Abstract. – Conventional open thyroidectomy is still considered the gold standard for thyroid surgery. Transoral endoscopic thyroidectomy vestibular approach (also known as TOETVA) is often considered to be more advantageous than the other approaches, such as minimally invasive video assisted thyroidectomy, thyroidectomy via breast/axillary/retroauricular access, bilateral axillo-breast approach and axillo-bilateral breast approach. In this scoping review, we discuss the risks and the benefits of this surgical approach and its medico-legal and ethical implications, particularly focusing on the importance of practice on cadavers. Currently, there is little scientific evidence supporting TOETVA, since there are few papers on the comparison with the traditional open thyroidectomy that have been published and thus little data on the long-term outcomes of TOETVA are available. Since the better cosmetic outcome currently represents the main indication for this surgical technique, substantial medico-legal and ethical issues arise. Moreover, practice on cadavers can help surgeons to develop the technical and non-technical skills required to perform efficiently and safely this new surgical procedure.

Key Words: TOETVA, Thyroidectomy, Medical malpractice, Ethics, Cadaver lab.

Introduction

Conventional “open” thyroidectomy is still considered the standard for thyroid surgery. Alternative surgical approaches to the thyroid have been developed to avoid neck scars for the last two decades. In particular, minimally invasive thyroidectomy and remote access endoscopic or robotically assisted thyroidectomy do not require visible incisions. Transoral endoscopic thyroidectomy vestibular approach (TOETVA), which has been recently developed and described, could be even more advantageous from a cosmetic point of view than other approaches, such as minimally invasive video assisted thyroidectomy (MIVAT), thyroidectomy via breast access, via axillary access, via retroauricular access, bilateral axillo-breast approach (BABA) and axillo-bilateral breast approach (ABBA). Patients who prefer to undergo TOETVA are particularly concerned by...
a negative cosmetic outcome. However, this approach has limited indications and is still at an investigational level. Indeed, it is burdened with a significant medico-legal risk, because it is a technically demanding procedure and is associated with a potential wider spectrum of complications with respect to the standard and other minimally invasive/remote access procedures (Table I). Unlike other remote accesses, novel complications, especially due to the vestibular access, could be clearly visible to the patient in the postoperative period, in the wide area that goes from the zygoma, lower lip, to the chin up to the neck. In this paper, we discuss the risks and the benefits of this approach and its medico-legal and ethical implications.

**General Considerations**

The increased incidence of thyroid pathology among young women and the increasing attention to the cosmetic outcome brought to the development of alternative surgical approaches. Transoral approach represents a technological advancement in minimally invasive endocrine surgery. According to current evidence, this technique would allow to achieve excellent cosmetic results because the skin incision is in a natural orifice (mouth), avoiding any visible scar. However, in the Western countries this technique is mostly limited to highly specialized centres. Moreover, there is little evidence supporting this procedure, long-term outcomes, and possible advantages over traditional open thyrodectomy. Anuwong et al compared these two different surgical approaches and found that TOETVA had similar recurrent laryngeal nerve (RLN) lesion and hypoparathyroidism rates to the open technique. Thus, the two techniques were equivalent in terms of safety and outcomes, with TOETVA not being associated with an increased risk of wound infection or other permanent complications. Their results also showed that TOETVA was associated with a significantly longer operating time, but with less postoperative pain. However, this study had two limitations: it is a retrospective study conducted in a single Asian center with an unbalanced population between the two groups of patients; furthermore, most patients had benign lesions, so there were not enough data regarding thyroid cancer. According to this evi-
dence, TOETVA could be an option for selected patients, after further long-term studies have confirmed the safety and efficacy of this approach, including in patients with thyroid cancer\(^\text{20}\). Another recent cross-sectional study, published by Grogan et al\(^\text{20}\), investigated how many patients undergoing thyroid and parathyroid surgery were eligible for scar-free transoral surgery, applying the current exclusion criteria. An admisibility of 56\% suggests that TOETVA can be applied to a large number of patients (about 140,000 patients per year in the USA) and that it could be considered a routine surgery in the near future; in this study the authors considered patients treated at academic institutions of endocrine surgery, and this limits the reliability of this work because currently most thyroidectomies are still performed in private facilities\(^\text{20}\).

