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| Author(s) | Wong, KP; Lang, BHH; Ng, SH; Cheung, CY; Chan, CTY; Lo, CY |
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A prospective assessor-blind evaluation of surgeons-performed transcutaneous laryngeal ultrasonography in vocal cord examination before and after thyroidectomy

Kai-Pun WONG¹ MBBS, FRCS

Brian Hung-Hin LANG¹ MS, FRACS

Sze-How NG² MS

Chung-Yeung CHEUNG¹ MBBS, MRCS

Christina Tin-Yan CHAN¹ MBChB, MRCS

Chung-Yau LO¹ MS, FRCS

¹Division of Endocrine Surgery, Department of Surgery, The University of Hong Kong, Queen Mary Hospital, Hong Kong SAR, China

²Breast & Endocrine Unit, Department of Surgery, Kuala Lumpur Hospital, Kuala Lumpur, Malaysia

Correspondence

Dr Brian HH Lang

Department of Surgery, University of Hong Kong

Queen Mary Hospital, 102 Pokfulam Road, Pokfulam

Hong Kong

Tel: (852) 2255 4232

Fax: (852) 2817 2291

Email: blang@hkucc.hku.hk

ABSTRACT

Introduction:

Transcutaneous laryngeal ultrasound (TLUSG) is a promising alternative to direct laryngoscopy (DL) in assessing perioperative vocal cord (VC) function. This study aimed to evaluate the accuracy of TLUSG in assessing VC function.

Methods:

Altogether 204 patients underwent TLUSG and DL before and after elective thyroidectomy. For both examinations, VC movements were independently graded. Grade I meant both VCs had normal movement while grade II meant ≥ 1 VC had reduced movement and grade III meant ≥ 1 VC had no movement. Grade II/ III on DL was defined as VC paresis or palsy (VCP). To assess accuracy, the TLUSG findings were correlated with DL findings.

Results:

No patient had preoperative VCP while 17 had unilateral postoperative VCP. The overall postoperative VCP rate was 5.1%. TLUSG failed to assess VCs in 11 (5.4%) postoperative patients. Of these, 2 had VCP while 9 had no VCP on DL. Postoperative TLUSG had a sensitivity, specificity, positive predictive value and negative predictive value of 93.3%, 97.8%, 77.8% and 99.4%, respectively. Of the 175 patients with grade I on TLUSG, only 1(0.6%) had a grade II VCP on DL.

Conclusion:

TLUSG is a promising, non-invasive tool for selecting patients to undergo DL before and after thyroidectomy.

INTRODUCTION

Thyroidectomy is a commonly-performed surgical procedure and because postoperative vocal cord paresis or palsy (VCP) is not only an important procedure-related complication but also a major contributor for medico-legal litigation in thyroid surgery, information on the patient's preoperative and postoperative vocal cord status is considered essential.¹ However, the opinion for routine preoperative and to some extent, postoperative laryngeal examination of the vocal cords remains somewhat divided.²⁻⁴ Those advocating routine preoperative examination would argue that in case of a preoperative VCP, the patient could be consulted appropriately before surgery, the surgeon could take "extra" care on the contralateral recurrent laryngeal nerve (RLN) to avoid a tracheostomy and it would suggest thyroid malignancy.^{3,5} On the other hand, those arguing against routine preoperative examination view that because preoperative VCP is rare, a great majority of patients (particularly those with no voice symptoms or previous neck operations) are subjected to unnecessary laryngeal examination.² Furthermore, laryngoscopy causes patient discomfort and that could potentially lead to poor patient compliance to the procedure.^{6,7}

Surgeon-performed transcutaneous laryngeal ultrasonography (TLUSG) has recently been shown to be a promising non-invasive tool in vocal cord examination.⁸⁻¹⁰ Apart from its relative non-invasiveness, it adds very little extra cost because it could be done as part of the preoperative examination of the thyroid gland and its regional lymph nodes and it takes as little as a few minutes.⁸ One study has found that up to 87% of the vocal cords are assessable by TLUSG and concluded that TLUSG could be a tool for selecting patients to undergo a preoperative direct laryngoscopy(DL).⁸ However, to our knowledge, none of these studies have prospectively evaluated the accuracy of TLUSG assessment in an assessor-blind fashion (i.e. the assessor being unaware of the patient's voice symptoms before assessment). Therefore, we prospectively evaluated the accuracy of perioperative TLUSG in vocal cord examination by blinding the assessor of the patient's voice symptoms and correlating it with the laryngoscopic finding in the same clinical setting.

