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Lymph node mapping with near-infrared fluorescence imaging during robotic surgery for gastric cancer: a pilot study

Abstract: Lymphadenectomy for gastric cancer is considered to be technically difficult to perform in conventional laparoscopic surgery. The robotic system has been introduced to overcome some of these technical limitations of laparoscopy. The daVinci robotic platform allows near-infrared fluorescence imaging (NIFI) with indocyanine green (ICG) to be integrated into the surgical field. This pilot study aimed at investigating whether the use of NIFI with ICG may improve the intraoperative visualization of lymph nodes and help to identify complete lymph node removal during robotic gastrectomy. Fourteen patients underwent robotic distal gastrectomy with D2 lymph node dissection for gastric cancer. A 0.2% ICG solution was injected into the submucosa endoscopically at four sites around the tumor. Fluorescence imaging with ICG was carried out with a robotic infrared camera system. Fluorescent lymph nodes were both dissected out intraoperatively and isolated in the dissected specimen with the help of the robotic camera. Eight males and 6 females were enrolled in the study. No adverse effects of the ICG were observed. The mean total number of examined lymph node was 43.3 (range, 27–78). The mean number of fluorescent lymph nodes was 19.4 (range, 1–36). Seven patients were found to have metastatic lymph nodes: in 3 patients, all the metastatic lymph nodes were fluorescent, in 3 they were non-fluorescent and in 1 patient they were both fluorescent and non-fluorescent. NIFI is a promising method of lymphatic mapping during robotic gastrectomy and may provide a valuable adjunct for identification of complete D2 lymphadenectomy.

Introduction

Laparoscopic surgery has emerged as a valid option for treatment of gastric cancer during the last two decades, especially in the East and for patients with early-stage tumors (1). In the Western world, minimally invasive surgery for gastric cancer has not garnered similar popularity and this is mainly due to the lower incidence of early gastric cancer and the complexity of the laparoscopic procedure (2,3).

Gastrectomy with D2 lymphadenectomy, i.e., lymph node dissection along the great vessels, is considered to be technically demanding to perform in laparoscopy (4-6). Robotic surgery has been introduced to overcome the technical difficulties of traditional laparoscopy: magnified 3D imaging and articulating instruments with a greater range of motion can help the surgeon to perform complex surgical steps during radical gastrectomy, such as an accurate lymph node dissection and intracorporeal anastomoses (7-9). Moreover, the daVinci Si robotic platform (Intuitive Surgical Inc., Sunnyvale, CA, USA) is equipped with a near-infrared fluorescence imaging (NIFI) system which allows intraoperative imaging with indocyanine green (ICG) (10). This technology has emerged as a promising intraoperative procedure for lymphatic mapping in gynecological (11), urological (12) and esophageal (13) cancers. In early gastric cancer, NIFI has already been used to identify the sentinel lymph node and thus modulate lymphadenectomy during minimally invasive surgery (14,15).

We hypothesized that robot-assisted NIFI with ICG could be developed for intraoperative lymph node visualization during gastric surgery with the specific aim to help the surgeons to perform a complete D2 lymphadenectomy.

Material and methods

Patients

Fourteen patients diagnosed with gastric adenocarcinoma and scheduled to undergo robotic gastrectomy were enrolled between January and October 2016 at the Center of Oncologic Minimally Invasive Surgery (COMIS), University of Florence, Florence, Italy. All patients underwent preoperative upper digestive endoscopy with gastric biopsy and computed tomography of the abdomen and chest. Patients with history of iodide or seafood allergy and pre- or intraoperative diagnosis of M1 or T4 lesions (i.e., with distant metastases, local invasion of peritoneum, spleen or pancreas), were excluded from the study. None of the patients had received any preoperative radiotherapy and/or chemotherapy. All patients had been thoroughly informed about the study and gave their written consent for the investigation in compliance with the Helsinki Declaration and in accordance with the ethical committee of our University Hospital, Azienda Ospedaliero-Universitaria Careggi (Florence, Italy).

Endoscopic and surgical technique

A 0.2% ICG solution was injected into the submucosa layer with 0.5 mL into the four quadrants around the tumor under endoscopic examination as previously described by Tajima *et al.* (14) (*Figure 1*). The dye was injected 1 day before surgery. All patients underwent curative distal gastrectomy with D2 lymph node dissection. The robotic procedures were performed by one surgeon (F.C.) as previously described (16). Intraoperative fluorescence imaging with ICG was carried out with a near-infrared camera system (Firefly Fluorescence Imaging Scope; Intuitive Surgical, Sunnyvale, CA, USA) built into the robotic platform. Lymph nodes which had taken up ICG appeared as green spots emitting clear fluorescence (*Figure 2*) and were defined as the fluorescent nodes (FNs). The FNs were intraoperatively dissected from the surrounding fatty tissue and pulled out through the assistant 12 mm trocar. The lymph nodes removed with the surgical specimens were isolated from the surrounding tissues on the back table and examined to determine, with the help of the robotic camera if they also exhibited

fluorescence. Location and fluorescence status were recorded for all the lymph nodes before they were sent for pathological analysis. Particularly, the dissected lymph nodes were grouped into five gastric lymphatic basins along the main arteries as previously described by Kinami *et al.* (17): left gastric artery (l-GA), right gastric artery (r-GA), right gastroepiploic artery (r-GEA), left gastroepiploic artery (l-GEA) and posterior gastric artery (p-GA). The l-GA area consisted of lymph node stations 1, 2, 3, 7 and 9. The r-GA area consisted of stations 5, 8a, 8p and 12a. The r-GEA consisted of stations 4d and 6. The l-GEA consisted of stations 4sa and 4sb. The pGA consisted of stations 10, 11p and 11d.

