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REVIEW ARTICLE

Transoral vestibule approach for thyroid disease: a systematic review

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Abstract

Objectives Transoral endoscopic/robotic thyroidectomy vestibule approach (TOETVA/TORTVA) is a novel technology that has been proposed for the treatment of thyroid disease. Its adoption has increased because of its satisfying cosmetic effects. The primary aim of this systematic review was to assess the feasibility and safety of this approach, and the secondary aim was to discuss the indications for this technology.

Materials and methods According to the Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines, we searched Pubmed, Embase and the Cochrane databases for published studies on the feasibility and safety of TOETVA or TORTVA.

Results 11 articles containing 864 patients met the inclusion criteria after full-text screening, of which two were reports of randomized controlled trial (RCT), two were retrospective cohort studies and the remaining seven studies were case series. Only studies that evaluated the feasibility and safety of this approach were included. TOETVA/TORTVA was successfully performed in 857 out of the 864 cases (99.2%). The mean operative time ranged from 60.4 to 265.4 min. In most articles, blood loss was less than 50 mL and the mean hospital stay ranged from 1.1 to 8.2 days. The safety outcomes were presented in all articles. The total incidence of adverse events was 14.5%, of which the main complications were transient hypoparathyroidism (5.6%) and transient recurrent laryngeal nerve (RLN) injury (3.1%).

Conclusions This review preliminarily suggests that TOETVA or TORTVA could be an effective and safe treatment for thyroidectomy. Due to the small sample size and low level of evidence, further large-scale, well-designed RCTs are required to validate our findings.

Keywords Thyroidectomy · Endocrine surgical procedures · Transoral endoscopic thyroidectomy vestibule approach · Transoral robotic thyroidectomy vestibule approach

Introduction

Open thyroidectomy(OT) has long been used as a standard procedure for thyroid disease. However, this operation leaves a 5–10 cm incision scar in the neck of the patient, which negatively affects the esthetic appearance and leads to psychological trauma in the patients, especially young women [1, 2]. It was until 1990s that thyroid surgery entered the era of minimally invasive surgery when Hüscher [3] applied endoscopy for thyroid disease treatment. However, endoscopic thyroid surgery too cannot avoid leaving scars in the neck of patients. The past two decades have witnessed tremendous developments in terms of surgical procedures or approaches in the field of endoscopic thyroid surgery. Such developments are mainly driven by the desire to conceal the surgical incision so as to achieve a minimally invasive esthetic effect after surgery. Currently, endoscopic thyroid surgery is performed using the axillary approach [4], areola approach [5], breast-chest approach [6], and related joint methods [7]. Although the esthetic effect is satisfying, the prolonged operation causes separation of

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the anatomical structure and increases the risk of complications [8]. There is also controversy on what standard of minimally invasive thyroid surgery is desirable. In the advent of "natural orifice transluminal endoscopic surgery (NOTES)", Wilhelm et al. [9] pioneered a sublingual approach to thyroidectomy in 2009. This new procedure is sufficiently scarless as it leaves no incision on the body surface. It has an excellent cosmetic effect, but similarly, the procedure is limited due to the associated complications. In 2012, Nakajo [10] reported, for the first time, that a vestibular approach for thyroidectomy was successfully performed on eight patients. Later, Wang et al. [11] and Anuwong et al. [12] improved the approach and formed three incisions in the vestibule, which is currently applied.

In recent years, because of the advantages and excellent cosmetic effect of this innovative approach, many institutions have adopted this technique and reported satisfying results [11, 13, 14]. To our knowledge, no systematic review has evaluated the use of this new surgical approach. The primary aim of this review is to assess its feasibility and safety. The secondary aim is to discuss the possible indications for the procedure.

Materials and methods

Search strategy

We used the Preferred Reporting Items for Systematic review and Meta-Analysis (PRISMA) [15] to perform a systematic literature review. The PubMed, EMBASE and Cochrane Databases were comprehensively searched for eligible studies. There were no publication year restrictions and the last search date was July 13, 2018. Reference lists of the included studies were also searched for potentially eligible studies. The search strategy is shown below (Fig. 1):

1. The search terms in the full-text articles. *vestibule* or *vestibular* or *transoral vestibular* or *oral vestibular*.
2. The same process was repeated with terms of *thyroidectomy* or *thyroid surgery*.
3. All studies searched (1 and 2) were used for screening.

