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内視鏡下頸部良性腫瘍摘出術

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I. 総括研究報告

厚生労働科学研究費（医療技術実用化総合研究事業）

総括研究報告書

内視鏡下頸部良性腫瘍摘出術

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研究要旨：頸部良性腫瘍に対して従来、行なわれてきた頸部切開による手術に比し、整容性の面で非常にすぐれた内視鏡下頸部良性腫瘍摘出術の手術手技を確立し、その有用性、安全性を評価する。国内外での臨床成績ならびに臨床実地状況を検討し、本研究で得られた臨床データとともに本手術が高度先進的な医療技術であることを明らかにする。また本手術において現時点では適応外の医療機器の使用についてもその有用性、安全性を確認する。

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A.はじめに

腹部、胸部外科領域では内視鏡を使用した手術は現在、広く普及しておりその安全性、有用性についての臨床データが多く蓄積されている。しかし頸部領域における内視鏡下手術は限られた施設でしか行なわれておらず十分な臨床的知見が得られていないのが現状である。そこで内視鏡下頸部良性腫瘍摘出術が先進医療として承認された国内5施設の症例を集約して検討することにより、早期に本術式の有用性、安全性が明らかになると考えられる。

B.研究目的

内視鏡下頸部良性腫瘍摘出術とは内視鏡を用いて、頸部良性腫瘍の切除を行なう方法である。従来、頸部良性腫瘍の摘出に際しては頸部に数cmの切開創を置いて行なっていた。その場合、術後に必ず露出部である頸部に手術創が残り、患者の精神的苦痛は少なくない。特に頸部良性腫瘍の中の甲状腺疾患は若年女性の罹患が多く、術後の整容性の改善は重要な課題である。本手術は前胸部の切開創から手術を行なう方法であるため、術創は衣服に隠れ頸部に切除痕は残らない。また内視鏡を用いることにより、従来法に比して非常に小さい創から手術操作を行なうことが可能であり、より低侵襲な手術であると考えられる。本研究の目的は現在、先進医療として行なわれている内視鏡下頸部良性腫瘍摘出術の手術手技を確立すること、術中術後経過、合併症等を詳細に検討しその有用性、安全性を検討することである。また本術式において現時点では適応外の医療機器の使用についても、その有用性、安全性を確認することを

目的とする。有効で安全であることが確認できれば頸部良性腫瘍摘出術の対象患者の多くは頸部に手術創を残さず低侵襲と考えられる本術式を受けることを希望すると思われる。そこで本研究が早急になされ、本術式の有用性、安全性についてのエビデンスを蓄積する必要があると考えられる。本研究の成果として内視鏡下頸部良性腫瘍摘出術の手術手技が確立され、有用かつ安全であることが証明されれば、本術式の普及につながると思われる。また頸部良性腫瘍を罹患した患者が本法にて摘出術を受けた場合、低侵襲手術のため現在より早期の回復、退院が見込まれる。術後に露出した切除痕に苦悩することもないと考えられ、国民の医療の向上に貢献できると思われる。手術術式の医療技術実用化のための臨床研究であるため、この術式を施行した症例を蓄積する必要があり各年度で達成できる予想成果はほぼ同様と考えられる。年度ごとに研究代表施設、研究分担施設の症例の臨床データを集積し、本術式の有用性、安全性を詳細に検討する。最終年度の平成21年度にはこの内視鏡下頸部良性腫瘍摘出術の手術手技の確立についての報告を行なう。また本術式の有用性、安全性が確認され、適応外の医療機器の使用における指針も確立されることが考えられる。

C.研究方法

甲状腺良性腫瘍、原発性上皮小体機能亢進症を適応症とし、患者本人のインフォームドコンセントを取得した上で、本内視鏡下頸部良性腫瘍摘出術を施行する。個々の患者の術中術後経過、合併症等を詳細に検討し本術式の有用性、安全性を検討する。

本研究の実施にあたっては各施設の倫理委員会での審査を受審し承認を受け、臨床研究に関する倫理指針および各施設で定められた倫理規定を遵守しつつ本研究を遂行する。研究代表者および分担研究者はそれぞれの所属施設で対象患者に本術式を施行しその有用性、安全性について検討するが、さらに研究代表者がその臨床データを集積し、解析を行なう。研究期間は3年間であるが各年度総計約50症例の蓄積を目標とし、研究代表者が平成19年度、20年度の解析の小括と平成21年度に本研究の最終的な報告を行なう。