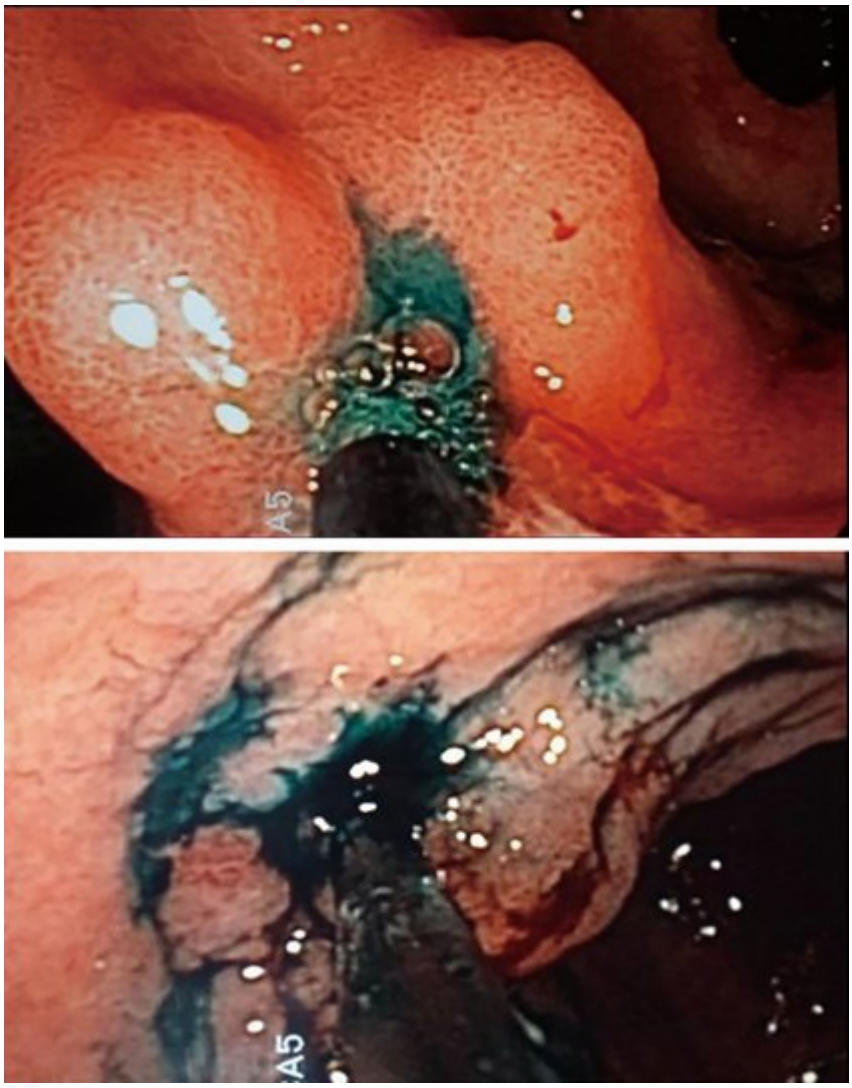

Figure 1 Preoperative submucosal injection of indocyanine green into the four quadrants around the tumor under endoscopic view.

