

Endoscopic minimally invasive thyroidectomy: ethical and patients safety considerations on the first clinical experience of an innovative approach

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The report entitled “Endoscopic minimally invasive thyroidectomy: first clinical experience” by Thomas Wilhelm (T.W.) and Andreas Metzig (A.M.) is associated with severe ethical and safety concerns regarding its application in patients. As the first initiator group of transoral thyroidectomy we feel obliged to bring important clarification to the attention of the medical community before clinical application starts [1, 2].

The acronym eMIT (endoscopic minimally invasive thyroidectomy) used by the authors is a renaming of the already presented totally transoral video-assisted thyroidectomy (TOVAT) [1], since the term TOVAT describes precisely the route (transoral) and also refers to the methodology (totally video-assisted).

TOVAT is an innovative project that was initiated in September 2007 by the New European Surgical Academy (NESA) and developed in cooperation with the Department of Neuroscience Anatomy at the Erasmus MC University in Rotterdam, The Netherlands. TOVAT is a product of

interdisciplinary consideration within a working group consisting of surgeons, otolaryngologists, and gynecologists. This idea was based on previous experience and practice [3]. The TOVAT procedure is based on the hybrid technique by Kai Witzel, who was the first to describe transoral access to the thyroid [4].

When a new suggested surgical method departs substantially from current standard of care, scientific evaluation is a *conditio sine qua non* [5, 6]. Feasibility and safety must be secured before starting clinical application. In this sense, initially together with T.W. and the Rotterdam Department of Neuroscience Anatomy, objective parameters were defined which described the suggested procedure in detail and allowed an evaluation of the method. For this purpose, a total of three human cadavers were used for extensive anatomic studies and for the development of optimal instruments. Following these studies, safety and reproducibility of the transoral thyroidectomy were assessed in two further cadavers, implementing the results of the first trial. TOVAT was performed using one 5-mm and two 3-mm trocars that were introduced through the floor of the mouth and under the platysma [1]. In Germany, in almost all hospitals, thyroid surgery is performed by surgeons. Thus, the part of T.W. was to create the sublingual access. The thyroidectomy itself was performed by T.B., who is a general surgeon experienced in traditional and endoscopic thyroid surgery [7]. We succeeded in defining the objective parameters, which describe the procedure in detail and allow the evaluation of the surgery performed. Although the surgical feasibility of TOVAT could be demonstrated on 14 May 2008, we still had concerns about its clinical application. Some of these were also raised by Paolo Miccoli and his colleagues in a letter to the editor as reaction to our video paper [8, 9]. A crucial point of TOVAT is the access itself, because the floor of the mouth

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is limited in size and might be damaged by an oversized instrument or large specimen. Since there are no data concerning this question, we started investigations on cadavers to determine the maximal diameter of an instrument that might be introduced and the specimen volume that can be removed without causing scar formation with consecutive chronic swallowing disorders. Furthermore, it is not possible to perform totally endoscopic thyroidectomy without using modern “energy” devices for hemostasis. For this, it is necessary to replace the right 3-mm trocar by a 5-mm one in order to be able to introduce a harmonic or bipolar scalpel. This diameter might be risky, because the lateral vestibulum trocar is located close to the mental nerve. Furthermore, innovative surgical procedures that have been tested in animal models cannot simply be transferred to clinical trials without further refinements and modifications [10]. This is particularly valid for TOVAT, because of the strong anatomical differences concerning the topographical anatomy of the thyroid gland between humans and animals. The neck in pigs, for example, is much larger than in humans, thus enabling better triangulation and manipulation of instruments. Moreover, thyroidectomy in pigs is much easier to perform due to the peculiar anatomical relationships of the gland, the absence of definite parathyroid glands, and its relatively simple blood supply [11]. This applies also to our successfully performed TOVAT in five pigs on 31 August 2008.

Clinical application has tremendous implications regarding expectations, surgeon responsibility, and most importantly patient safety [5]. If preclinical feasibility and safety are established, approval for clinical study should be given by an external institution within the constraints of the legal framework pertaining to the particular country (Research Ethics Committee). All research involving humans or their identifiable data must be reviewed by the appropriate body for ethical approval according to the relevant legal requirements [5]. This is why we decided to await results of the ongoing studies before clinically applying TOVAT. Unfortunately, T.W. did not share our view and retired from our group on 11 December 2008. Three months later, on 18 March 2009, T.W. and A.M. performed TOVAT in a 53-year-old man. In the meantime, T.W. and A.M. operated on more patients. Although they encountered the above-cited difficulties and concerns that led to conversion and recurrent nerve palsy, they did not consider it imperative to report on these severe adverse events, even though these complications already occurred as T.W. submitted the video paper to *Surgical Endoscopy*. Adverse events need to be documented and communicated in order to prevent complications in patients with similar medical conditions [5]. In the meantime, this hazardous “experiment” has been stopped, and the involved surgical community in Germany has been informed about these complications.

As for the video paper itself:

1. All thyroid resections were performed by A.M. and not by T.W. A.M. did not participate in any of the preclinical trials, which is a prerequisite and *conditio sine qua non* for performing such a complex operation for the first time in human beings.
2. The total video clip duration is 7 min. The first 3 min 55 s is a repetition of our already reported preclinical study [1].
3. The whole surgical procedure itself takes just 1 min 50 s and does not contain any single continuous sequence of the operation; most sequences are incoherent film pieces.
4. At point 5 min 10 s, a structure is declared as recurrent laryngeal nerve. What the authors present is not the nerve and also not the plane where it runs.
5. What about visualization of the parathyroids?
6. Neither in the text nor in the video itself is approval by the institutional review board mentioned. Did the authors present any protocol with all above-mentioned concerns of the preclinical trial to an ethical committee?
7. Is there any independent steering committee that was appointed to overview this human trial?
8. Why did the authors not stop this “experiment” when difficulties and complications occurred?

To conclude, we are convinced that TOVAT is a promising approach. However, to achieve safe and optimal results, further refinements of the access and instruments as well as preclinical studies are mandatory.

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