The literature search was performed by two authors independently (SW.C and M.Z). At the end of the search, duplicate articles were discarded, then titles and abstracts of the studies were reviewed. If they appeared to meet the inclusion criteria, a full-text review was then performed for in-depth reading. If multiple publications from

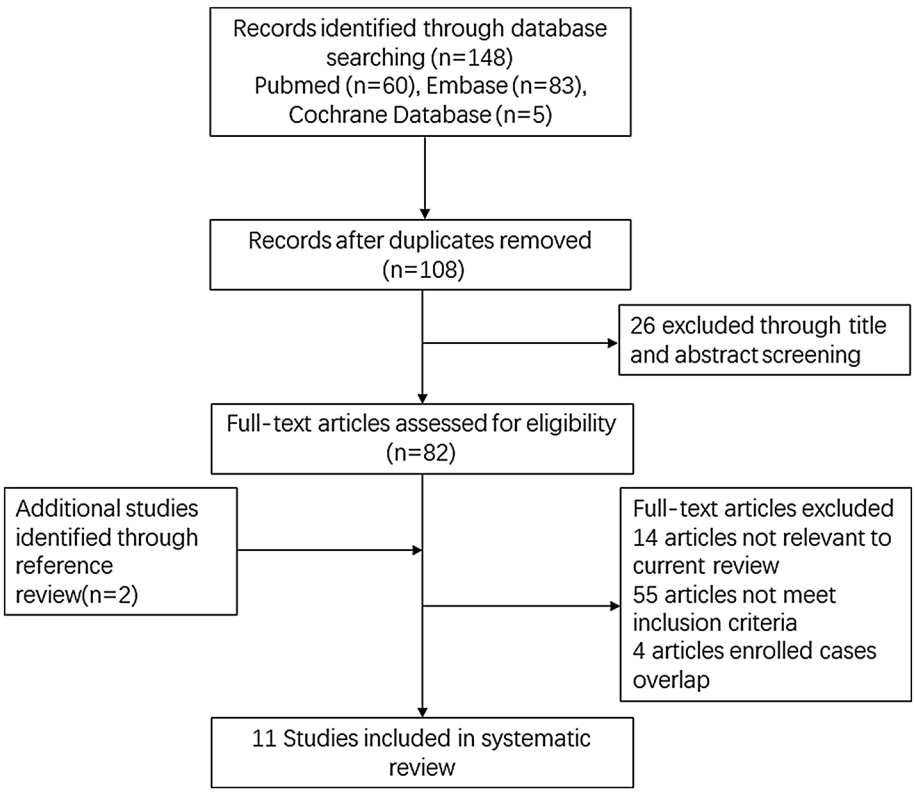

Fig. 1 Study screening and data extraction process

the same trial meet the inclusion criteria, only the more informative study was chosen.

Inclusion and exclusion criteria

Original articles published in English that assessed the feasibility or safety of transoral vestibular approach for thyroidectomy were included. Eligible studies must provide sufficient data of the patient's characteristics and perioperative outcomes. The following types of articles were excluded: not English articles, reviews, single case reports, letters, conference abstracts, videos, animal and cadaver studies. Small studies (< 5 cases) were also excluded.

Data extraction

The following variables were extracted from included articles: study's author, origin, study type, patient characteristics, and group. Other variables different among studies were also extracted: perioperative outcomes (operative time, blood loss, hospital stay, converted to open surgery, pain score), complications (RLN injury, mental nerve injury, SLN injury, etc.). As a new type of surgery, TOETVA or TORTVA has not been widely promoted and practiced. Because of the differences in culture and medical environment, heterogeneity between study outcomes is unavoidable, hence it is not appropriate to conduct a meta-analysis.

