extra-peritoneal inguinal hernia repair because they enable easy dissection of the correct plane, resulting in better exposure and bloodless surgery with reduced operation time, conversion rates, and complications (7,24). Liang et al. (10) reported the use of the Foley catheter balloon to create a working space in TOETVA, and concluded that Foley balloon dilatation helps overcome the difficulties of initial working space formation. Bertelli et al. (9) later reported the use of the same Spacemaker balloon dilator for working space formation in TOETVA as we used in the present study. While they mention in their abstract and video presentation that flap dissection time became considerably shorter after the use of the Spacemaker and that no abnormal bleeding or adverse events were observed, the Bertelli et al.' study (9) did not present any data for their results. On the other hand, our study quantitatively shows that the Spacemaker group had a significantly shorter working space formation time compared to the Routine group. Not only did the balloon dilator allow faster working space formation, but it also optimized efficient dissection while providing good hemostasis and facilitating subsequent trocar insertions. Using balloon

dilators, vessel ligation is not needed during flap dissection and the direct pressure of the balloon also helps control bleeding, which we believe may have helped reduce perioperative bleeding events and conversions to open surgery, both of which were not encountered by any of the patients in either group.

There are complications specific to TOETVA, the most problematic being mental nerve injury (16). The mental nerve, a branch of the inferior alveolar nerve, is a sensory nerve that provides sensory innervation to the lower lip and chin (25). Mental nerve injury may occur due to stretching of the midline trocar site upon camera movement or during the process of widening the midline incision for specimen removal, and may result in temporary or permanent paresthesia in the lower lip and chin region (26). We used Hegar cervical dilators for widening the midline site to reduce the risk of mental nerve injury. No mental nerve injury occurred in any of the patients in either group. However, we were not able to objectively measure the sensory change of the patients' chin and lower lip. Thus, further studies are needed for the objective evaluation of the advantages of using Hegar dilators for midline widening in TOETVA.

The limitations of this study include its retrospective design and small sample size. Higher evidence studies with larger sample sizes are needed to prove both the efficacy and safety of using balloon dilators in TOETVA. Another limitation is the lack of objective mental nerve function measurement. Mental nerve function after TOETVA was measured subjectively in this study. We may have received more objective results if we had used a more systematic questionnaire or other objective methods such as monofilaments for sensory testing or performed two-point discrimination tests. However, the patient's subjective symptoms play a significant role in mental nerve injury assessment, and we followed up on the patients' symptoms for three months after surgery. Lastly, although balloon rupture did not occur in any of our patients, it could possibly rupture within the flap if the inflation pressure becomes too high. Balloon rupture may cause injury to the patient, and it may be difficult to retrieve the balloon fragments. Therefore, we suggest careful handling of the balloon dilator device and following the guidelines in the product's instruction manual, such as never inflating the dissection balloon with more than 10 hand pumps of air. If modifications of the device could be made, adding a pressure gauge to the device may be useful for measuring balloon pressure so that objective measurements could be made and ultimately ensure a safe procedure.

CONCLUSION

In conclusion, the Spacemaker group resulted in significantly shorter working space formation time than the Routine group, and no adverse intraoperative events or postoperative complications occurred in either group. Thus, the use of the Spacemaker balloon can provide a fast, efficient, and safe method for working space formation in TOETVA.

SUPPLEMENTARY MATERIAL

Supplementary Video 1

The Spacemaker balloon is fully inflated by manually pumping the rubber bulb pump (delivering 20–30 cc per pump) to separate the tissue layers along the naturally occurring planes and ultimately to form working space. The balloon inflation procedure is done with

the camera in place within the balloon, so that the process of working space formation can be observed from inside the balloon real-time. The patient's neck is also manually palpated during this process to monitor for excessive dilation.

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