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Original Article

Application of fibrin sealant in drain-free transoral endoscopic thyroidectomy vestibular approach

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Abstract

Objective: The transoral endoscopic thyroidectomy vestibular approach (TOETVA) is a minimally invasive technique. This study aimed to compare the safety of TOETVA with fibrin sealant (Tisseel) and TOETVA with drainage. **Materials and Methods:** Patients who underwent TOETVA between January 2018 and December 2021 were divided into drainage (n = 20) and Tisseel (n = 30) groups. **Results:** The primary outcome was the incidence of complications. The secondary outcomes were operative time and postoperative pain. There were no significant differences in patient demographics, tumor size, intraoperative blood loss, and hospitalization days between the two groups. No patient required conversion to open thyroidectomy. The incidence of complications and postoperative pain was similar in the two groups. The operative time for TOETVA with Tisseel was significantly shorter than for TOETVA with drainage (P = 0.038). **Conclusion:** TOETVA with Tisseel is a safe alternative to TOETVA with drainage, having a short operative time.

Keywords: *Thyroid cancer, Thyroid surgery, Transoral thyroidectomy*

Introduction

The transoral endoscopic thyroidectomy vestibular approach (TOETVA) is a type of natural orifice transluminal endoscopic surgery used to treat thyroid lesions. It was first reported by Anuwong in 2016 [1]. The procedure uses incisions in the oral vestibule to avoid visible neck scars.

Previous studies have demonstrated the safety and feasibility of TOETVA [2,3]. However, other research has found the incidence of postthyroidectomy hemorrhage or hematoma, which are severe complications, to be between 0.45% and 4.2% [4]. Following thyroidectomy, drainage tubes are usually used to monitor neck hematoma and reduce seroma. However, this can result in a scar over the drainage wound. Drainage tubes can also be used intraoperatively to avoid neck hematoma [1,5,6]. Although drainage tube wounds heal over time, they can cause discomfort.

Heyes *et al.* have shown the application of tissue fibrin sealant (Artiss™) during open thyroidectomy to reduce the risk of hematoma and the need for drainage. Tisseel™ is another commercially available tissue fibrin sealant. It is a unique formulation of fibrinogen and thrombin that mimics a physiological clot to provide active hemostasis during surgery. Tisseel use has previously been reported in head-and-neck surgery, and fibrin sealants have been used successfully in open thyroidectomies to reduce the amount of drainage required or avoid the placement of drainage tubes [7,8]. However, the feasibility of Tisseel use in TOETVA has not yet been established.

Therefore, we compared TOETVA patients who had a drain tube placed with drain-free Tisseel patients and looked for differences between the two in patient profiles, surgical outcomes, pathologies, and complications.

Materials and methods

Study design, data collection, and statistical analysis

This retrospective case–control study was conducted in accordance with the Declaration of Helsinki and was approved by the institutional review board of our hospital (IRB number: REC 111-27). Informed consent was waived by the IRB. All patients who underwent TOETVA at our institution between January 2018 and December 2021 were enrolled. All TOETVA were performed by a single surgeon. TOETVA was initially

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performed with a drainage tube and transitioned to the use of Tisseel without a drainage tube in June 2020. Thus, patients enrolled were divided into a drain tube placement (mini VacR) control group and a drain-free Tisseel study group. Patient demographics, thyroid tumor size, extent of thyroidectomy, surgical time, days of hospitalization, postoperative pain, drainage amount, pathologies, and surgical complications were compared between groups. All patients were followed up for at least 6 months.

Statistical analyses were performed using SPSS version 22 (SPSS Corp., Armonk, NY, USA). Data were expressed as the mean (± standard deviation [SD]) or percentage. Either the Chi-squared test or Fisher's exact test was used to compare categorical data. Mann–Whitney *U* tests were used to compare nonparametric variables. Statistical significance was set at $P < 0.05$. G*Power version 3.1.9.7 (Heinrich-Heine-Universität Düsseldorf, Düsseldorf, Germany) was utilized to conduct power analysis for determining the required sample size. We expected a mean difference of 15 min in operation time between the groups, with a pooled SD of 15.5. The effect size was calculated using Cohen's *d* (15/15.5 = 0.97), with a desired power of 0.8 and α set at 0.05. The computed sample size was determined to be 19 for each group.