Quality assessment

Oxford Centre for Evidence-Based Medicine ratings [16] was used to assess the quality of the included studies. Cochrane Handbook for Systematic Reviews of Interventions [17] was also used to assess the level 1b evidence and above. For evidence < level 1b, The Methodological Index for Non-Randomized Studies (MINORS) criteria [18] for bias was applied. Definition of the score for each criterion: 0, not reported; 1, reported but insufficient; 2, reported and adequate. For non-comparison studies, scores < 10 were considered to have high risk for bias, scores 10–14 were considered moderate risk, and scores 15–16 were considered low risk. For comparison studies, scores < 18 were considered high risk, scores 18–22 were considered moderate risk, and scores 23–24 were considered to have a low risk of bias.

Results

The initial search identified 148 articles from the three databases. 40 of them were excluded due to duplication. 26 were removed during title and abstract screening, leaving 82 articles for full-text evaluation. According to the inclusion and exclusion criteria, 73 articles were excluded. Two qualified articles were retrieved from the reference list. A total of 11 articles were included [10, 11, 13, 14, 19–25].

The characteristics of the included studies are shown in Table 1. Two studies [11, 19] were randomized control trials (RCT), whereas two [14, 24] were retrospective cohort

Table 1 Characteristics of included studies

Study ID	Origin	Study type	Approach	*N* (male/female)	Age (years) (mean + SD)	Diagnosis
Wang 2018	China	Case series	TOETVA	0/18	33.7 ± 6.6	6 NG, 12 PTC
Park 2017	Korea	Case series	TOETVA	4/13	42.2 ± 12.2	1 FC, 1 FA, 4 NH, 11 PTC
Dionigi 2017	Italy	Case series	TOETVA	3/12	29.4 ± 5.5	13 NG, 2 PTC
Udelsman2016	America	Case series	TOETVA	0/5	42.8 ± 9.3	1 HTA, 2 CN, 1 NH, 1 PTC
Yang 2016	China	Case series	TOETVA	1/5	34.3 ± 5.6	5 NG, 1 TA
Nakajo 2013	Japan	Case series	TOVANS	1/7	54.9 ± 10.9	1 FC, 3 FA, 1 NG, 3 PTC
Kim 2018	Korea	Case series	TORTVA	0/24	39.6 ± 11.6	1 FC, 3 BG, 20 PTC
Yang 2015	China	RCT	TOETVA	8/33	31.9 ± 8.8	34 BG, 4 PTC, 3 hyperthyroidism
Wang 2014	China	RCT	TOETVA	2/10	24.0 ± 6.2	3 NH, 3 FN, 4 CN, 2 FA
Anuwong 2018	Thailand	Retrospective cohort study	TOETVA	33/389	35.5 ± 12.1	245 single-NG or cyst, 118 multiple-NG, 33GD, 26PTC
Razavi 2018	America	Retrospective cohort study	TOETVA	4/16	41.3 ± 12.2	15 BG, 2 PTC, 1 NIFT-P, 2 HCC
			TORTVA	0/7	41.3 ± 15.8	5 BG, 1 NIFT-P, 1 PTC

TOETVA transoral endoscopic thyroidectomy vestibular approach; *TORTVA* transoral robotic thyroidectomy vestibular approach; *TOVANS* transoral video-assisted neck surgery, *NG* nodule goiter; *PTC* papillary thyroid carcinoma; *FC* follicular carcinoma; *FA* follicular adenoma; *NH* nodular hyperplasia; *HTA* hyperplastic toxic adenoma; *CN* colloid nodules; *TA* thyroid adenoma; *BG* benign goiter; *FN* follicular nodule; *GD* Graves disease; *HCC* Hürthle cell carcinoma; *NIFT-P* noninvasive thyroid neoplasm with papillary-like nuclear features, *RCT* randomized controlled trial; *N* number; *SD* standard deviation

studies. The remaining seven studies [10, 13, 20–23, 25] were case series. Although Kim [23] compared the discrepancy of the incision in the vestibule, it is essentially the same method. We included it in non-comparison trials in this review. Most of the research was conducted in the Asia-Pacific region. Two RCTs [11, 19] were performed in China, comparing TOETVA and endoscopic thyroidectomy axillary approach (ETAA). Anuwong et al. study included more than 2 years of cases in their institution, including 422 patients receiving TOETVA and 216 patients receiving OT. Razavi et al. performed a retrospective review comparing TOETVA and TORTVA. In the remaining eight studies, Kim et al. used the Da Vinci robot to complete the thyroidectomy and others used endoscopy for surgery.