Errors in Thyroid Surgery

General surgery is one of the most exposed fields to medical malpractice claims\(^\text{12-28}\). The high exposition to medico-legal claims is also due to the fact that in general surgery most of the errors are considered preventable\(^\text{20,30}\). Thyroid surgery is associated with minor and major risks. The minor risks are: delayed bleeding, haematomata of the superficial and deep layers\(^\text{19}\), scars\(^\text{1}\). The major risks are represented by: bleeding, RLN injury\(^\text{19}\), lesion of the external branch of superior laryngeal nerve\(^\text{30}\), hypoparathyroidism\(^\text{19}\). Some of these complications could be avoided by improving technical skills. For instance, hypoparathyroidism could be a less frequent complication by performing a more accurate dissection, avoiding the use of hot blades, and identifying the parathyroid glands with specific techniques (e.g., indocyanine green)\(^\text{30,31,32}\). Moreover, intraoperative RLN monitoring has been advocated to reduce the risk of RLN injury, even if definitive data are not available\(^\text{33}\). According to Promberger et al., one of the factors increasing the risk of developing haemorrhage after thyroidectomy is incorrect haemostasis performed by the surgeon\(^\text{34}\). Therefore, improving technical skills is essential to reduce the risk of complications. New complications have been observed with the vestibular approach, rarely found with traditional surgery, so TOETVA involves additional risks\(^\text{80}\). A unique complication of this procedure is paralysis or injury to the mental nerve, which causes transient—or even permanent—sensory disturbances of lower lip and chin, with lack of sensitivity to hot liquids. The correct execution of standard 5 mm vestibular incisions, located just below lower lip lateral to the canine teeth, prevents damages to the mental nerve\(^\text{60,35}\).

The Advantages of Practice on Cadavers

The use of cadavers represents a model close to reality that allows an effective understanding of human anatomy. Moreover, cadavers allow to perform new surgical techniques safely and to fulfil them in the living later. In detail, simulation allows replicating aspects of the real world in an interactive way. Simulation-based training allows trainees to learn technical and non-technical skills while avoiding risking patient safety\(^\text{16}\). Pfandler et al\(^\text{37}\) investigated the correlation between technical skills (TS) and non-technical skills (NTS) in a simulated spine procedure and noticed that they are interconnected. In the operating room, errors often occur because of failure in NTS\(^\text{36}\). NTS include intraoperative communication, situational awareness, leadership, teamwork and decision-making. Low levels of NTS have been found to be associated with an increased probability of making technical errors\(^\text{38,39}\). In addition, according to Gaba\(^\text{16}\), simulation may have considerable power in improving technical skills as it allows surgeons to gain experience with even uncommon clinical or anatomical presentations. Furthermore, Rashid et al\(^\text{40}\) analyzed the emerging role of simulation in urological surgery and concluded that simulation is the best instrument in surgical education. Currently cadaveric dissection is one of the techniques of surgical simulation\(^\text{41}\). Lewis et al\(^\text{42}\) proved that the use of cadavers is an efficient way to improve surgical skills and is not only a good tool for training residents but also a great exercise that allows increasing confidence in performing operations. Indeed, performing surgery on cadaver allows a better visualization of anatomical structures, which can in turn help during endoscopic procedures, where organs are usually displayed on a screen in two dimensions\(^\text{42}\). Reed et al\(^\text{43}\) investigated the possible use of fresh cadavers in vascular surgery training and stated that using fresh frozen cadaver is advantageous because tissue planes are preserved. For this reason, tissue handling is very realistic, and has enabled improved suturing skills. Ocel et al\(^\text{44}\) reported that students appreciated simulation on cadavers, preferring it over simulation with inanimate trainers, and felt more confident and efficient after training with cadavers. A very interesting example of the use of cadaver is the live cadaver model which combines human anatomy with pulsatile blood-flow\(^\text{45}\). In their study, Pacca
et al. evaluated the live cadaver model for ICA (Internal Carotid Artery) injury simulation in endoscopic endonasal skull base surgery. The authors found that live cadaver model is an excellent means of simulating a surgical crisis and improving skills in the management of an intraoperative endoscopic endonasal ICA rupture. Olabe et al. advocated training on cadavers after they performed microneurosurgical procedures on four human cadaveric brains. McCrary et al. considered the use of cadavers in teaching medical students to practice a US-guided breast biopsy which was a very effective method. Practice on cadavers to test minimally invasive endocrine surgery procedures on the thyroid gland has already been performed in the past. In particular, oral vestibular approach was first described by Richmon et al., using three oral doors in the oral vestibule, assisted by da Vinci robot (Intuitive Surgical, Inc. Sunnyvale, CA, USA) in cadavers. In a recent paper, Oliva et al. simulated thyroid surgery in a cadaver laboratory. Six individuals (four were males and two females) underwent thyroidectomy using TOETVA technique, which allows transoral access to the thyroid gland (Table II). The Authors performed each step of the procedure as they would have done in the operating room, repeating the entire operation six times. Repetition of the procedure is the best tool to become familiar with the performance of surgery and to improve technical and non-technical skills.