Preoperative protocol

Preoperatively, all patients were evaluated for serum levels of calcium and parathyroid hormone and underwent thyroid function tests and neck ultrasonography with fine-needle aspiration cytology. Computed tomography was performed to establish the relations between anatomical structures and nasopharyngoscopy to assess the vocal cords.

Surgical techniques

A general anesthetic was administered through oral intubation. A 1.2 g dose of amoxicillin-clavulanic acid antibiotic was given 30 min before the initial incision. The incision was made over the middle lip and both gingivobuccal sulci, followed by blunt dissection and placement of ports, including one midline 11 mm camera port and two lateral 5 mm working ports. Carbon dioxide was used to insufflate the operative field at 6 mmHg. The strap muscle was dissected, and the thyroid gland was dissected gently from the trachea and transected through the isthmus. The upper part of the strap muscle was retracted laterally with a 2-0 hanging suture, and the upper pole of the thyroid was identified and dissected using a harmonic scalpel (36 cm, Ethicon Endo-Surgery, Inc., Cincinnati, Ohio, USA) until the superior thyroid vessels were ligated. The recurrent laryngeal nerve (RLN) was approached from the upper side after medial thyroid rotation, and its electrosignal was confirmed and recorded using NIM® 3.0 Nerve Monitoring Systems (Medtronic Xomed, Inc., Jacksonville, FL, USA). The inferior thyroid vessels were ligated after dissecting along the RLN and thyroid lateral border. The thyroid was then removed, and the RLN nerve signal (R2) was recorded. Hemostasis was then instigated using either drainage or fibrin sealant.

In the drainage group, a mini Hemovac drainage tube was inserted through the 11 mm camera port, extending from the lower neck and fixed with 2-0 silk. A separate incision is made in the neck. The strap muscles and lower lip mucosal wounds were then sutured.

In the drain-free group, 5 mL of fibrin sealant (Tisseel) was sprayed over the thyroid bed and pretracheal region. After the formation of an artificial fibrinogen clot, the strap muscles and lower lip mucosal wound were sutured. External gauze compression was applied to the lower neck and chin region to complete the surgery. The decision to insert a drainage tube or use Tisseel is based on patient preference.

Postoperative care protocol

Postoperatively, all patients were administered amoxicillin/clavulanic acid intravenously for 1 day and then orally for the subsequent 7 days to prevent infection. For the first postoperative day, patients were restricted to an oral liquid diet. A regular oral diet was resumed on the 2nd day, and good oral hygiene was ensured to promote healing. Non-steroidal anti-inflammatory drugs were given orally for 7 days.

Results

Patient demographics and surgical outcomes

During the study period, 50 patients underwent TOETVA; 20 with drainage and 30 using Tisseel without drainage. All patients consistently follow-up at our outpatient department for a minimum of 6 months. Surgeries performed on patients in the drainage group consisted of 17 hemithyroidectomies and three total thyroidectomies. In the drain-free group, they consisted of 23 hemithyroidectomies and seven total thyroidectomies. The tumor sizes were comparable between the two groups, with a mean of 3.35 ± 1.91 cm in the drainage group and 3.68 ± 1.45 cm in the drain-free group ($P = 0.4911$).

The duration of hospitalization was not significantly different between the two groups, with a mean of 3.2 ± 1.92 days in the drainage group and 2.8 ± 1.12 days in the drain-free group. However, the operative time was significantly longer in the drainage group than in the drain-free group, with a mean of 150 ± 42 min versus 129 ± 28 min, respectively ($P = 0.0388$).