Of the seven non-comparison studies, five [10, 13, 22, 23, 25] were scored as a moderate risk of bias and two [20, 21] were scored as high risk (score 9–10). Of the twoi [14, 24] comparison studies, they were scored 20 and 21, which were considered as moderate risk of bias. The remaining two RCTs [11, 19] were scored at moderate risk as they did not mention blinding. The quality assessment outcomes are shown in Online Resource 1.

Transoral vestibular approach

All of the included studies were performed using a similar surgical procedure. After anesthesia, the patient was laid in the supine position to expose the neck and then injected with diluted adrenaline solution into the vestibular and anterior cervical regions to form the subplatysmal layer. Then, three incisions were made in the middle of the oral vestibule in the lower lip and the level of bilateral first premolar. A 30° angle camera was placed in the middle 10–20 mm incision. The other two 5 mm incisions were used for instrument operation. The tissue was bluntly separated with dissectors and insufflated with CO_2 at 6 mmHg to maintain the operating space. After removal of the thyroid, the specimens were placed in a specimen bag and pulled out through the middle incision. There were differences in managing postoperative compression and drainage tubes among the studies. Six [10, 13, 14, 22, 23, 25] of the 11 studies used drainage tubes. Park et al., Dionigi et al., and Anuwong et al. placed a drainage tube after total thyroidectomy while Kim et al. placed a drainage tube through the axilla incision. Eight studies [11, 14, 19–24] used postoperative compression in the neck, while two studies [10, 25] did not mention the methods used. Nakanjo et al.'s operative method was different from the others. Only a 25 mm incision was made in the middle of the oral vestibule. The K-line was applied externally to pull the neck skin to create a surgical space instead of insufflation with CO_2. Wang et al. [25] and Yang et al. [19] combined K-line (or suture) and CO_2 insufflation.

Outcomes

The detailed outcomes of the included studies are shown in Table 2. All studies recorded the duration of surgery, with an average surgery time ranging from 60.4 to 365.4 min. Razavi et al. reported a median time of 322 min (287–377) for RA and 188 min (89–343) for EA. Eight studies [10, 11, 13, 14, 19–21, 25] reported blood loss during surgery, with an average ranging from 10.8 to 97 mL, of which Nakajo et al.

Table 2 Outcome measures of included studies

Study ID	Evidence level	Operation time (mean, min)	Blood loss (mean, mL)	Hospital stay (mean, days)	Coversion to open (no. of cases)	VAS pain score
Wang 2018	IV	151.6	26.9	4.1	1	NR
Park 2017	IV	170.6	NR	4.1	0	NR
Dionigi 2017	IV	96.3	48.8	1.6	0	NR
Udelsman 2016	IV	244.8	< 20	1.1	0	NR
Yang 2016	IV	122	30	8.2	0	NR
Nakajo 2013	IV	265.4	97	4.3	0	NR
Kim 2018	IV	232	NR	3.3	0	0
Yang 2015	Ib	72.1	11.1	5	0	Day 1: 1.7, day 3: 0.6
Wang 2014	Ib	60.4	10.8	4.9	0	NR
Anuwong 2018	III	96.6	35.8	NR	3	Total: 1.3, day 1: 2.3, day 2: 1.1, day 3: 0.4
Razavi 2018	III	RA: 322 (287–377)[a] EA: 188 (89–343)[a]	NR	NR	RA:2[b] EA:1	NR

RA robotic approach; *EA* endoscopic approach; *NR* not reported

[a]Median operation time

[b]One case converted to endoscopic procedure and the other converted to open thyroidectomy

was 97 mL, and the others were less than 50 mL. Hospital stay was mentioned in nine studies [10, 11, 13, 19–23, 25] and the time of each study was quite different. The average length of hospital stay ranged from 1.1 to 8.2 days. Of the 864 subjects, only three studies [14, 24, 25] reported that six subjects converted to open surgery and one subject switched from RA to EA. The major reasons were excessive bleeding and oversized specimen.