D.研究結果

まず下記の如く研究計画を立案し、対象となる適応症を規定した。

適応症、選択基準：

1)術前に細胞診検査にて悪性腫瘍が否定されている甲状腺濾胞腺腫、腺腫様甲状腺腫症例。バセドウ病、原発性上皮小隊機能亢進症症例。

2)上記疾患で腫瘍径が極端に大きくないもの(約5cm以下)。また著明なびまん性甲状腺腫大のないもの。

3)患者本人への説明文書を用いた説明を行い、文書による手術の同意が得られていること。

除外基準：出血傾向、重篤な心肺疾患、頸部伸展困難例、急性期感染症、全身麻酔不可症例など

治療計画：全身麻酔下に前胸部に小切開創を置き、内視鏡手術器具挿入用のトラカールを留置する。吊り上げ法もしくはCO₂気嚢法にて術野を展開しつつ前胸部から前頸部の剥離を行い、手術操作腔を確保する。

内視鏡の拡大視にて血管、神経を確認し出血を軽減する超音波切開凝固装置を使用し頸部良性腫瘍を切除する。

有効性および安全性の評価：安全性判定重篤な有害事象の発現、軽度の有害事象の発現の有無や頻度を調べる(後出血、反回神経麻痺、その他の合併症が含まれる)。

有効性判定 手術評価として切除標本の大きさ、重量、手術時間、出血量を記録する。整容性を含めた患者満足度を評価する。

モニタリング体制および実施方法：入院(約1週間)、退院後2週・1ヶ月に外来で経過観察、検査(甲状腺機能など)施行し、その後も3-6ヶ月毎の定期的な外来通院となる予定である。

患者に対し重大な事態が生じた場合の対処方法：術中、出血などの事態が生じた場合は速やかに通常の直視下手術に移行することにより対処可能である。また術後も当施設では各科当直体制が確立し、24時間体制で必要な検査、治療が可能である。

本研究に係る記録の取り扱いおよび管理・保存方法：当該研究に係る手術記録、入院サマリー、病理組織診断報告書などについては入院診療録とともに診療録管理室に一括保存している。

患者負担について：先進医療「内視鏡下頸部良性腫瘍摘出術」で各研究参加施設が承認された本治療に関する諸費用(約11-13万円)は自己負担。その他の入院・外来診療経費については保険診療である。

起こり得る利害の衝突および研究者等関連組織との関わり：本研究実施にあたり薬品・機器提供、資金出所などに関し、特定の研究者、組織との間の利害関係はない。

個人情報保護の方法：患者の同定や照会

は初診時に発行される登録ID番号、患者イニシャル、生年月日を用いて行い、専用のコンピュータで管理する。最小限の識別情報としてID番号を用いるが、本研究に携わる全ての研究者は個人情報保護のために最大限の努力を払う。具体的にはカルテなど書類の院内限定使用の徹底をグループ診療の同グループ内医師をはじめ、コメディカルと頻繁に確認する。

上記、研究計画に基づき各研究施設ごとに平成20年3月までに医学倫理委員会の倫理審査を受け、本臨床試験への症例登録を開始する準備を整えた。

E. 考察

本研究は現在、自費診療または限られた先進医療承認施設でのみ施行されている内視鏡下頸部良性腫瘍摘出術の有用性、安全性を確認することを目的としている。内視鏡および超音波切開凝固装置などの手術機器は腹部、胸部領域では汎用されており手術手技は保険収載され安全に一般医療として施行されている。本術式施行例の多い国内5施設の症例を集約して検討することで頸部領域においても内視鏡下手術の有用性、安全性が確認されうると考えられる。平成20年度は症例を蓄積し、各研究施設分を集計してその臨床データを解析することとしている。

F. 結論

内視鏡下頸部良性腫瘍摘出術が先進医療として承認されている国内5施設にて、本術式の有用性、安全性を確認するために症例の解析研究を開始した。本研究に先立ち各施設において必要な倫理委員会の承認を得

た。

G. 研究発表

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H.知的財産権の出願・登録状況(予定を含む。)

1. 特許取得

なし

2. 実用新案登録

なし

3. その他

なし

II. 研究成果の刊行に関する一覧表

研究成果の刊行に関する一覧表

雑誌

発表者名	論文タイトル名	発表誌名	巻号	ページ	出版年
A Sasaki, J Nakajima, K Ikeda, K Otsuka, K Koeda, G Wakabayashi	Endoscopic thyroidectomy by the breast approach: A single institution's 9-year experience	World Journal of Surgery	32	381-385	2008

III. 研究成果の刊行物・別刷

Endoscopic Thyroidectomy by the Breast Approach: A Single Institution's 9-year Experience

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Abstract

Background The aim of this study was to evaluate the feasibility and cosmetic results of endoscopic thyroidectomy by the breast approach for patients with thyroid diseases.