PATIENTS AND METHODS:

Patients

Over a 10-month period, a total of 212 consecutive patients undergoing elective thyroidectomy at our institution consented and were prospectively recruited for this study. To evaluate the accuracy of TLUSG in assessing preoperative and postoperative vocal cord function, all patients underwent a TLUSG followed immediately by a confirmatory DL within the same setting one day before and 7 – 10 days after thyroidectomy. The reason for choosing 7 – 10 days after thyroidectomy was because that was the time when most of our patients had their dressing and steri-strips taken off. Although all patients completed preoperative vocal cord function assessment, 6 (2.8%) patients failed to have postoperative TLUSG and DL while 2 (0.9%) patients refused DL and had TLUSG only. As a result, only 204 (96.2%) patients were analyzed. To calculate the accuracy of the TLUSG, the TLUSG findings were correlated with the DL findings

Preoperative and postoperative TLUSG and DL assessments

After obtaining informed consent, all patients were specifically asked if they had any voice and laryngeal symptoms or complaints before TLUSG and DL assessments. After that, a nurse directed the patient to another room where the TLUSG was performed. Before entry, the patient was instructed to keep silence during the TLUSG while the surgeon performing the TLUSG was also instructed to not talk to the patient so that he was unaware of the patient's voice quality throughout the assessment. To reduce any assessment variability, all TLUSG examinations was performed by one endocrine surgeon (KPW) using the same portable ultrasound (USG) machine (iLook™ 25 Ultrasound System, Sonosite®, SonoSite Inc., Washington, United States) and 5-10MHz linear transducer (L25). During the assessment, the patient was positioned flat with the neck slightly extended and arms on the side. After applying ample amount of gel over anterior neck, an USG transducer was placed transversely over the middle portion of the thyroid cartilage and scanned cranio-caudally until both true and false cords were visualized. If the vocal cords could not be easily visualized or assessed, a 200cc saline filled balloon (latex glove) was placed between the thyroid

cartilage and the transducer to improve the wave conduction (see figure 1). To optimize the images, the grey-scale was adjusted until false cords became hyperechoic while true cords became hypoechoic. Both passive (i.e. quiet spontaneous breathing) and active (phonation with a sustained vowel “aa”) movement of the vocal cords were assessed during the assessment. The extent of movement was graded from I to III. Grade I meant full or normal symmetrical movement of both vocal cords (Figure 2) while grade II meant impaired or reduced movement in ≥ 1 vocal cord and grade III meant no movement in ≥ 1 vocal cord (Figure 3).¹¹ Immediately after the TLUSG, the patient was directed to the endoscopy suite where a flexible direct laryngoscopy (DL) (Olympus BF-P40, Bronchoscope, Olympus®, Tokyo, Japan) was performed by an experienced endoscopist who was also unaware of the patient’s voice quality and the TLUSG findings. Using a similar grading system to the TLUSG, the extent of vocal cord movement on DL was graded from I to III. Patients with grade II or III on DL were defined as having VCP. To calculate the rate of VCP, the number of nerves at risk was used as denominator. Patients with either grade II or III VCP were referred to otolaryngologists and speech therapists for assessment.¹²

RESULTS

Table 1 shows the patient characteristics of the 204 patients. The total number of nerves at risk was 331.

Figure 4 shows a flow chart of the 204 patients who underwent preoperative and postoperative TLUSG and confirmatory DL. None of the 204 patients had preoperative VCP on DL (i.e. no preoperative grade II or III on DL). Preoperatively, the vocal cords were clearly visualized and assessable by TLUSG in 196 (96.1%) patients while 8 patients had un-assessable vocal cords by TLUSG. Of the 8 preoperative patients with un-assessable vocal cords, 5 remained un-assessable in the postoperative period. On the other hand, of the 196 patients with clearly assessable vocal cords by TLUSG in the preoperative period, 6 had un-assessable vocal cords in the postoperative period. Therefore, a total of 11 patients had un-assessable vocal cords by TLUSG in the postoperative period. In the preoperative setting, the assessable group (n=196) was significantly younger (52.0 years vs. 66.5 years, $p=0.027$) and more likely to be female (160/196 vs. 1/8, $p<0.001$) than the un-assessable group (n=8). Similar findings were also found in the postoperative setting (*data not shown*).