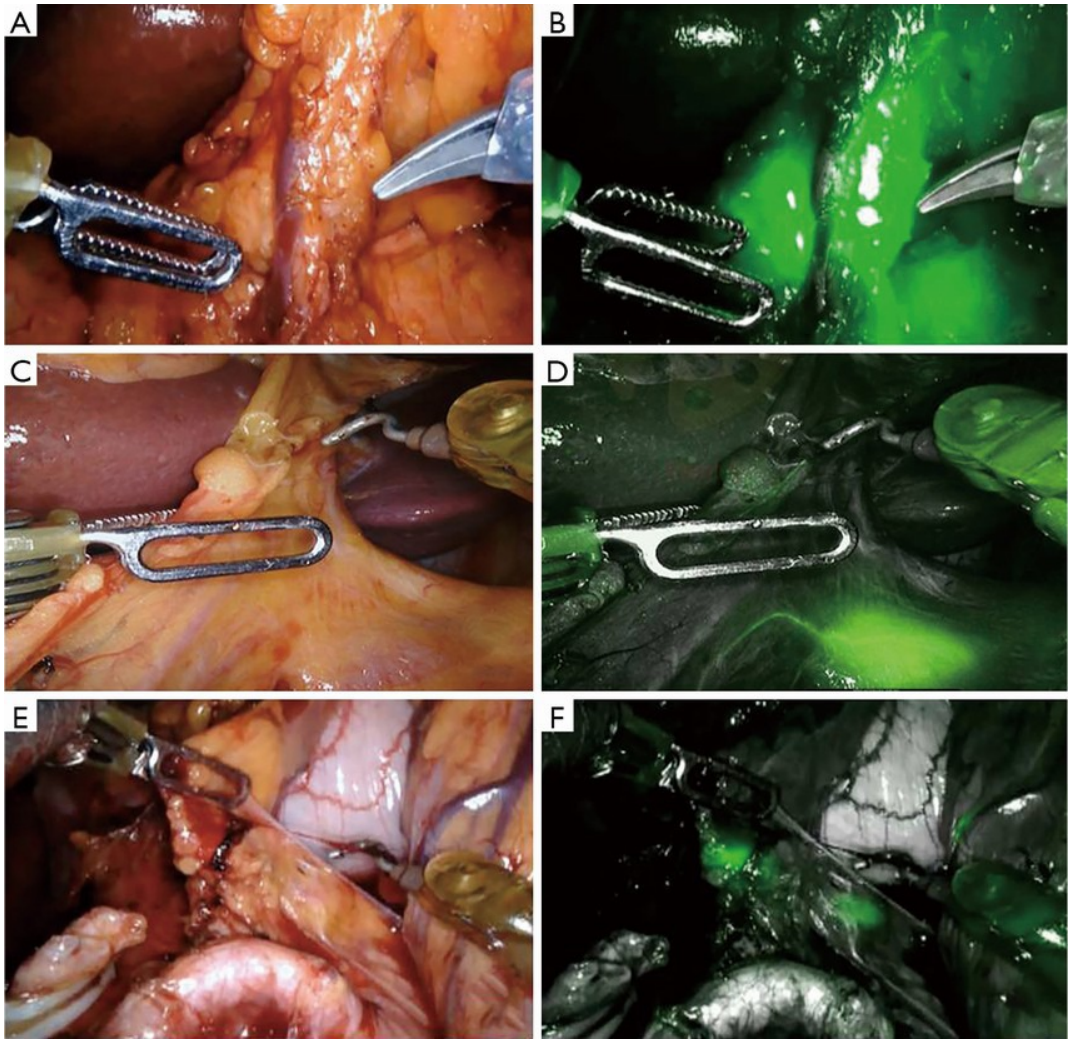

Figure 2 Lymph node dissection during robotic gastrectomy: aspects of station 6 without (A) and with near-infrared fluorescence imaging (B), station 8a without (C) and with near-infrared fluorescence imaging (D) and station 11p without (E) and with near-infrared fluorescence imaging (F).

Pathological analysis

Clinicopathological findings such as tumor location, histotype, tumor differentiation, Lauren classification, depth of invasion, lymph node metastasis and stage distribution were reviewed according to the Japanese gastric carcinoma classification (18). All dissected lymph nodes were examined histologically one slice per node and stained with H&E.

Results

Fourteen patients (8 males and 6 females) were enrolled in the study. Their median age was 76 years (range, 49–81 years) and mean BMI was 25.2 kg/m^2. Patients' clinicopathological characteristics are shown in *Table 1*. There were no patients with complications or adverse events after ICG injection in this pilot study. All patients underwent a robotic distal gastrectomy with standardized D2 lymphadenectomy. *In situ* detection of NIFI at the site of the gastric tumor was achieved in all cases. The mean total number of retrieved and examined lymph nodes was 43.3 (range, 27–78) (*Table 2*). The mean number of FNs was 19.4 (range, 1–36) (*Table 2*). Dye diffusion to lymph nodes was observed in all the patients (*Table 2*). No ICG staining was observed in those lymph nodes (namely station 2, 4sa, 10 and 11 d) for which dissection is not suggested during distal gastrectomy. Patient 11 had only one FN retrieved, and this was most likely due to the pathological finding of massive infiltration of the submucosa (linitis plastic) that might have occluded the lymphatic vessels and prevented ICG diffusion. The histopathological analysis indicated that 7 patients had metastatic lymph nodes: all the metastatic lymph nodes were fluorescent in 3 patients, they were non-fluorescent in 3 and both fluorescent and non-fluorescent in 1 (*Table 2*). The distribution of lymph nodes and their metastatic/fluorescent status within the five lymphatic basins are shown in *Table 3*. It is of interest that in patients n. 1 and 6, the metastatic non-fluorescent lymph nodes were found within the lymphatic basins which were marked by at least one FN (*Table 3*).

Table 1 Clinicopathological characteristics of patients undergoing robotic distal gastrectomy

Characteristics	Patients (N=14)
Gender (male/female)	8/6
Age (year) [median, range]	76 [49–81]
BMI (kg/m^2) [median, range]	25.2 [23–30]
Tumor location (%)	
Middle third	7 (50.0)
Lower third	7 (50.0)
Lauren classification (%)	
Intestinal	8 (57.2)
Diffuse	1 (7.1)
Mixed	5 (35.7)
Tumor differentiation (%)	
Well differentiated	4 (28.6)
Moderately differentiated	7 (50.0)
Poorly differentiated	3 (21.4)
Tumor size (cm) (mean ± SD)	3.8±2.1
Stage distribution (%)	
I	6 (42.9)
II	5 (35.7)
III	3 (21.4)

Table 1 Clinicopathological characteristics of patients undergoing robotic distal gastrectomy

Table 2 Characteristics of lymphadenectomy specimens according to fluorescence and metastatic status

Pt n.	TNM	Total examined LNs	Fluorescent LNs (%)	Fluorescent metastatic LNs	Non-fluorescent metastatic LNs
1	T1N2	42	35 (83.3)	0	3
2	T1N0	60	34 (56.6)	0	0
3	T2N1	47	36 (76.5)	1	0
4	T2N0	49	34 (69.3)	0	0
5	T2N0	44	5 (11.3)	0	0
6	T3N1	27	5 (18.5)	0	1
7	T2N0	49	23 (46.9)	0	0
8	T3N3	78	31 (39.7)	7	7
9	T1N0	53	8 (15.0)	0	0
10	T1N0	34	12 (35.2)	0	0
11	T3N3	27	1 (3.7)	0	7
12	T2N2	45	7 (18.4)	5	0
13	T2N2	63	36 (57.1)	4	0
14	T2N0	27	5 (18.5)	0	0
Overall (mean ± ESM)		43.3±3.7	19.4±3.8	1.2±0.6	1.2±0.6

Table 2 Characteristics of lymphadenectomy specimens according to fluorescence and metastatic status

Table 3 Distribution of harvested lymph nodes and their metastatic/fluorescence status within the five lymphatic basins

Pt n.	Tumor location	Tumor size (cm)	Left GA		Left GEA		Posterior GA		Right GEA		Right GA	
			Fluorescent	Non	Fluorescent	Non	Fluorescent	Non	Fluorescent	Non	Fluorescent	Non
1	Middle	2	6	2	0	0	9	1	18	1	2	3 (3)
2	Middle	2.5	15	6	0	0	0	0	3	19	16	1
3	Lower	4	18	0	0	1	8	0	7 (1)	2	3	8
4	Lower	4	9	7	0	0	8	0	5	5	12	3
5	Lower	2.5	3	7	0	0	0	5	2	12	0	15
6	Lower	5.5	2	10	0	0	0	2	2	9	1	1 (1)
7	Middle	4	11	10	0	0	2	1	5	4	5	11
8	Lower	8	7	5	0	5	0	8	13 (3)	6 (3)	11 (4)	23 (4)
9	Middle	2	1	24	0	0	0	4	7	6	0	11
10	Lower	5	5	6	0	0	0	0	7	10	0	6
11	Middle	7	0	18 (5)	0	2	0	1 (1)	5	1 (1)	0	0
12	Lower	2.5	0	16	0	0	0	5	5 (4)	8	2 (1)	9
13	Middle	1	12	0	0	0	5 (1)	2	11 (3)	6	8	19
14	Middle	2.5	0	1	0	0	0	0	5	1	0	20

GA, gastric artery; GEA, gastroepiploic artery; ( ) : number of metastatic lymph nodes.