Methods From August 1998 to July 2007, 92 patients with benign thyroid diseases underwent endoscopic thyroidectomy at our institution. Of these patients, 54 underwent thyroid lobectomy for a thyroid nodule, and 38 selected subtotal thyroidectomy for Graves' disease.

Results Ninety of the 92 procedures were successfully completed endoscopically. Mean operative time for thyroid lobectomy and subtotal thyroidectomy was 121.1 min and 231.9 min, respectively. Postoperative complications included one wound infection, one transient and one permanent recurrent laryngeal nerve palsy, one transient hypocalcemia, and five hypertrophic scars in the right breast medial margin. At 84 months of follow-up, one patient reported paresthesia in the anterior chest and one had experienced swallowing discomfort. Patient satisfaction was recorded as "satisfied," "equivocal," and "unsatisfied" in 54, 2, and 0 patients. Mean satisfaction score was 9.7, 9.5, 9.5, and 8.9 points in patients in their teens, 20s, 30s, and 40s, respectively, with an overall mean score of 9.3 points, showing more satisfaction in the young.

Conclusions Endoscopic thyroidectomy by the breast approach for patients with thyroid diseases is an effective procedure that allows an excellent cosmetic result.

Since the first reported endoscopic parathyroidectomy for hyperparathyroidism in 1996, various endoscopic techniques have been applied to benign thyroid diseases including those that involve access via breast, anterior chest wall, axilla, and cervix [1–21]. In August 1998, we introduced endoscopic thyroidectomy by the breast approach for excision of thyroid nodule, and we also applied endoscopic subtotal thyroidectomy for Graves' disease [6, 11]. Total endoscopic thyroidectomy differs greatly from the conventional approaches in that it requires creation of a subcutaneous working space. Its possible merits include high levels of cosmetic satisfaction, because no noticeable incision scar is left on the neck, and it eliminates the discomfort commonly felt after cervical operation, which contributes to the patient's well-being. In addition, endoscopic thyroidectomy can reduce complaints associated with a cervical incision, such as postoperative hypesthesia or paresthesia in the neck or swallowing discomfort [16]. The aim of this study was to evaluate the feasibility and cosmetic results of endoscopic thyroidectomy by the breast approach for patients with thyroid diseases at single institution during a 9-year period.

Materials and methods

Patients

From August 1998 to July 2007, 92 patients with thyroid diseases underwent endoscopic thyroidectomy by the breast approach. Of these patients, 54 underwent thyroid lobectomy for a thyroid nodule, and 38 underwent subtotal thyroidectomy for Graves' disease. Endoscopic thyroidectomy was selected only if patients desired a procedure that leaves no operative wound in the neck and gave informed

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consent. Patients with a thyroid nodule smaller than 5 cm in diameter were selected for endoscopic thyroid lobectomy. If there is any suspicion of thyroid cancer by fine-needle aspiration cytology, open thyroidectomy is recommended. Indications for Graves' disease were as follows: contraindication to antithyroid drug because of adverse drug reactions and no desire for radioiodine therapy; or large goiter refractory to antithyroid drug; and expected thyroid weight smaller than 100 ml as measured by computerized tomography (CT) volumetry.

All patients were assessed by retrospective review of a prospective database. To evaluate the feasibility and cosmetic results of our endoscopic procedure, surgeons other than the patients' attending doctors administered a telephone questionnaire to patients more than 1 year postoperation. The items surveyed were as follows: presence or absence of swallowing discomfort, hypesthesia or paresthesia in the anterior chest or neck, satisfaction with postoperative appearance of the neck, presence or absence of hypertrophic scar, cosmetic satisfaction score ranging from 0 to 10 (extremely dissatisfied to extremely satisfied).

Categorical variables were compared with the χ^2 test or unpaired *t*-test using StatView software (SAS Institute Inc., Cary, NC, USA). Values are expressed as mean (standard deviation) and a value of $p < 0.05$ was considered statistically significant.