Table 2 shows the correlation between postoperative TLUSG and DL findings. In the immediate postoperative period, there were altogether 17 patients with unilateral VCP by DL. There was no patient with bilateral VCP. In terms of grading, 9 were graded as II while 8 were graded as III by DL. Therefore, the overall rate of vocal cord palsy was 17/331 or 5.4%. The sensitivity of detecting grade II and III by TLUSG were 4/9 (44.4%) and 4/8 (50.0%), respectively.

Table 3 shows a 2 x 2 table of patients with assessable vocal cords by postoperative TLUSG. Among the 15 patients with VCP by postoperative DL, 14 (93.3%) were correctly identified as VCP by postoperative TLUSG. One patient with grade II VCP on postoperative DL was missed (i.e. misdiagnosed as normal) on the postoperative TLUSG. This patient was asymptomatic postoperatively and the paretic cord returned full movement 2 months after surgery. Among the 178 patients with normal mobile vocal cords by postoperative DL, 174 (97.8%) were correctly identified

as normal mobile vocal cords by postoperative TLUSG while 4 patients were thought to have impaired vocal cord movements (i.e. grade II) by postoperative TLUSG. Therefore, the sensitivity, specificity, positive predictive value and negative predictive value of TLUSG in diagnosing VCP were 93.3%, 97.8%, 77.8% and 99.4% respectively.

Table 4 shows the relationship between post-operative hoarseness and DL finding. Of the 24 patients with hoarseness of voice, half had VCP while the other half had no VCP.

Figure 5 shows a proposed algorithm for using TLUSG as a tool for selecting DL before and after thyroidectomy. Hypothetically, if we apply this proposed algorithm in the preoperative setting, only 8 patients would require DL while the other 196 patients would not need to undergo a DL. Therefore, using TLUSG as first line, the total number of preoperative DL could potentially be reduced by 96.1%. Similarly, if we apply the same proposed algorithm in the postoperative period, 29 patients would require DL while the other 175 patients would not need to undergo a DL. Therefore, using TLUSG as first-line, the total number of postoperative DL could potentially be reduced by 85.8% but this is at a cost of missing 1 (0.5%) patient with asymptomatic / grade II VCP.

DISCUSSION

Despite the ongoing controversy on whether or not to perform routine DL before and after elective thyroidectomy, they serve different purposes. In the preoperative setting, identification of a VCP may indicate a possible malignant thyroid problem with local extension and may help the surgeon to better plan the extent of surgery. On the other hand, postoperative DL helps the operating surgeon to analyze his or her nerve injury-related complication rate (i.e. self-auditing) so as to avoid or reduce future occurrence.³ However, DL causes patient discomfort, requires special instrument and / or expertise and in our setting, it is considered more expensive than USG.¹³

Since the first report describing the potential use of TLUSG in detecting VCP in 1992,¹⁴ there had been several studies supporting its clinical role and application in both pediatric and adult populations.^{7,15,16} However, the initial results in the adult population were not as promising as that of the pediatric population. Sidhu et al. reported one of the first adult series on thyroidectomy patients and found reported the sensitivity and specificity of detecting VCP using TLUSG were only 62.0% and 94%, respectively. They concluded that it was not a reliable alternative to DL.⁷ However, with improvement in USG quality and technique over time, more recent studies have reported significantly better sensitivity and specificity than earlier reports.^{8-10,17} Some recent authors have even suggested that TLUSG could be used to select patients for DL before thyroidectomy.^{8,9} In the era of minimally invasive procedure and cost containment, the implication of this is great because potentially fewer patients would require DL before and after thyroidectomy and would be subjected to unnecessary procedure.

Similar to recent studies, our prospective study also found a high success rate in visualizing and assessing the vocal cords with TLUSG.^{8-10,16} However, unlike other studies, this was a prospective study with consecutive patients being included and so the chance of selection bias was relatively less. Also the compliance rate (i.e. the proportion of patients having completed both preoperative and postoperative TLUSG and DL) was relatively higher when compared other similar studies and so this would further reduce the chance of selection bias. Lastly, the TLUSG and DL assessments

were both performed in an assessor-blind fashion such that both assessors were unaware of the patient's voice quality and symptoms before examination. By carrying out our study this way, we believe the assessors' bias was greatly minimized.