Table 3 Distribution of harvested lymph nodes and their metastatic/fluorescence status within the five lymphatic basins

Discussion

Adequate lymph node sampling during radical gastrectomy is crucial for proper staging of patients with gastric cancer. In this pilot study, we evaluated the feasibility and safety of a novel application of NIFI with ICG for real-time intraoperative mapping of lymph nodes during robotic surgery for gastric cancer. ICG is a diagnostic reagent that has excitation and fluorescence wave-lengths in the near-infrared range. Nimura *et al.* (19) have reported that lymphatic vessels and lymph nodes containing ICG particle can be easily distinguished from surrounding fatty tissue using infrared ray technology system. In addition, ICG deposition and fluorescence imaging are characteristically found for prolonged periods of time in the lymph nodes (>3 days).

An intraoperative imaging system based on NIFI with ICG has already been proposed for sentinel lymph node mapping in early gastric cancer (14,15,20,21). To our knowledge, this is the third pilot trial designed to visualize intraoperatively the lymphatic pathways draining gastric tumors using NIFI with ICG without the purpose of sentinel lymph node retrieval. Herrera-Almario *et al.* (22) used this technique in 29 patients who had undergone robotic resection for gastric adenocarcinoma: they demonstrated the safety and feasibility of the procedure and stated that it could be a valuable adjunct for overall lymph node retrieval. They found that a mean of 29 lymph nodes were examined and, in all cases, at least 5 lymph nodes were seen along the main nodal compartments. Lan *et al.* (23) compared 14 and 65 patients who underwent robotic gastrectomy with or without ICG fluorescence, respectively. They did not find any significant differences in the total number of lymph nodes retrieved in the two groups, but all the metastatic lymph nodes were found in the lymph node stations which showed fluorescence signals. Our preliminary study confirmed the feasibility and safety of the procedure and interestingly, we found a higher number of lymph nodes in the surgical specimens than the other two previously published studies, with a mean of 43.3. We hypothesize that this advantage was due to the different method of dye injection. In the study by Herrera-Almario (22), ICG was injected intraoperatively into the

subserosa around the tumor in all their 31 patients whereas the same method was adopted in 9 out of the 14 patients investigated by Lan *et al.* (23). It is most likely that, with subserosal injection, the dye did not have enough time to spread into the lymphatic vessels and deposit in all draining lymph nodes. Furthermore, the endoscopic submucosal injection of ICG, unlike the subserosal approach, avoids any potential lymphatic disruption that can occur with intraoperative dissection and permits direct visualization of the lesion at the time of surgery. Other important limitations of subserosal injection are the potential intraoperative leakage of ICG with spoiling of the near infrared view and the difficulty to identify tumor location from the outside of the stomach without intraoperative localization of the tumor, especially in the cases of early gastric cancer.

We found that the most important factor in determining the image quality during intraoperative fluorescence imaging is the dosage of ICG injection. In our very first cases, not considered in the present study, we injected 1 mL of 0.2% ICG solution into the four quadrants around the tumor but the patients had a dissemination of the fluorescence signal in the omentum, mesocolon and pancreatic surface. We obtained a better quality of fluorescence imaging by reducing the ICG dosage to 0.5 mL.

Importantly, the mean value of retrieved and examined lymph nodes in the present study was even higher than that we found in a group of patients who were operated on by robotic distal gastrectomy without intraoperative ICG-NIFI (43.3 *vs.* 39.1, respectively) between June 2014 and September 2015 (16).

We also found that metastatic disease was present in FNs in 4 out of our 7 patients classified as N+, whereas metastatic non-fluorescent lymph nodes were found within lymphatic basins with fluorescence signals in 2 other cases. These findings confirmed those reported by Lan *et al.* (23) and suggest that intraoperative lymphatic mapping with ICG fluorescence has the potential to improve the likelihood of an adequate lymphadenectomy by identifying those lymphatic basins that most likely contain metastatic disease.

In conclusion, we recognize that this pilot trial includes only a small patient sample and that future trials are needed to truly determine the impact of intraoperative lymphatic mapping with ICG fluorescence on gastric cancer surgery. However, our preliminary results suggest that this technique is feasible and can help the surgeon to have a real-time visual reference of the lymph nodes during dissection along the main gastric vessels, thus adding a potentially valuable adjunct to perform a complete D2 lymphadenectomy.

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From TransOral Endoscopic Thyroidectomy Vestibular Approach (TOETVA) to TransOral Endoscopic Thyroidectomy Submandibular Approach (TOETSA). A little change for better results

Abstract

Background: In our first experience transoral endoscopic thyroidectomy vestibular approach (TOETVA) had some limitations and adverse events. We changed the technique switching the central vestibular to a submandibular approach (TOETSA). The aim of this paper was to describe our TOETSA technique and present prelimirary results.

Methods: 5 TOETVA and 5 TOETSA were performed at the Unit of Endocrine Surgery-Florence University Hospital.