Surgical procedures

Our endoscopic thyroidectomy procedure was originally developed by the breast approach of Ohgami et al. [9]. Dressing forceps were inserted via an incision in the right breast medial margin, and blunt dissection was made between platysma and strap muscles. For thyroid nodule, subcutaneous dissection of the anterior chest wall was limited to the minimum necessary for trocar insertion at the circumference of the affected lobe of the thyroid. For Graves' disease, the working space was extended to the level of the thyroid cartilage superiorly and to the medial border of each sternocleidomastoid muscle laterally. A 12-mm trocar for endoscopy was inserted, with CO₂ insufflation pressure set at 5 mmHg. A 5-mm trocar for the operator was endoscopically inserted into the bilateral areola superior to its margin. In subtotal thyroidectomy for Graves' disease, strap muscles were transversely divided along the thyroid diameter. The superior thyroid artery was clipped and divided on the thyroid side to the maximum extent possible to preserve the external branch of the superior laryngeal nerve. For cases of enlarged thyroid, to ensure visualization of the superior pole, two silk threads were inserted under the skin and strap muscles to lift them forward. The inferior thyroid vein was divided using the

Harmonic Scalpel (Johnson & Johnson Medical, Cincinnati, OH, USA). The isthmus of the thyroid was divided using the Harmonic Scalpel and then the thyroid was rotated, to confirm the location of the inferior parathyroid and the recurrent laryngeal nerve (RLN). The thyroid around the Berry's ligament was resected from the inferior pole upward, toward the superior pole, so as to leave thyroid dorsal capsule intact in the superior position, thereby preventing impairment of blood flow from the inferior thyroid artery to parathyroid and avoiding damage to the RLN. To avoid recurrent hyperthyroidism due to erroneous estimation of residual thyroid weight, a sponge model of 1 g measuring the residual thyroid weight was placed adjacent to the thyroid, and the thyroid parenchyma was excised in comparison with the thyroid model [11]. In endoscopic thyroid lobectomy, the strap muscles were then longitudinally incised with the Harmonic Scalpel immediately over the tumor, to expose the thyroid.

Results

Final pathological diagnoses of the thyroid nodules were as follows: 26 adenomatous hyperplasia, 24 follicular adenoma, 2 toxic adenoma, 1 follicular carcinoma, and 1 papillary carcinoma (53 women and 1 man; mean age, 42.1 years). Two patients were histopathologically diagnosed with malignant tumors by endoscopic thyroidectomy. One of these two patients had minimal invasion of follicular carcinoma of 16-mm in diameter without vessel invasion, which with deeper pathological sectioning later showed a capsular microinvasion. The other patient had an extranodal, incidental papillary carcinoma of 7 mm in diameter. These patients gave informed consent and are now under observation for prognosis. There have been no signs of recurrence or metastasis after the thyroidectomy as of 5 months and 21 months, respectively. The procedure for all Graves' disease was subtotal thyroidectomy (31 women and 7 men; mean age, 29 years). Thyroid lobectomy required a mean operative time of 121.1 min, with mean blood loss of 9.9 ml and mean resected thyroid weight of 20.5 g. Subtotal thyroidectomy required a mean operative time of 231.9 min, with mean blood loss of 34.6 ml and mean resected thyroid weight of 31.7 g (Table 1).

Comparison of Graves' disease surgery outcomes between early ($n = 19$, November 1998–March 2001) and late ($n = 19$, April 2001–July 2007) periods revealed longer operative time with more cases of enlarged thyroid but a tendency for a reduction in blood loss as the surgeons gained experience with the procedure (Table 2). Conversion to an open procedure occurred in two patients (2.2%), both because of obstructed visual field and difficulty in

Table 1 Patient characteristics and operative outcomes

	Lobectomy (<i>n</i> = 54)	Subtotal thyroidectomy (<i>n</i> = 38)
*Age, years	42.1 (14.4)	29.0 (11.1)
Male/female, <i>n</i>	1/53	7/31
*Operative time, min	121.1 (36.0)	231.9 (75.6)
*Blood loss, ml	9.9 (19.5)	34.6 (90.0)
*Resected thyroid weight, g	20.5 (13.4)	31.7 (26.5)
Conversion to open surgery, <i>n</i>	1	1
Complications, <i>n</i>	1	2

* Values are expressed as mean (standard deviation)

achieving thyroid rotation, and both specifically at the patient's request: one was a case of adenomatous hyperplasia with a tumor size of 7 cm, and the other was a case of Graves' disease with a resected thyroid weight of 107 g.