However, despite differences in design, the assessability (i.e. ability to visualize and assess both vocal cords) and accuracy rates were comparable to other studies.⁸⁻¹⁰ The assessability rates in the preoperative and postoperative settings were 96.1% and 94.6%, respectively whereas other studies reported rates up to 90%.^{8,9} However, there might be several reasons for the high assessability rates. Firstly, as shown in our analysis and other studies, the assessability rate of the vocal cords often depends on both the age and sex of the patient. Those with assessable vocal cords by TLUSG were generally younger in age and more likely female than those with un-assessable vocal cords by TLUSG. Progressive ossification of thyroid cartilage occurs in the elderly population and that tends to act as a barrier for propagation of USG waves, and thus poor image in sonogram.¹⁸ Other patient and disease characteristics did not affect visualization rate.⁹ This was true both in the preoperative and postoperative settings. Therefore, one possible reason for the higher rates might have been related to the patient demographics within the cohort itself. Secondly, all TLUSG examinations were performed by one dedicated endocrine surgeon who has had years of USG experience, although it remains unclear whether the assessability rate deteriorates with less USG experience. Nevertheless, we believe the skill of TLUSG could be quickly learned with appropriate training. Thirdly, to improve our overall assessability rate, we have developed a new technique of placing a saline-filled balloon as a medium for USG transduction. The purposes of using this balloon, instead of the coupling gel, were to overcome the angle of the thyroid cartilage and to maximize the contact area between the thyroid cartilage and the linear probe. This technique was very useful particularly in male patients whom the thyroid notch is more angulated and prominent.^{9,18} Fourthly, the relatively low USG frequency (5-10MHz) allows better tissue penetration and increases rate of vocal cord visualization.

Although our data showed that TLUSG had a sensitivity, specificity and negative predictive value (NPV) of close to 95 to 100%, one of the most significant findings was actually the high sensitivity because missing an actual VCP (i.e. false negative) would have a more significant clinical impact than “over-calling” a normal vocal cord as VCP by TLUSG (i.e. false positive). In our experience, the chance of missing a VCP by TLUSG was 1/15 or 6.7%. Other studies have also reported similar values.⁷⁻⁹ The other significant finding was the high NPV. The implication is that for those who are negative (i.e. grade I or normal vocal cords movement) on TLUSG, the chance of missing a real VCP (i.e. grade II or III) on DL is extremely low. In fact, our data showed that the chance of missing a VCP on DL in a postoperative patient with normal assessable TLUSG was only 1/175 or 0.6%. As a result, we proposed an algorithm for using TLUSG in the postoperative setting. Hypothetically, if we adopt this algorithm (i.e. we use TLUSG as a screening tool and select DL only for postoperative patients with grade II/III or un-assessable vocal cords on TLUSG), the total number of postoperative DL could potentially be reduced by 85.8% with the chance of missing 1 asymptomatic grade II VCP. Although potentially its impact on reduction in preoperative DL could be even more significant (196/204 or 96.1%) because there were fewer patients with un-assessable vocal cords, it was difficult to interpret because none of the patients had a preoperative VCP and so the sensitivity and positive predictive value were not available.

However, despite these encouraging results, we do not believe TLUSG could become an alternative to DL. This is because firstly, there was still a small but significant proportion (5.3%) of postoperative patients whom their vocal cords were not assessable on TLUSG. Secondly, since missing a postoperative VCP (i.e. a false negative) probably has a more profound implication on subsequent treatment than over-calling a VCP (i.e. a false positive) on TLUSG, routine TLUSG still misses in 1/15 or 6.7% of postoperative VCP. Lastly, the overall sensitivity of detecting grade II and III by TLUSG were only 4/9 (44.4%) and 4/8 (50.0%), respectively.

Despite our data, there were several shortcomings with our study. Firstly, given the low incidence of preoperative and postoperative VCP (i.e. the number of events), our study would still be

considered underpowered and small in size. This was particularly true in the preoperative setting because the incidence of preoperative VCP is generally even lower than postoperative VCP. Also unlike DL, TLUSG does not produce good enough images to diagnose co-existing laryngeal conditions and / or other finer details of the vocal cords (e.g. bowing or haematoma of vocal cords) and so without DL, some of these conditions which could affect voice quality might be missed. Also in this study, we did not apply other quantitative measurements such as arytenoid angle and tissue displacement velocity with the Doppler mode which may further improve our results.^{10,18} However, we found that they were generally too complex and difficult to apply in a busy surgeon's practice. Since only one dedicated person performed all TLUSG, it remains uncertain to what extent our results could be reproduced if different surgeons with different USG experience performed TLUSG. We do acknowledge the fact that the cost of USG may be similar to that of DL in some countries and so the cost advantage of TLUSG over DL may not be applicable everywhere. Perhaps, future studies are required to address some of these unresolved issues.