Safety

The impact of transoral vestibular approach on safety was formally assessed in all studies. The main complications included damage of nerves and parathyroid gland. Hypoparathyroidism was the main complication that occurred in 48 (5.6%) cases. RLN injury occurred in 27 (3.1%) patients. There were 13 mental nerve injuries, accounting for 1.5%. All other symptoms were transient except for three cases of mental nerve injury, all of which were reported in Kim et al study. In addition, there were 22 (2.5%) patients with symptoms of seroma after surgery, and only one had infection postoperatively. Other complications included ecchymosis, skin pierced and hematoma. Detailed complications of the included studies are summarized in Table 3.

Discussion

Following the first report on the vestibular approach by Nakajo, more researchers have focused on this new procedure due to its strengths, such as compatibility with the NOTES concept, excellent cosmetic effect, and low postoperative infection among others. Later, Wang et al. [11] and Anuwong et al. [14] improved the procedure by designing a transoral tri-vestibular incision approach. Presently, TOETVA is widely used as a novel treatment of thyroid disease, and as such, we conducted a systematic review of its feasibility and safety.

The results show that TOETVA has a longer operative time compared to OT [14], which is consistent with other endoscopic approaches [6, 7, 26]. The mean time of operation varied among the studies. The average operation time reported in some studies [11, 13, 14, 19] was less than 100 min, while others [10, 20, 23] reported more than 200 min. A possible explanation for this might be that some surgeons are not familiar with this new procedure, hence they take longer time to ensure safety. If the surgeons gets familiar with the technique, the operative time could be decreased [27, 28]. The pain score of patients after TOETVA is significantly less than that of traditional OT due to the scarlessness of the skin [14]. Differences were also observed in the length of hospital stay among studies. Several factors may explain this observation, such as different health insurance policies, economic constraints, and differences in treatment guidelines across regions. With the improvement of postoperative management, we believe that the hospital stay time will gradually decrease. TOETVA is safe compared to traditional OT, in terms of blood loss and complications [14]. The most common complications of TOETVA are temporary RLN injury and hypoparathyroidism, which often occur after traditional OT. The incidence of complications after TOETVA in this study is similar to that of OT [29]. Presently, RLN injury can be effectively avoided by perioperative nerve monitoring system [30, 31], and parathyroid gland angiography with indocyanine green fluorescence [32, 33] is used to predict parathyroid function and the risk of postoperative hypocalcemia after thyroid surgery. These two methods are expected to be routinely applied in

Table 3 Adverse events of included studies

Study ID	RLN injury (T/P)	SLN injury (T/P)	Mental nerve injury (T/P)	Hypoparathyroidism (T/P)	Infection	Seroma	Others
Wang 2018	0	3/0	1/0	0	0	0	NR
Park 2017	0	0	0	1/0	0	2	NR
Dionigi 2017	0	0	0	1/0	0	0	1 emphysema
Udelsman 2016	0	0	0	0	0	0	NR
Yang 2016	0	0	0	0	1	0	NR
Nakajo 2013	1/0	0	0	0	0	0	NR
Yang 2015	1/0	0	0	0	0	0	2 skin ecchymosis, 1 skin pierced 1 skin burn
Wang 2014	0	0	0	0	0	0	2 skin ecchymosis
Anuwong 2018	25/0	0	3/0	46/0	0	20	1 hematoma
Kim 2018	0	0	6/3	0	0	0	2 bruising, 1 perforation 1 tearing of commissure of lips
Razavi 2018	0	0	0	0	0	0	NR

RLN recurrent laryngeal nerve; *SLN* superior laryngeal nerve; *T* transient; *P* permanent; *NR* not reported

thyroidectomy as auxiliary technology in the future. Finally, although TOETVA is not significantly different in terms of efficacy and safety compared to traditional OT, TOETVA is entirely a scarless procedure and it is currently the most minimally invasive surgery in thyroidectomy.