Postoperative complications included one wound infection, one permanent RLN palsy, and one transient RLN palsy with transient hypocalcemia. Mild hypertrophic scars in the right breast medial margin developed in 5 patients at 1 year after surgery (Table 3). Transient RLN palsy and transient hypocalcemia resolved 2 months and 3 days postoperatively, respectively. Following subtotal thyroidectomy, thyroid function was euthyroidism, hypothyroidism, and recurrent hyperthyroidism in 5, 30, and 3 patients, respectively. Treatment for the 3 patients with recurrence: radioiodine therapy for 2 patients, and antithyroid administration for a 15-year-old patient. A questionnaire was administered to 78 patients more than 1 year postoperatively. A total of 56 patients (thyroid nodule; *n* = 27, Graves' disease; *n* = 29) responded. Median follow-up before administration of the questionnaire was 84 months postoperation. Postoperative complaints among the patients surveyed included one case of swallowing discomfort and one report of paresthesia in the anterior chest wall

Table 2 Comparison of operative outcomes for Graves' disease between two time periods

	November 1998-March 2001 (<i>n</i> = 19)	April 2001-July 2007 (<i>n</i> = 19)	<i>p</i> Value
*Operative time, min	263.6 (115.8)	273.6 (45.3)	0.448
*Blood loss, ml	95.1 (107.4)	56.2 (65.6)	0.530
*Resected thyroid weight, g	44.3 (27.2)	56.1 (27.4)	0.247
Conversion to open surgery, <i>n</i>	1	0	0.317
Complications, <i>n</i>	1	1	0.999
Recurrent hyperthyroidism, <i>n</i>	3	0	0.075

* Values are expressed as mean (standard deviation)

Table 3 Postoperative complications and patient complaints after endoscopic thyroidectomy by the breast approach

	Lobectomy (<i>n</i> = 54)	Subtotal thyroidectomy (<i>n</i> = 38)
Complications, <i>n</i>		
Wound infection	1	0
Transient RLN palsy	0	1
Permanent RLN palsy	0	1
Transient hypocalcemia	0	1
Hypertrophic scar	2	3
Patient complaints, <i>n</i>		
Swallowing discomfort	1	0
Hypesthesia or paresthesia	1	0

RLN recurrent nerve palsy

(Table 3). Fifty-four patients were satisfied with preservation of appearance of the neck, and two patients felt equivocal satisfaction; none were dissatisfied (Fig. 1). Overall level of satisfaction with endoscopic thyroidectomy as "satisfied," "equivocal," and "unsatisfied" was reported by 54, 2, and 0 patients, respectively. Mean satisfaction score was 9.7, 9.5, 9.5, and 8.9 points in patients in their teens, 20s, 30s, and 40s, respectively, with overall mean score of 9.3 points, showing more satisfaction in the young (Table 4).

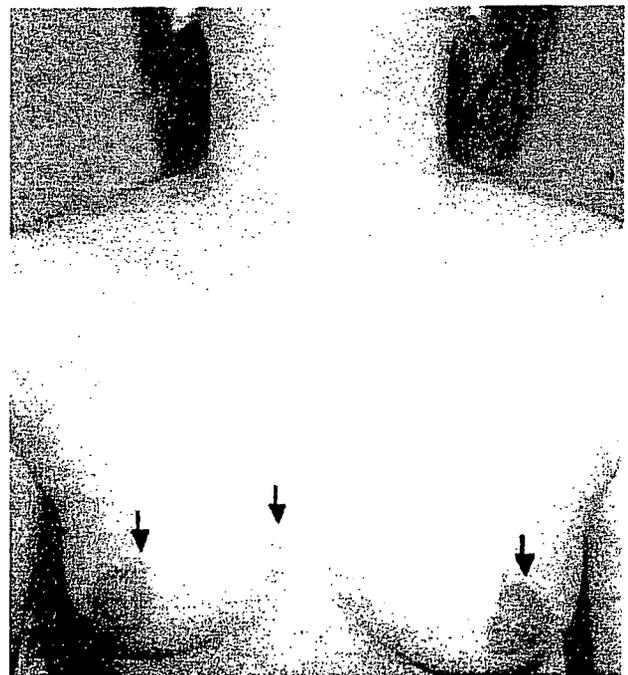
**Fig. 1** Photograph of the patient's cervical appearance 1 month after endoscopic subtotal thyroidectomy for Graves' disease. Black arrows indicate operative scars