Medico-Legal Considerations

The cadaver model is important to allow the forensic pathologists to appreciate in detail all the surgical steps of the TOETVA. In this way, the medical examiner can learn the new surgical technique in person. The forensic pathologist can have an overview of the advantages and limitations of this technique. Furthermore, the interaction between the medical examiner and the surgeon can foster discussions on possible alternatives, preventive interventions and solutions to avoid surgical errors. Moreover, as said before, TOETVA is not the golden standard for thyroidectomy (national and international guidelines generally recommend open surgery, MIVAT or transaxillary approach) and is associated to more complications than the traditional approaches. Because of these issues, in case of malpractice claims, it is hard for the defendant (the surgeon) to prove to have complied with the standard of care and thus to prevail. The surgeons who choose this approach must know all its possible complications and carefully adopt all the interventions of primary and secondary prevention (Table III). Exercitations on cadaver allow to carefully evaluate and learn all the aspects of this approach.

Ethical Issues

As discussed, TOETVA seems to be a promising technique with some advantages in comparison with other approaches. However, currently it is requested by patients because it provides a better aesthetic outcome than the open technique. This consideration implies substantial ethical issues since it is associated to additional risks for the patient and only few centers have the experience and the expertise needed to perform it correctly and safely. As showed by our paper, technical and non-technical skills can play a pivotal role in avoiding errors and significantly improve when the surgeon has the possibility to learn and practice the technique on cadavers. In other words, practice on cadavers can help surgeons to avoid more errors and thus to reduce the medico-legal risk. Anyway, the fact that this very complex technique is indicated mainly because of aesthetic reasons generates a serious ethical dilemma, since it exposes patients to more risks in absence of benefits for their health.

Conclusions

TOETVA is an innovative procedure, but it is still at an investigational level and is far to be considered the gold standard. TOETVA should be performed in high volume centers and by sur-
geons who have extensive experience in endocrine and endoscopic procedures. Therefore, it is necessary to train and improve surgical skills. In our experience, cadaver simulation proved to be an effective training modality to perform minimally invasive surgery and to gain confidence in operationa.

Conflict of Interest
All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest or non-financial interest in the subject matter or materials discussed in this manuscript.

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Authors’ Contribution
AO, RB and MR developed the project. All the authors participated in reviewing the literature and writing the draft.

Data Availability Statement
Data are available on reasonable request to the corresponding author.

Ethics Approval
The described procedures were performed during routine post-mortem diagnostic procedures in the setting of a post-graduate teaching program issued and approved by the Faculty of Catholic University of the Sacred Heart, School of Medicine.

Consent for Publication
Not required.

Table III. TOETVA complications and possible interventions of primary/secondary prevention.

<table>
<thead>
<tr>
<th>Complication</th>
<th>Prevention/Solution</th>
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<tbody>
<tr>
<td>Mental nerve injury</td>
<td>Careful vestibular tunnelling for tracer insertion</td>
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<tr>
<td></td>
<td>No use of electrocautery</td>
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<tr>
<td>Bruise over zygoma</td>
<td>Protective sponge on the entire face</td>
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<tr>
<td>Chin/neck flap perforation</td>
<td>Careful axial and parallel dissection</td>
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<tr>
<td></td>
<td>Use of blunt mosquito forceps</td>
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<tr>
<td></td>
<td>No use of electrocautery</td>
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<tr>
<td>Mouth commissure tearing</td>
<td>Oral mucosal commissure protection sutures</td>
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<tr>
<td></td>
<td>Plaster application over commissures</td>
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<tr>
<td>Broken teeth</td>
<td>Use of mouthguards</td>
</tr>
<tr>
<td>Sense of tension/stiffness in the chin, neck</td>
<td>Early postoperative physiotherapy and massages extended to chin and neck</td>
</tr>
<tr>
<td>Injury of the tongue (and migration of secretions and clots to the airways)</td>
<td>Placing gauze in the mouth and pushing the tongue down</td>
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</table>

References