There was no significant difference in intraoperative blood loss between the two groups, with a mean of

Table 1: Baseline characteristics of patients

Patient variable	Drain (*n*=20)	Drain-free (*n*=30)	*P*
Age	50.8±9.3	51.2±8.5	0.8759
Gender			1.0000
Male	3	5	
Female	17	25	
Surgery			0.7199
Lobectomy	17	23	
Total thyroidectomy	3	7	
Tumor size	3.35±1.91	3.68±1.45	0.4911
Hospitalization (days)	3.2±1.92	2.8±1.12	0.3567
OP time (min)	150±42	129±28	0.0388
Blood loss (cc)	31±18	30±23	0.8707

OP: Operation

31 ± 18 cc in the drainage group and 30 ± 23 cc in the drain-free group (P = 0.8707) [Table 1].

Tumor pathology

In the drainage group, 15 (75%) had nodular goiters, 2 (5%) had follicular lesions, 1 (5%) had papillary microcarcinoma, 1 (5%) had Graves' disease, and 1 (5%) had an adenomatous goiter with oncocytic change [Table 2]. In the Tisseel group, 12 (73.3%) patients had nodular goiters, 3 (10%) had follicular lesions, 3 (10%) had papillary microcarcinoma, 1 (3.3%) had Graves' disease, and 1 (3.3%) had an adenomatous goiter with oncocytic change. There was no significant difference between the two groups in thyroid lesion types.

Postoperative pain and drainage amount

The postoperative pain, as measured by Visual Analog Scale (VAS) scores, of the drainage group and the Tisseel group were not significantly different on the day of surgery (3.4 ± 2.36 vs. 3.2 ± 2.84, respectively, P = 0.7957), postoperative day 1 (2.8 ± 1.96 vs. 2.9 ± 1.89, respectively; P = 0.7957), or postoperative day 2 (1.8 ± 1.46 vs. 1.7 ± 1.23, respectively, P = 0.7957). In the drainage group, the amount of drainage was 22 ± 10 cc on postoperative day 1 and 8 ± 2 cc on postoperative day 2. There was no drainage in the Tisseel group [Table 3].

Surgical complications

Transient RLN palsy occurred in 1 (5%) patient in the drainage group and 1 (3.3%) patient in the Tisseel group. Both patients recovered within 3 months. Transient hypoparathyroidism occurred in 4 (20%) patients in the drainage group and 5 (16.6%) in the Tisseel group. There were no cases of permanent hypoparathyroidism in either group. Transient mental nerve paresthesia occurred in 2 (10%) patients in the drainage group and 1 (3.3%) patient in the Tisseel group. All three cases were resolved without intervention within 6 months. Subcutaneous emphysema occurred in 4 (20%) patients in the drainage group and 4 (13.3%) in the Tisseel group. Neck ecchymosis occurred in 4 (20%) patients in the drainage group and 2 (6.6%) in the Tisseel group. Seroma occurred in 2 (10%) patients in the drainage group and none in the Tisseel group. None of the patients in either group suffered wound infection or hematoma [Table 4].

Table 2: Tumor pathology after thyroidectomy

	Drain (n=20), n (%)	Drain-free (n=30), n (%)	P
Tumor pathology			1.0000
Nodular goiter	15 (75)	22 (73.3)	
Follicular lesion	2 (10)	3 (10)	
Papillary microcarcinoma	1 (5)	3 (10)	
Grave's disease	1 (5)	1 (3.3)	
Adenomatous goiter with oncocytic change	1 (5)	1 (3.3)	

Table 3: Postoperative pain scale and amount of drainage

	Drain (n=20)	Drain-free (n=30)	P
VAS: OP day	3.4±2.36	3.2±2.84	0.7957
POD 1	2.8±1.96	2.9±1.89	0.8574
POD 2	1.8±1.46	1.7±1.23	0.7950
Drainage			
POD 1	22±10	Nil	
POD 2	8±2	Nil	