Results: operative time was shorter in the TOETSA group (68 $\pm$ 13.5 vs 98.7 $\pm$ 21.7). Complications among TOETVA patients were: lip/chin edema and dysaesthesia (100%), tissue infarction (40%), surgical field seroma (20%). One TOETSA patient presented temporary recurrent nerve paralysis; 1 chin/lip dysaesthesia. Main differences between the 2 groups were in postoperative pain and perceived aesthetic results.

Conclusions TOETVA and TOETSA are both feasible and safe but they have still limited indications. In our experience TOETSA had some technical and clinical advantages compared to TOETVA.

Introduction

Until the end of the last century thyroidectomy was performed with the Kocher's neck incision. The progresses in endoscopic surgery, indications at lower thyroid volumes and an increasing attention to the aesthetic results lead to the development of less invasive operations initially with shorter neck incisions and reduced neck dissection, later with a research of extra cervical approaches. Unfortunately these were not always minimally invasive procedures and did not guarantee the expected aesthetic results. Nevertheless the incisions were placed outside the neck, these were extended or multiple and the access to the thyroid area required wide dissection to overcome the distance between the surgical access and the gland. These reasons together with the spreading of an endoscopic or robotic approach lead to increasing operative time and costs.

Transoral endoscopic thyroidectomy vestibular approach (TOETVA) is the last proposed operation and at the present it is the only "scarless" technique with a surgical access close to the thyroid area[1-2] . The operation follows all the steps of a conventional thyroidectomy and the central access for the camera allows a good vision of both the thyroid loggias. This technique does not require dedicated endoscopic or robotic intruments, expensive and not always available[3].

Original TOETVA technique

Antibiotic profilaxis and oral cavity hygene were preoperatively administered. The patient was placed supine with the neck mildly hyperextended as for a conventional thyroidectomy and under general anesthesia with naso- or oro-tracheal intubation *(figure 3)*. The surgeon position was above the patient's head, the assistant standed at the surgeon's side. The oral cavity was disinfected with povidone-iodine. A 10-12 mm incision was performed at the center of the oral vestibule*(Figure 4).*. The working space was created down to the sternal notch with needle hydrodissection (30 ml solution of 1 mg adrenaline diluited with 500 ml of saline) *(Figure 5).* A subsequent space was created passing the mandibular area to the anterior neck using Kelly clamp forceps. A blunt-tipped 10 mm trocar was inserted for a 10 mm 30° laparoscopic camera. After CO2 insufflation at 6 mmHg two 5 mm trocars were inserted at the uppermost and lateral areas near the lower lip, in front of the canine tooth on both sides pointing down to the anterior neck. Additionally, the working space was completed beneath the platysma. The upper border of the dissected area was the larynx, the lower border was the suprasternal notch and the lateral borders were the anterior margins of the sternocleidomastoid muscles. Strap muscles (SMs) were divided by cutting the midline raphe. Thyroid istmus was transected with an energy device. This maneuver allowed the division and medialisation of the thyroid lobes as well as their separation from the muscles. The craniocaudal orientation allowed an easy visualization and ligation of the superior thyroid pedicle and middle thyroid vein together with the preservation of the superior parathyroid. The upper pole of the gland was lifted up and medialised in order to see the recurrent laryngeal nerve and the inferior parathyroid gland. The following step was the division of the inferior thyroid pedicle and the rest of Berry's ligament. The specimen was removed using an endobag via the central incision. The surgical wounds were closed using adsorbable sutures.

Figure 3

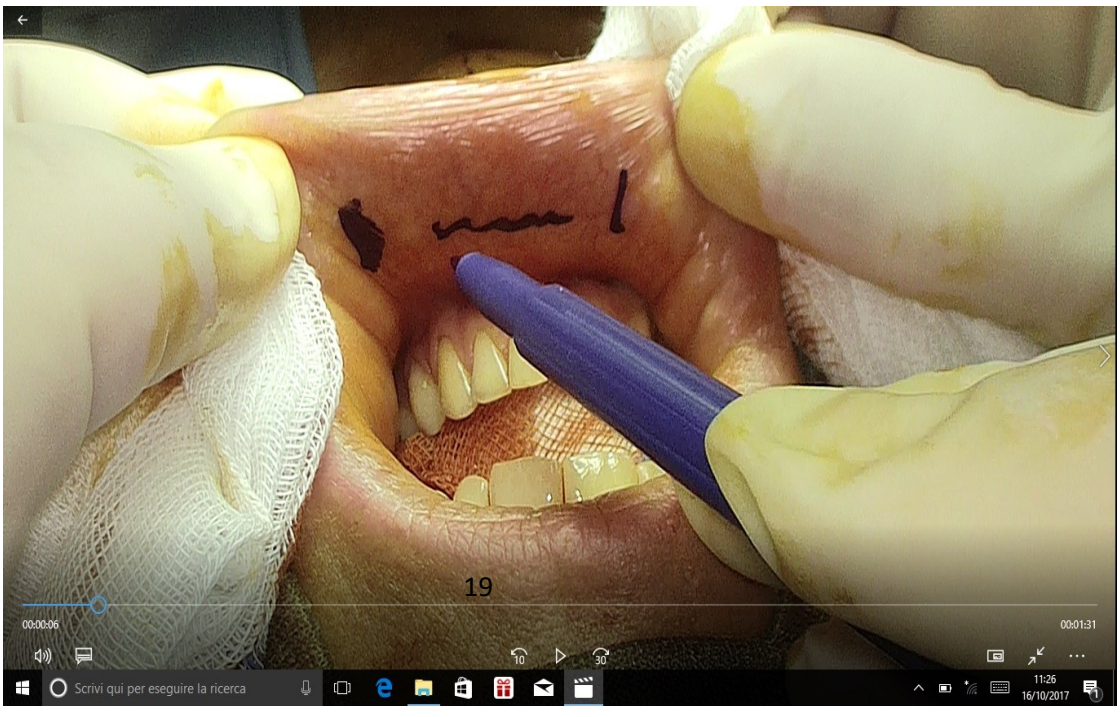
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Figure 4

Figure 5

Our modified surgical technique (TOETSA: TransOral Endoscopic Thyroidectomy Submandibular Access)

TOETVA was introduced in our unit in September 2017 with the standard technique as described before. In our first experience this procedure resulted to have some limitations and postoperative adverse events. The placement of the 10 mm central trocar was not always easy due to difficulties in the detachment of the chin tissue from the mandibular periostium: this maneuver lead to a painful postoperative edema. The placement of the 2 lateral trocars was easier, but it caused ecchymosis, edema and lower lip dysaesthesia. Furthermore, the conflict between the 3 trocars lead to limitations in the movement of the laparoscopic instruments.