CONCLUSION

Although TLUSG was able to clearly assess vocal cord function in 196/204 (96.1%) patients before thyroidectomy and 193/204 (94.6%) after thyroidectomy, the sensitivity of discriminating between different VCP grades was moderate. Using TLUSG as a screening tool to select DL for patients with grade II / III or un-assessable vocal cords, the total number of post-operative DL could be reduced by more than 85%. Therefore, TLUSG is a promising, non-invasive tool for selecting patients to undergo DL before and after thyroidectomy.

Table 1. Patient baseline characteristics

| | |
|--|-------------|
| | n = 204 |
| Median age at operation (years) | 52 (20-85) |
| Sex | |
| - Male | 43 (21.1%) |
| - Female | 161 (78.9%) |
| Surgical indication / final pathology | |
| - Benign nodular goiter | 117 (57.3%) |
| - Graves' disease | 28 (13.7%) |
| - Malignancy | 52 (25.5%) |
| - Thyroid nodular hyperplasia with parathyroid adenoma | 3 (1.5%) |
| - Multinodular goiter and renal hyperparathyroidism | 4 (2.0%) |
| Type of operation | |
| - Total thyroidectomy | 111 (54.3%) |
| - Hemithyroidectomy | 70 (34.3%) |
| - Reoperative completion thyroidectomy | 15 (7.4%) |
| - Hemithyroidectomy with Sistrunk's procedure | 1 (0.5%) |
| - Hemithyroidectomy with excision of parathyroid adenoma | 3 (1.5%) |
| - Total thyroidectomy with total parathyroidectomy | 4 (2.0%) |

Table 2. Correlating between postoperative ultrasonographic findings and postoperative laryngoscopic findings in the 204 patients who underwent both transcutaneous laryngeal ultrasound (TLUSG) and direct laryngoscopy (DL)

| | | TLUSG findings | | | | Total |
|--------------------|-----------|----------------|---------|----------|-----------|-------|
| | | Un-assessable | Grade I | Grade II | Grade III | |
| DL findings | Grade I | 9 | 174 | 4 | 0 | 187 |
| | Grade II | 2 | 1 | 4 | 2 | 9 |
| | Grade III | 0 | 0 | 4 | 4 | 8 |
| | Total | 11 | 175 | 12 | 6 | 204* |

Grade I = full or normal movement in both vocal cords; Grade II = reduced or impaired movement in at least 1 vocal cord, Grade III = no movement in at least 1 vocal cord.

*no patient suffered bilateral vocal cord palsy

Table 3. A 2x2 table of patients with assessable vocal cords with postoperative transcutaneous laryngeal ultrasound (TLUSG)

| | | TLUSG | | Total |
|-----------|--------|--------------|----------|-------|
| | | VCP | Normal | |
| DL | VCP | 14 (TP) | 1 (FN) | 15 |
| | Normal | 4 (FP) | 174 (TN) | 178 |
| Total | | 18 | 175 | 193 |

Abbreviations: VCP = vocal cord paresis or palsy; DL = direct laryngoscopy; FP = false positive; TP = true positive; TN = true negative; FN = false negative

Table 4. A 2x2 table of patients with post-operative hoarseness

| | | DL | | Total |
|--------------------------------|------------|-----------|----------|-------|
| | | VCP | Normal | |
| Post-operative symptoms | Hoarseness | 12 (TP) | 12 (FN) | 24 |
| | No | 5 (FP) | 175 (TN) | 180 |
| Total | | 17 | 187 | 204 |

Abbreviations: VCP = vocal cord paresis or palsy; DL = direct laryngoscopy; FP = false positive; TP = true positive; TN = true negative; FN = false negative

Legends

Figure 1. Surgeon performed TLUSG with saline-filled balloon (latex glove) placed between the thyroid cartilage and linear probe

Figure 2. A sonographic view of the normal symmetrical true and false vocal cords.

Figure 3. A sonographic view of a right vocal cord palsy. Noted that there was asymmetry of the two vocal cords.

Figure 4. A patient flow chart showing proportion of patient had assessable VC in TLUSG before and after thyroidectomy.

Figure 5. A proposed algorithm for selecting patients for direct laryngoscopy.

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