VAS: Visual Analog Scale, POD: Postoperative day, OP: Operation

Table 4: Complications

	Drain (n=20), n (%)	Drain-free (n=30), n (%)	P
RLN injury			
Transient	1 (5)	1 (3.3)	1.0000
Permanent	0	0	1.0000
Hypoparathyroidism			
Transient	4 (20)	5 (16.6)	1.0000
Permanent	0	0	1.0000
Mental nerve paresthesia			
Transient	2 (10)	1 (3.3)	0.5561
Permanent	0	0	1.0000
Subcutaneous emphysema	4 (20)	4 (13.3)	0.6974
Neck subcutaneous ecchymosis	4 (20)	2 (6.6)	0.2017
Seroma	2 (10)	0	0.1551
Infection	0	0	1.0000
Hematoma	0	0	1.0000

RLN: Recurrent laryngeal nerve

Discussion

In this study, our analysis of the demographic and clinical characteristics of TOETVA patients in a drain-free Tisseel group and a drainage group found no significant differences in sex, age, tumor size, intraoperative blood loss, and hospitalization days. All patients underwent TOETVA without intraoperative conversion to open thyroidectomy. Previous studies have found TOETVA to open thyroidectomy conversion rates of 0.7%–1.3% [9,10]. None of the patients in either group required a second surgery. It is worth noting that previous studies have approximated the learning curve for surgeons performing TOETVA to span around 15 cases [11,12]. However, in this study, the procedure was performed by a well-trained and experienced head-and-neck surgeon. This may explain our higher rate of successful outcomes and the absence of conversion surgeries.

The use of drainage in thyroid surgery is a topic of debate, and there are differing opinions on its utility and effectiveness. The findings of a systematic review and meta-analysis of open thyroid surgery suggest that routine drainage may not be necessary [13]. Conversely, numerous studies of endoscopic thyroid surgery indicate that drainage is associated with reduced rates of hematoma and seroma [1,5,6,9,11,12,14]. However, recent research has shown that the use of ultrasonic shears can also reduce the risk of seroma or hematoma formation, potentially eliminating the need for drainage [15-17]. Our study compared the use of drainage and no drainage (with the addition of fibrin sealant) in TOETVA, providing valuable insights into this topic.

Tisseel is a type of fibrin sealant composed of thrombin and fibrinogen complex. When combined, these components generate a fibrin clot that can help achieve hemostasis, seal the wound, and support wound healing. A prospective

randomized trial has compared the use of drainage tubes with or without fibrin sealant in undergoing total thyroidectomy with bilateral central neck dissection. The study found no difference in drainage removal time and a nonsignificant lower total drainage amount in the fibrin sealant group [8]. A randomized controlled trial that compared the use of either suction drains or fibrin glue in total thyroidectomy patients found no difference in complication rates or surgical outcomes [18]. Another study comparing suction drains or fibrin glue use in total thyroidectomy patients found no evidence that the use of suction drains improves patient outcomes [19]. However, to date, there have been no studies comparing TOETVA with drainage with no drainage and fibrin sealant.

In this study, the mean operative time for patients in the drainage group was 150 ± 42 min; while, in the Tisseel group, it was 129 ± 28 min. The shorter operative time in the Tisseel group was because the placement of a drainage tube requires transcutaneous puncture using an assistant device and 5 mm working ports, which can be time-consuming. Previous reports have found operative times for thyroidectomy ranging from <100 [20-22] to more than 200 min [23,24]. A systematic review identified a median operative time for thyroidectomies of 130 ± 36.19 min [2]. This is similar to the findings of the present study.

Postoperative pain was not significantly different between the two groups. An observational study comparing the VAS scores of TOETVA and open thyroidectomy patients found no significant difference in postoperative pain [25]. Similarly, a study that compared TOETVA patients fitted with regular or small drainage tubes found no significant difference in postoperative pain scores [26].