In order to overcome these problems after the first 5 cases we introduced some changes to the TOETVA technique firstly described by Wang[(1)] and modified by Anuwong [(2)]. A 10 or 5 mm central trocar for the camera was placed on the natural skin depression immediately under the chin (*Figure 6).* A left 3 mm trocar for 3 mm laparoscopic rigid instruments (Ab Medica s.a.s.-Mery Sur Cher-France) was placed in the standard position. A common right vestibular 5 mm trocar was used for the energy instrument (at the moment not available under 5 mm) and for the 5 mm endobag (Fannin UK Limited T/A-Espiner Medical- Clevedon, Somerset-UK) insertion (*Figures 7-8*). We named this approach TOETSA (TransOral Endoscopic Thyroidectomy Submandibular Access)

Figure 6

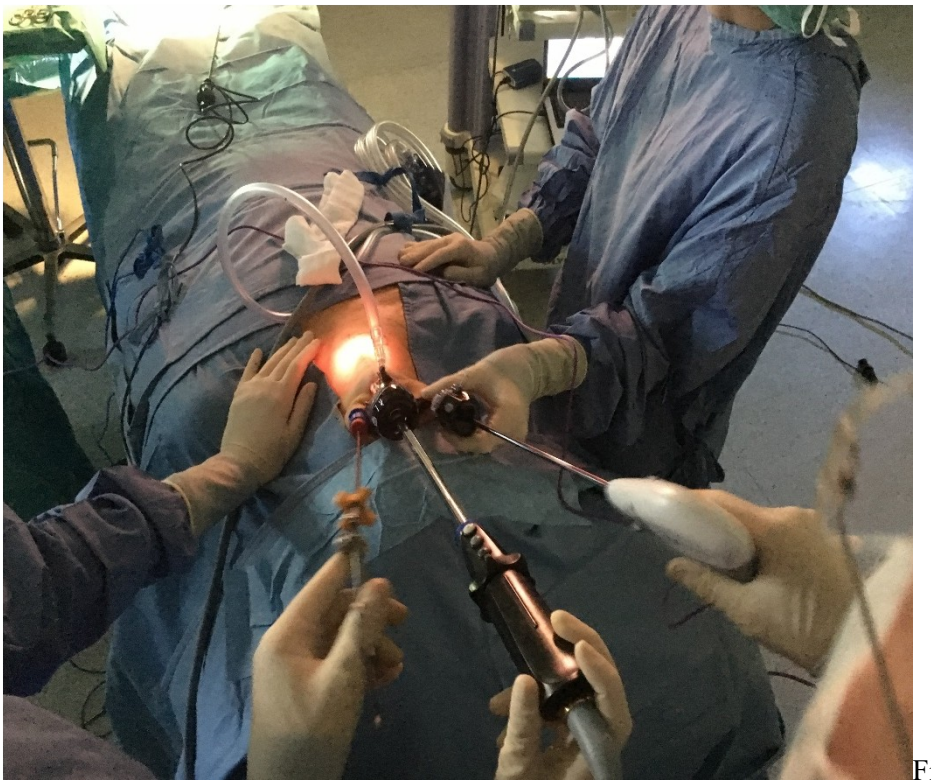
Figure 7

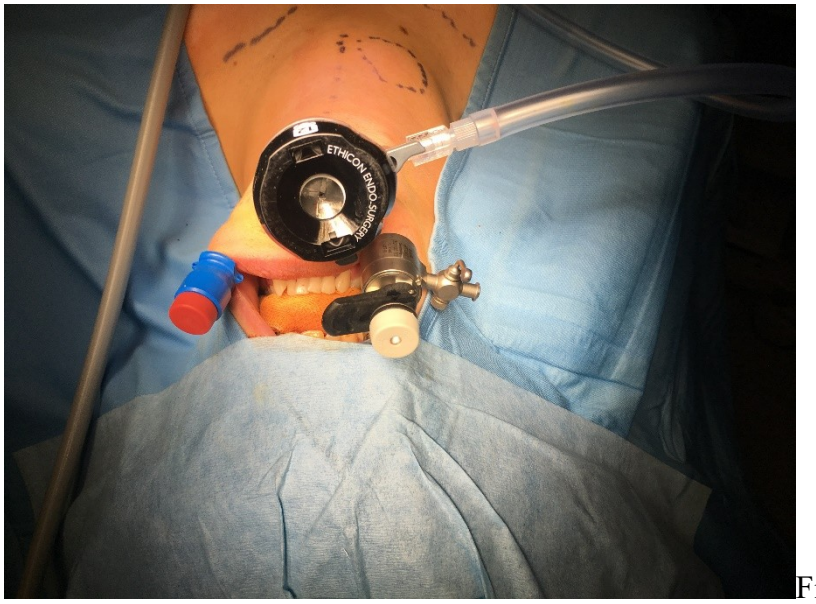

Figure8

Patients and Methods

From September 2017 to March 2018 5 TOETVA and 5 TOETSA were performed at the Unit of Endocrine Surgery-Florence University Hospital. Patients data were prospectively registered on the Unit database.

All patients underwent routine investigation including thyroid function test, neck ultrasonography and fine needle aspiration .