Table 4 Cosmetic results after endoscopic thyroidectomy by the breast approach

	Patients' decade of life				Total (n = 56)
	10s (n = 9)	20s (n = 13)	30s (n = 9)	40s (n = 25)	
Cosmetic result					
Satisfied	9	13	9	23	54
Unsatisfied	0	0	0	0	0
Equivocal	0	0	0	2	2
Mean satisfaction score	9.7	9.5	9.5	8.9	9.3

Discussion

Several procedures for endoscopic and video-assisted thyroidectomy (VAT) have been reported since 1997 [2–21]. Endoscopic thyroidectomy varies in visual direction among approaches, demanding a paradigm shift from an endoscopic perspective. The merits of our procedure, endoscopic thyroidectomy by the breast approach, include a minimal operative wound because of the use of 12-mm or smaller trocar and no need to change endoscope insertion site or number of trocars between thyroid lobes. Furthermore, the visual field is easy to understand anatomically, making the procedure suitable for Graves' disease surgery. Disadvantages include the extensive operation range owing to the approach from the breast, away from the thyroid. In the procedure for mediastinal goiter, there is a high incidence of conversion to an open procedure because of the difficulty in achieving thyroid rotation given the awkward visual field. Video-assisted thyroidectomy is advantageous in that it is less invasive, involves more limited subcutaneous dissection compared with total endoscopic thyroidectomy, and allows the surgeon a sense of performing an operation similar to conventional thyroidectomy, while it requires a minimum of 2-cm to 3-cm skin incision [3, 14, 15, 20]. For patients with malignant tumor, our breast approach has disadvantages when compared with VAT, because the breast approach involves difficult operative technique and prolonged operative time. For these reasons, VAT may be a better approach to the endoscopic procedure for excising a malignant lesion than the breast approach, both for the extent of resection required for invasive lesions and the precision necessary in accomplishing lymph node dissection. However, the breast approach is extremely useful for presumed indications of small low-risk papillary and minimally invasive follicular carcinomas, which require no lymph node dissection.

With the axillary approach, the cosmetic results are excellent leaving no operative scars on either the neck or

the anterior chest. However, for Graves' disease, the axillary approach requires bilateral operative wounds.

For endoscopic thyroidectomy, which places a priority on cosmesis, the approach should be selected according to the needs of the patient.

Endoscopic surgery seems advantageous in that it satisfies all conditions: less invasiveness, high safety, and favorable cosmesis. Nevertheless, endoscopic thyroidectomy is not necessarily less invasive than conventional procedures, and therefore great attention must be paid to safety evaluation. Maeda et al. [20] reported an incidence of RLN palsy of 5.9% (transient) and 0% (permanent) after subtotal or near-total thyroidectomy for Graves' disease. In contrast, our patients had an incidence of 1.1% for both transient and permanent RLN palsy. Bron et al. [22] reported incidences of RLN palsy following total thyroidectomy of 2.3% (transient) and 1.1% (permanent), suggesting that our results are not poor. Endoscopic thyroidectomy by the breast approach, which allows the operative wound scar to be completely hidden by clothing, is cosmetically advantageous; however, it requires creation of a working space in the anterior chest and a more extensive operative range than conventional procedures. Ikeda et al. [16] compared patient complaints 3 months postoperatively among three groups of patients treated by different approaches: endoscopic thyroidectomy by the anterior chest approach, endoscopic thyroidectomy by the axillary approach, and conventional procedures. The reported incidence of hypesthesia or paresthesia in the neck was 0, 0, and 67%, respectively, and the incidence of swallowing discomfort was 0, 0, and 33%, respectively. In the present study, a questionnaire was administered to determine whether dysfunction specific to the breast approach would develop after some interval. At 84 months of follow-up, hypesthesia or paresthesia in the anterior chest or neck and swallowing discomfort occurred at low incidences of 1.1% and 1.1%, respectively, providing evidence for long-term safety of this procedure.

Given that the evaluation of satisfaction with endoscopic thyroidectomy by the breast approach was subjective and biased, the results still show extremely high patient satisfaction with operative wound and appearance of the neck. In particular, all patients in their teens to 30s were satisfied with the surgery, deepening recognition of the need to explain availability of the approach as an option, especially to girls and women in this age range.

In conclusion, endoscopic thyroidectomy by the breast approach for patients with thyroid diseases is an effective procedure and allows excellent cosmetic result. Our future study will focus on establishing an approach that meets the needs of more patients, and on further dissemination of endoscopic thyroidectomy.

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