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The Learning Curve of Transareola Single-site Laparoendoscopic Thyroidectomy: CUSUM Analysis of a Single Surgeon's Experience

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Background: Transareola single-site laparoendoscopic thyroidectomy (TASSET) is a rapidly advancing minimally invasive procedure. The purpose of this study was to evaluate the learning curve for TASSET.

Subjects and Methods: Forty-five consecutive patients were prospectively divided into group 1 (initial phase), group 2 (intermediate phase), and group 3 (advanced phase) according to their surgical order (15 patients in each group). The operative time, operative blood loss, duration of hospital stay, postoperative pain, and postoperative complications were compared using phases.

Results: Statistically significant differences were observed in the different learning phases, among operative time ($P < 0.05$), operative blood loss ($P < 0.05$), hospital stay ($P < 0.05$), and postoperative pain ($P < 0.05$). The postoperative complication rate was low (3/45).

Conclusions: Learning curve of the TASSET are improved synchronized at different phases and technical indicators. The establishment of operative space take longer time to skilled master.

Key Words: learning curve, transareola, thyroidectomy

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Over the past decade, there has been a global trend toward a minimally invasive approach for thyroidectomy. Since endoscopic parathyroidectomy was first introduced in 1996,[1] various endoscopic surgical procedures for the thyroid have been devised, including cervical, axillary, breast, and anterior chest approaches. In particular, a higher level of surgical technique is necessary in minimally invasive thyroidectomy because of no natural cavity that is an unfavorable circumstance to carry the surgery. The concept of a learning curve for an operation refers to the number of cases a surgeon needs to perform before the operative time and complication rate become reproducibly minimized.[2] Few have addressed a learning curve for transareola single-site laparoendoscopic thyroidectomy (TASSET). We have documented the use of a TASSET technique.[3–5] This study focused on the analysis of a learning curve in an attempt to determine how many surgeries must be performed before a surgeon feels confident and efficient in performing a TASSET. We evaluated the learning curve for TASSET based on a cumulative summation technique.

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SUBJECTS AND METHODS

Subjects

This study included 45 consecutive patients undergoing thyroid nodule surgery at the Fengxian Central Hospital, Shanghai, between January 2011 and March 2014. Data from all patients who underwent a thyroidectomy were prospectively recorded. Patients were not amenable to TASSET if any of the following conditions existed: (1) a malignant tumor was diagnosed by fine-needle aspiration; (2) large-volume nodule of >30 mm; (3) a large-volume goiter of >20 mL; (4) previous history of thyroiditis; or (5) neck surgery or irradiation.

The number of patients included in the present study was determined by the operative time to complete the thyroidectomy as the main criteria of judgment. One expert surgeon (S.Y) performed the operations for all patients. The SD of the operative time for TASSET identified in previously published data was 20 minutes.[6] The maximum significant value (α) chosen for the study was 5%. The minimum statistical power ($1-\beta$) chosen for the study was 80%. The calculation for the minimum sample size (n) in each group was calculated by the equation $n = 2 \times (S^2/\Delta^2) \times Z_{\alpha/2} - Z_{1-\beta})$ according to previous studies.[7] This calculation required inclusion of at least 10 patients in each group, and for this calculation, we included 15 patients in each group. Patients were chronologically arranged into 3 phases for the cumulative summation analysis, meaning that patients were consecutively assigned to a group corresponding to their operative order. This procedure was divided into initial (group 1), intermediate (group 2), and advanced phases (group 3). We explained the following to all patients: the characteristics of TASSET; its advantages in terms of cosmetic results and postoperative pain; and the possibility of conversion in case of complications. This study was approved by the ethics committee of Fengxian Central Hospital (No. FH2011032203), and all patients signed an informed consent form.