Inclusion criteria were: benign thyroid nodules no more that 5 cm in size, low risk malignant nodules no more than 2 cm in size and goiters not exceeding 50 ml in volume.

Average Visual Analog Pain Scale (VAS) was assessed 6 hours after the intervention, at postoperative day 1 and postoperative day 7. The patients were assessed for vocal cord function by flexible laryngoscope at postoperative day 7 and 30. Hypoparathyroidism was defined with the level of PTH and Ca lower than 1.3 pmol/l and 8.5 mg/dl respectively at postoperative day 1 and 30. The aesthetic result was evaluated at postoperative day 1 and 30 submitting to the patient the Numerical Score System (NSS) that is a scale ranging from 1 to 10.

Results

Table 1 shows results of the first unselected consecutive TOETVA and TOETSA. All patients were affected by a single benign nodule, hyperfunctioning or not. Patients and surgical theater set up and operating time were shorter in the TOETSA group (32 $\pm$ 2.7 vs 37 $\pm$ 3.4 and 68 $\pm$ 13.5 vs 98.7 $\pm$ 21.7). Mean thyroid volume was similar in the 2 groups. No conversions were observed. All patients were discharged the morning after the intervention. One temporary recurrent nerve paralysis was observed in the TOETSA group. No permanent recurrent nerve paralysis nor surgical site hematoma nor permanent hypocalcemia were observed in both groups. All 5 patients that underwent TOETVA experienced lip/chin edema and 2 of these presented also tissue infarction. Lip/chin dhysaesthesia was complained by all patients in the TOETVA vs 1 among the TOETSA group. One TOETVA patient experienced a seroma in the surgical field that was conservatively treated. Main differences between the 2 groups were in pain and perceived aesthetic results at all the postoperative intervals.

	TOETVA	TOETSA
Operating time	68 +/-13,5 m’	32 +/- 2,7 m’

Conversions	-	-
Blood loss	negligible	negligible

Tab 1

Discussion

A poor correlation between the scar length and the aesthetic result is well known[4], this is mainly related to short incisions due to the trauma given by the excessive skin traction. Therefore, this suggests that the best patient's satisfaction is reached avoiding cervical scars.

Our modified technique with a submandibular approach (TOETSA) requires the same strict patients selection as the original technique with a total vestibular approach (TOETVA). The main candidates to this intervention are patients with clinical history of cheloids or hypertrophic scars, strongly motivated to avoid a visible cervical incision. Indications related to the thyroid pathology are benign nodules no more that 5 cm in size, low risk malignant nodules no more than 2 cm in size and goiters not exceeding 50 ml in volume. Exclusion criteria are thyroiditis or previous cervical interventions.

Safety and feasibility with the transoral vestibular approach are possible only if the surgeon has a laparoscopic and thyroid surgery experience. This our initial experience confirms the feasibility and reproducibility of TOETVA[3,5] and TOETSA. In

comparison to our large experience with conventional thyroidectomy and minimally invasive approach (minimally invasive video-assisted thyroidectomy-MIVAT and mini-incision thyroidectomy-MIT)[6,7] we confirmed longer operative time and no infectious or permanent nerve complications of the transoral approaches. We did not report parathyroid complications since we performed only lobectomies (*Figures* 9-10-11). After our first 5 cases of TOETVA we did not report the expected results: patients complained of pain and lower lip dysaesthesia. Even early aesthetic results were not those expected. Maybe it was due to the trauma caused by the difficult separation of the chin tissue from the mandible periostium to place the central trocar and to the need to enlarge it to remove the specimen. For this reason we wondered if a sub-mandibular incision could simplify the access to the surgical area. The opportunity was given by a young patient who already had a little scar under the chin due to a trauma. The incision for the central trocar was performed on the pre-existing scar whereas the 2 lateral trocars (3 mm on the left and 5 mm on the right for the energy device) were placed in the vestibulum. Since the first case we noticed that our approach simplified the technique with better early aesthetic results when compared with those we had with TOETVA.

In summary, our technique with the submandibular approach (TOETSA) resulted to have some advantages when compared to the standard technique (TOETVA):

- decreases the distance between the surgical access and the gland and less tissue dissection when compared to all the other extra-cervical techniques.
- increases endo-oral space without the need of a nasotracheal intubation, often traumatic and cause of bleeding of the nasal mucosa.
- avoids the detachment, often very challenging, of the chin tissue from the mandibular periostium.
- decreases lower lip trauma and consequently potential lesions of the mental nerves (medial branches) with lower incidence of postoperative dysaesthesia.
- eliminates the conflict between trocars thanks to a better instrument triangulation
- avoids the contact of the central trocar with the mandible with less potential periostitis and dental trauma.

- allows a visual and direct access to the platysma and an easier creation of the subplatysmal space with hydrodissection and blunt instruments such as curved forceps and dilators of increasing diameter.
- increases the degree of movements of the 2 lateral trocars in the working space thanks to the extra-oral position of the central trocar
- allows the insertion of the endobag directly through the central access (without the trocar) and an easier extraction since it is not conditioned by the low distensibility of the subchin tunnel. In fact, the submandibular incision is much more elastic and can be adapted to the dimension of the specimen extending the indication to goiters of higher volumes.
- reaches better aesthetic results: the left 3 mm trocar does not leave any sign at the end of the procedure.
- decreases the risk of lower lip and surgical site infections thanks to the placement of the central trocar outside the mouth. In fact, in our experience at the end of TOETVA the vestibulum, particularly on the central access, presented a flesh-wound due to the trocar trauma.

Nevertheless this is a preliminary experience, we expect a decrease of postoperative complications such as lower lip dysaesthesia, hemorrhagic tissue infarction and surgical site infections. The aesthetic result (*Figure 12*), primary endpoint in this kind of intervention, was comparable or even better to that of the traditional TOETVA (*Figure 13*).