In this review, there were two studies that included 31 subjects who performed surgery using a robot. A total of 29 subjects completed this procedure. The reason for not completing the surgery as scheduled was that the specimen was too large. The average time of robotic surgery was greater than 200 min, exceeding most of the thyroid surgeries with endoscopy. A total of 13 subjects had adverse reactions, but they were all reported in the Kim et al. study. We consider that the reason for the high complications was mainly due to the unfamiliarity with this new technology and robotic operations. This phenomenon will improve as the technology matures. According to the studies previously reported, the pros and cons between endoscopic surgery and robotic surgery are still controversial [34–36]. Similarly, in transoral vestibular thyroid surgery, the sample size is too small to draw a conclusion of which kind of surgery is better. Further large-scale and high-quality studies are required to determine whether using robots is superior to endoscopy in transoral vestibular thyroid surgery. However, the validity of the studies is limited by some methodological shortfalls. This review included two RCTs, two retrospective cohort study and seven case series. These studies were limited by the lack of blinding or randomization. Additionally, the overall evidence level of the remaining seven studies is low. Although the patients were satisfied with the cosmetic results of the operation, none of the studies considered quality-of-life endpoints. This limits the extent to which one can determine whether TOETVA is suitable in thyroidectomy. The difference between the inclusion and exclusion criteria among studies also limits the external validity, for example, the exclusion of carcinoma patients or Grave's disease. This may lead to recruitment bias.

At present, due to the lack of uniform standards, the indications and contraindications of this procedure are different in each study. According to this review, we believe that TOETVA can be considered for any thyroid disease requiring surgical intervention, but there are several key points that need to be considered. First, due to the limitation of the surgical operation space and visual field, it is difficult to perform lymph node dissection in addition to the median cervical lymph node. Therefore, patients with cervical lateral lymph node metastasis or distant metastasis are not suitable for TOETVA, nor in patients with invasion of trachea, esophagus or RLN. Second, since the specimen is removed through the incision site, the size of the specimen is an important factor in choosing the surgical procedure. Eight studies [10, 11, 13, 14, 19, 22, 23, 25] gave a detailed inclusion or exclusion criteria. Park et al. mentioned the criteria with thyroid cancer of less than 2.5 cm and benign nodules of less than 8 cm, but with a central 2.5 cm incision. In the study where the central 10 mm incision was used, the thyroid cancer was required to be no more than 2.0 cm and the benign nodules were required to be less than 6.0 cm. Third, the lower jaw of the Asian population is flatter than that of European and American people, hence when using TOETVA in Europe and America, a careful preoperative assessment may be needed. In addition, the degree of obesity of the patient, the history of neck surgery or radiotherapy, and the patient's personal preferences are factors that need to be considered before surgery. In cases where TOETVA is difficult to continue, it is possible to perform an open surgery to complete the thyroidectomy.

Limitations

Overall, the conclusions of this review need to be carefully considered due to the following limitations. First, most of the included studies were retrospective studies. We used the MINORS items to assess their quality and most of them had a moderate risk of bias. The two RCTs included did not mention the blinding process in the articles, and this may cause performance and assessment bias. Second, there are potential differences among studies, such as the experience of the surgeons, the criteria of enrolling patients, and differences in local treatment guidelines, leading to heterogeneity of the outcomes of the studies. Third, we conducted a comprehensive search strategy to obtain the full texts on transoral vestibular approach thyroidectomy, but we did not perform a manual search, which may lead to the omission of some relevant articles. Fourth, there are few published articles on thyroidectomy using the oral vestibular approach, hence the sample size of the included studies is generally small.

Conclusion

In summary, this review preliminarily suggests that TOETVA or TORTVA may be an effective and safe treatment for thyroidectomy. Due to the small sample size and low level of evidence, the reliability of these conclusions is limited. Further large-scale, well-designed RCTs are required to validate our preliminary findings. Being a new technology, the surgeons or institutions must have sufficient medical equipment and acquire sufficient experience before adopting this new approach to ensure patient's safety.

Author contributions Each of the authors has contributed to reading and approving this manuscript.

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Compliance with ethical standards

Informed consent For this type of study formal consent is not required.

Conflict of interest The authors declare that they have no conflict of interest.

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