Surgical Techniques

The preoperative fine-needle aspiration results were a thyroid adenoma in all patients. A partial thyroidectomy

was performed. The TASSET procedure was characterized by a 20-mm incision delineated along the ipsilateral areola margin of the lesion side. A narrow subcutaneous tunnel from the areola to the anterior neck area was bluntly dissected on the anterior surface of the pectoralis major muscle and clavicle under endoscopic guidance. A space between the platysma and strap muscles was created with ultrasonic shears (Harmonic Scalpel; Johnson & Johnson Medical, Cincinnati, OH). After longitudinally incising the medial border of the sternohyoid and sternothyroid muscles, the ipsilateral strap muscles were suspended anteriorly and laterally with transcutaneous Prolene sutures. Through this incision, a 10-mm trocar was first inserted to pump CO_2 into the cavity, with pressure maintained at 6 to 8 mm Hg, and a 30-degree 10-mm rigid laparoscope (Stryker Endoscopy, CA) was used to visualize the operative space throughout the procedure. The operating port was closed to the observation port in TASSET, increasing the procedural difficulty. Similar to Liang et al's[8] experience, a right-shifted observation port deflects the video image that could help the endoscope holder in adjusting the position and angle of the 30-degree 10-mm rigid laparoscope. The workspace was extended from the anterior chest to the thyroid cartilage level and laterally to the medial edge of each sternocleidomastoid muscle. The middle thyroid vein and inferior thyroid vessels were identified and divided. After the isthmus was divided, the lower lobe of the thyroid gland was drawn upward and bluntly dissected. The inferior parathyroid gland was identified and carefully preserved, with intact blood supply. The superior thyroid vessels were identified and dissected close to the thyroid gland to avoid injuring the superior laryngeal nerve. The recurrent laryngeal nerve was traced and dissected with great care during the complete lobectomy procedure. The resected specimen was placed into a removal bag, extracted through the subcutaneous cavity to the skin incision, and sent for frozen histological examination. After adequate irrigation, a single drain was placed in the cavity through the skin incision. The midline raphe of the strap muscles and skin incision were closed with absorbable sutures. The TASSET procedure was divided mainly into 2 parts: part 1, establishment of manipulation room; part 2, incision of the linea alba cervicalis, excision of the tumor, suture of the sternohyoid muscle, and specimen extraction. The computing method utilized for the operative time was as follows: mean operative time for the total surgical procedure, mean time for part 1, and mean time for part 2.

Surgical Outcome

Patients in all 3 groups underwent laryngoscopic examinations for evaluation of their recurrent laryngeal nerve status before surgery and on the third postoperative day. The operation time, intraoperative bleeding volume, postoperative pain score, and cosmetic satisfaction score were compared among the 3 groups. Postoperative pain was assessed using a visual analog scale (VAS), which ranged from 0, "no pain" to 10, "worst pain imaginable."[9]

Statistical Analyses

Statistical analyses were performed using SPSS statistical software, version 17.0 (SPSS Inc., Chicago, IL) for Windows. Data are expressed as mean ± SD. Comparisons between groups were performed using the Student t test, Fisher exact test, and Mann-Whitney U test. A P-value of < 0.05 was considered statistically significant.

RESULTS

Demographic and Clinical Characteristics of Patients

In total, 45 consecutive patients were assigned to 3 groups (n = 15). Demographic and clinical characteristics are presented in Table 1. The 3 groups demonstrated no significant difference in age, sex, or mean thyroid nodule diameter. No difference was found among the 3 groups concerning the preoperative and final pathologic diagnoses for the thyroid nodules. The total number of thyroid nodules in each of the 3 groups were 16, 19, and 20. Postoperative histopathology indicated that all the resected nodules were a thyroid adenoma. The same surgical team operated on all patients, and all of their data were analyzed.

Postoperative Outcomes

The mean operative time decreased with experience and remained stable after 30 cases. Comparing 2 neighboring groups (Table 2), there were significant differences in mean operative time. The mean operative time for parts 1 and 2 was significantly less during the intermediate and advanced phases, as compared with the initial phase ($P < 0.05$). There were no significant differences in terms of mean operative time for part 2 between the intermediate and advanced phases.