TOETSA has the same limitations of TOETVA: they are still limited to low glandular volumes, to benign or low-risk malignant lesions and need a laparoscopic and thyroid surgery experience and background.

A common advantage of TOETVA or TOETSA is that they do not require dedicated endoscopic or robotic instruments, decreasing costs with comparable or even better aesthetic results.

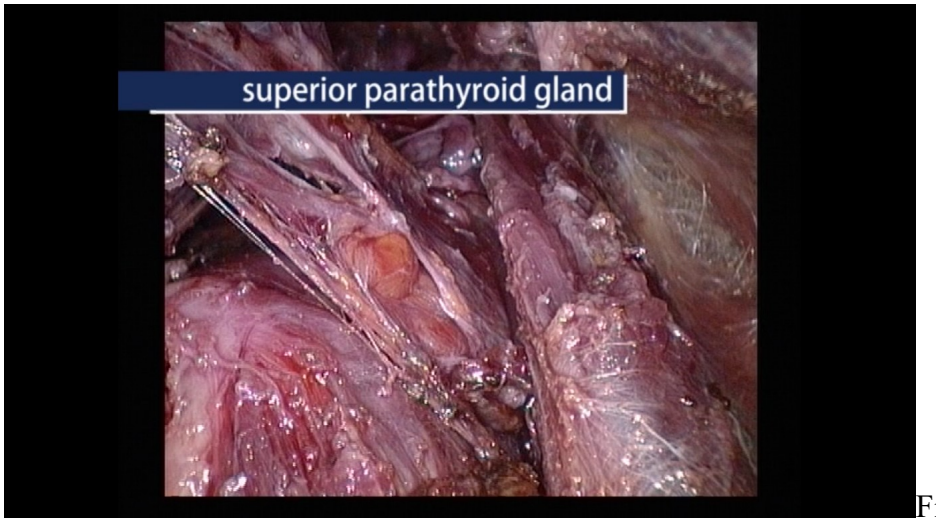

Figure 9

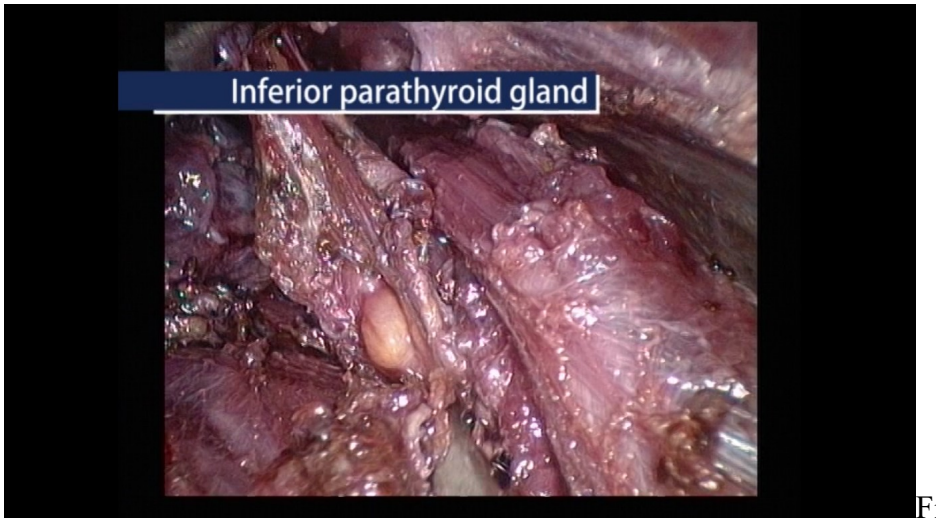

Figure 10

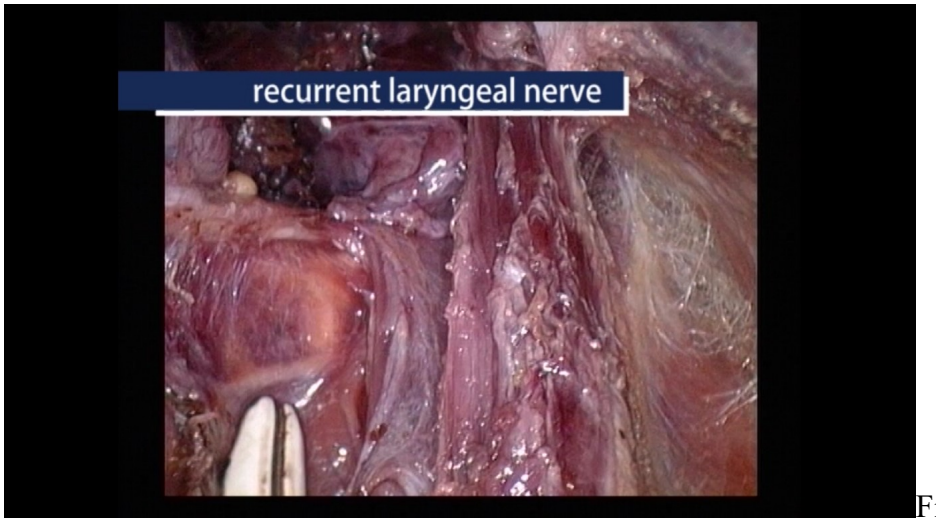

Figure 11


Figure 12


Figure 13

Future perspectives

Our future aim is to improve the proposed technique with the adoption of a 3 mm vessel sealing energy device (JustRight Surgical, Louisville, Colorado-USA) and a 3 mm bipolar forceps (Gunter Bissinger Medizintechnik Gmbh, Teningen-Germany). Both of these tools allow the placement of a 3 mm vestibular trocar also on the right side, furtherly decreasing the trauma and improving the aesthetic result. A 3 mm camera (ConMed Corporation, New York-USA) could be interchangeable in all the 3 trocars making the intervention even easier adding also to a better lateral vision.

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