Among our sample, one patient in each group suffered transient RLN injury, but there were no cases of permanent RLN injury. A previous review has reported the incidence of RLN injury to be around 4.5%, with 92.9% of cases being transient in nature [2]. Intraoperative neuromonitoring (IONM) during TOETVA has been shown to reduce the risk of nerve injury [27] and, in our institution, IONM is routinely used.

Three patients had transient mental nerve injuries, two in the drainage group and one in the Tisseel group. All three cases were resolved within 6 months. Mental nerve injury can result in numbness of the chin and lower lip and buccal gingiva of the mandibular anterior teeth and premolars. The incidence of mental nerve injury has been reported to be around 4.3% [28].

Nine patients experienced transient hypoparathyroidism, four in the drainage group and five in the Tisseel group. There were no cases of permanent hypoparathyroidism in either group. Reported incidence rates for transient and permanent hypoparathyroidism are 0.94%–22.2% and 1.33%–2.22%, respectively [2,12,29].

Subcutaneous emphysema is typically self-limiting and resolves within 3–5 days [30]. In this study, four patients in the drainage group and four in the Tisseel group developed subcutaneous emphysema. Seroma is a minor complication with reported incidence rates of 3.5%–5% [31,32]. Two (10%) patients in the drainage group and none in the Tisseel group developed seroma. Hematomas are rarer complications [33]. The surgical incision in TOETVA results in a clean-contaminated wound, and perioperative antibiotic protection against polymicrobial flora of the mouth is essential to decrease the risk of wound infection [34]. None of the patients in either group suffered wound infections or hematoma.

Postoperative hematoma is a rare but serious complication after thyroidectomy. The patients undergoing total thyroidectomy or those suffering with Graves' disease may be at higher risk [4]. Recent guidelines have proposed the SCOOP approach (skin exposure, cut sutures, open skin, open muscle, and pack wound) for the urgent evacuation of hematoma after open thyroidectomy [1]. However, the vestibular approach used in TOETVA precludes direct access to the surgical site through the skin. Instead, we recommend preoperatively marking an incision site for potential hematoma drainage based on endoscopic visualization of the resection field. A local anesthetic cream can be applied postoperatively for preparation. If hematoma occurs, the vestibule incision can be reopened, and the cavity can be inspected under endoscopy for evacuation and hemostasis [2]. In addition, prophylactic use of fibrin sealant, especially in patients with high risk may help prevent postoperative hematoma formation after TOETVA [7]. Further study is required to optimize strategies for hematoma prevention and management specific to the TOETVA technique.

Based on our study findings, performing TOETVA using Tisseel without drainage offers the advantages of reduced operation times and the avoidance of scarring from neck drainage tube insertions. These benefits are attained without compromising on postoperative complication rates, pain scores, or hospitalization duration. However, the additional cost of approximately US$900 for Tisseel may pose a significant financial burden for some patients. Therefore, discussions with patients regarding this additional expense are essential to ensure informed decision-making.

The present study had some limitations. First, this was a retrospective study, and all procedures were conducted by a single surgeon, which may have introduced bias. Second, the follow-up period was relatively short. Further randomized, controlled trials with larger samples and multiple surgeons are recommended to confirm our findings, and longitudinal studies are required to compare the long-term outcomes of the two procedures.

Conclusion

Our results suggest that TOETVA using Tisseel without drainage is a safe option. We found similar postoperative complication rates, pain scores, and hospitalization days, and shorter operative times in TOETVA patients treated with Tisseel and no drainage compared to those with drainage and no Tisseel. This is the first study to compare the outcomes of TOETVA with or without drainage. Further randomized, controlled trials with larger samples and longer follow-up

periods are needed to confirm these findings and establish the optimal surgical approach for TOETVA.

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Data availability statement

Data will be made available upon request from the authors.

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Conflicts of interest

TThere are no conflicts of interest.

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