Operative Blood Loss and Postoperative Hospital Stay

There were significant differences in operative blood loss and length of postoperative hospital stay between the initial and intermediate phases (Table 2). The operative blood loss was significantly less during the intermediate phase, as compared with the initial phase ($P < 0.01$). In group 2, the length of the postoperative stay was significantly reduced. As shown in Table 2, there were no significant differences in terms of operative blood loss or hospital stay between the intermediate and advanced phases. The operative blood loss and length of the postoperative stay decreased with experience and remained stable after the intermediate phase.

VAS Scale

Patients in the initial phase had significantly higher VAS scores, as compared with those in the intermediate phase 24 hours after the operation ($P < 0.05$, Table 2). The VAS scale remained low with experience and remained stable after the intermediate phase (Table 2).

TABLE 1. Demographic and Clinical Characteristics of Patients in the 3 Groups

	Initial Phase	Intermediate Phase	Advanced Phase	*P*
Age (y)	27.21 ± 9.25	28.67 ± 7.92	28.70 ± 8.90	> 0.05
Sex (male/female)	2/13	1/14	1/14	> 0.05
Diameter of nodule (mm)	17.68 ± 9.75	18.05 ± 9.30	18.76 ± 8.79	> 0.05

TABLE 2. Postoperative Outcomes of Different Phases

	Initial Phase	Intermediate Phase	Advanced Phase
Mean operative time (min)	171.30 ± 33.20*	136.02 ± 30.86**	125.20 ± 28.70***
Mean time for part 1 (min)	68.50 ± 20.10*	58.25 ± 17.20**	42.85 ± 15.30***
Mean time for part 2 (min)	96.30 ± 28.25*	77.56 ± 21.35	76.85 ± 20.80***
Operative blood loss (mL)	34.82 ± 15.30*	20.09 ± 12.56	19.56 ± 9.89***
Postoperative hospital stay (d)	4.20 ± 0.80*	4.20 ± 0.80	3.45 ± 0.85***
VAS scale	3.85 ± 1.65	3.05 ± 1.23*	3.08 ± 1.08***
Complications			
Transient recurrent laryngeal nerve palsy	0	0	1
Subcutaneous seroma	1	0	1

Part 1, establishing manipulation room; part 2, incision of the linea alba cervicalis, tumor excision, suture of the sternohyoid muscle, and specimen extraction; initial stage versus intermediate stage.

VAS indicates visual analog scale.

*$P < 0.05$; intermediate stage versus advanced stage.

**$P < 0.05$; initial stage versus advanced stage.

***$P < 0.05$.

Surgical Complications

The postoperative complication rate was low. Two patients developed subcutaneous seromas, and 1 patient developed a tracheal injury after surgery (Table 2).

DISCUSSION

Since endoscopic thyroidectomy was first introduced by Hüscher et al,[10] various approaches for endoscopic thyroid surgery have been devised, including cervical, axillary, breast, and anterior chest approaches. However, TASSET requires knowledge of specific handling techniques, and few reports have addressed any learning curve issues. Thanks to the endoscopic approach, TASSET features a short incision (1.5 to 2 cm) and less extensive dissection, which have been shown to improve cosmetic results and postoperative comfort.[11,12] With these new techniques, scars have been shifted to areas that are usually covered by clothing. Endoscopic thyroidectomy is steadily gaining acceptance. However, because these procedures require a wide subcutaneous dissection (at least 3 tunnels) in the anterior thoracic wall to reach the target site, endoscopic treatment of thyroid disease did not show a clear advantage.[6] Laparoscopic single-incision surgery was first described in 1998,[13] and laparoendoscopic single-site (LESS) surgery most accurately conveys the broad philosophical and practical aspects of the field.[14] We initially performed an endoscopic thyroidectomy via a single areola approach to perform a TASSET using a LESS technique. The TASSET procedure significantly minimized the subcutaneous dissection area, which was similar to that of conventional open surgery.[3] Compared with natural abdominal cavities in LESS laparoscopic cholecystectomy procedures, artificially created workspaces are more limited in TASSET. Thus, collisions between the instrument and camera can be bothersome, and the learning curve with TASSET has its own features.[15] In the present study, 45 consecutive patients were prospectively divided into an initial phase, intermediate phase, and advanced phase corresponding to their surgical order, and 15 patients were assigned to each group. The operative time, estimated blood loss, postoperative complications, hospital stay, and cosmetic outcomes were compared using phases and surgical procedures. These clinical parameters truly reflected surgical skills and outcomes, which are also consistent with the parameters comprising the learning curve of international minimally invasive surgery.[16–20]

Analyses of the previous study showed that the mean operative time could be reduced with increasing experience, and the operative time for the different parts of the entire surgical procedure reflects an improvement in manipulation skills.[21] In our study, the mean operative time for endoscopic thyroidectomy with a breast approach was 171.30 ± 33.20 minutes for the first 15 cases, 136.02 ± 30.86 minutes for the second 15 cases, and 125.20 ± 28.70 minutes for the third 15 cases. We found a significant reduction in the mean operative time among the 3 groups. The time for part 1 (establishment of manipulation room) was significantly reduced in the advanced phase, but the time for part 2 was greatly reduced in the intermediate phase, indicating establishment of manipulation room need more practice. The results indicated that surgeon's procedural skills in endoscopic thyroidectomy significantly increased during the initial phase of the learning curve for the first 15 cases, reaching an advanced level after 30 cases in terms of skill, proficiency, and stability of the operation. We will now provide additional details regarding our experiences. First, we repeatedly observed a classic surgery video. The performance of a safe and effective surgery requires in-depth knowledge of the biology and pathology of thyroid diseases and details of the operation. As suitable surgical skills evolve from an appropriate understanding of the details of and important steps in the operative procedure, we attended academic conferences, watched live surgeries, and directly communicated with surgeons on surgical difficulties. Second, we selected patients with solitary thyroid nodules (diameter of < 3 cm) and benign signs in the present study, which was helpful for gaining experience and avoiding accidental injury secondary to improper surgical techniques.[22] Moreover, to facilitate dissection and reduce bleeding, dissection should be conducted in the loose connective tissue of the chest wall without injury to the mammary gland or duct and under the platysma in the neck, while establishing room for manipulation.[23]

Our study demonstrated that there were significant differences in operative blood loss, length of postoperative hospital stay, and postoperative pain assessed using a VAS scale between the initial and intermediate phases. There were no significant differences in terms of operative blood loss, postoperative hospital stay, and VAS scale between the intermediate and advanced phases. The operative blood loss and length of postoperative hospital stay decreased with experience and remained stable after the intermediate

phase. As surgeons gained experiences during the initial phase, complications from endoscopic thyroidectomy were reduced during the intermediate and advance phases. A significant advantage of the current study is that all procedures were executed by an experienced laparoscopic surgeon. This particular surgeon had prior experience in laparoscopic surgery; consequently, he had been previously familiarized with endoscopic thyroidectomy. As a result, it is possible that a shorter learning curve might be expected for more experienced surgeons. As for the surgical team, there is another important factor concerning an operation. While performing an operation, it is of importance to do the same job with minimal effort.

The postoperative complication rate was low in the present study. We have observed a number of technical details that play an important role in the surgical procedure. The inferior thyroid artery and its branches were divided proximal to the thyroid gland to avoid the recurrent laryngeal nerve. Avoidance of too much tension is imperative while using ultrasonic shears, and less clamp force should be applied while dissecting vessels and tissues to minimize potential nerve injury.[24] The branches of the thyroid vessels were divided using ultrasonic shears in a proximal to distal direction before the thyroid gland was divided to avoid postoperative bleeding.

In conclusion, the TASSET method enables the safe handling of surgical instruments, resulting in a reduction in operative time, blood loss, and postoperative pain. Learning curve of the TASSET are improved synchronized at different phases and with different technical indicators. The establishment of manipulation room take longer time to skilled master.

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