Original Article

A single-arm, prospective study comparing translaryngeal ultrasonography with direct visualisation by flexible laryngoscopy for vocal cord assessment in patients undergoing oesophagectomy or mediastinoscopy

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ABSTRACT

Background and Aims: Translaryngeal ultrasonography (TLUSG) for diagnosis of vocal cord palsy, a relatively new, safe and noninvasive bedside technique with minimal risk of respiratory infection transmission, has been effective in patients with thyroid disease. We studied its use as an alternative method to visual inspection by flexible laryngoscopy (FL) for vocal cord assessment in patients undergoing thoracic surgeries. **Methods:** After Institutional Ethics Committee approval and trial registration, in this single-arm, prospective study, the vocal cord function of 110 patients who underwent either total oesophagectomy or mediastinoscopy was assessed immediately after extubation by both FL and TLUSG. A follow-up assessment was done by laryngoscopy using Hopkin's endoscope (HL) and a repeat TLUSG. The primary outcome was the concordance between direct visualisation (FL or HL) and TLUSG. **Results:** Vocal cords were successfully visualised by TLUSG in 90% of male and all female patients. Findings of FL and TLUSG done at the first assessment matched in 89 (86.4%) out of 103 patients, and the degree of concordance was 0.69 (95% confidence interval [CI] =0.52–0.83). At the second assessment, HL and TLUSG findings matched in 83 (94.3%) out of 88 patients, and the degree of concordance was 0.89 (95% CI = 0.77–0.98). **Conclusion:** TLUSG is an effective noninvasive alternative to direct visualisation for vocal cord assessment in both male and female patients undergoing thoracic surgery.

Key words: Mediastinoscopy, oesophagectomy, translaryngeal ultrasonography, ultrasonography, vocal cord assessment, vocal cord palsy, flexible laryngoscopy

INTRODUCTION

Vocal cord (VC) palsy has been reported in up to 30% of patients undergoing total oesophagectomy, mediastinoscopy and lung surgery.[1-4] Its early detection in these patients could prompt interventions to reduce the risk of aspiration, retained secretions and airway compromise.[1,3] Visual inspection of the VCs by laryngoscopy using a direct laryngoscope, flexible laryngoscope or rod endoscope has been the standard for diagnosing VC palsy. However, laryngoscopic procedures can be distressing to awake patients due

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to reflexes like gagging and coughing. Translaryngeal ultrasonography (TLUSG) of VCs can be easily and safely performed at the bedside, presenting a promising alternative. A recent systematic review of TLUSG has reported a pooled sensitivity and specificity of 0.91 and 0.97, respectively, when compared to laryngoscopy.[5]

We hypothesise that TLUSG can be an effective alternative to laryngoscopy for postoperative VC assessment. The study's primary objective was to determine the accuracy of TLUSG compared to direct visualisation for VC assessment in patients undergoing oesophagectomy or mediastinoscopy. The secondary objective was to investigate the ability to visualise the VCs by TLUSG in this group of patients.

METHODS

This was a single-arm, prospective, interventional study conducted from March 2018 to February 2019 in a tertiary care cancer centre. The study was approved by the Institutional Ethics Committee of Tata Memorial Centre, Mumbai (vide approval number IEC/0218/1992/001 dated 21 February 2018). It was carried out in accordance with the principles of the Declaration of Helsinki, 2013. The trial was registered with Clinical Trial Registry- India (vide registration number CTRI/2018/03/012437, www.ctri.nic.in). All adult patients undergoing total oesophagectomy by transthoracic approach or mediastinoscopy (with or without lung resection surgery) were screened. Patients with preexisting VC palsy, deformity of the anterior neck, anatomical deformity of the nose, poorly controlled hypertension and history of sensitivity to local anaesthetics or xylometazoline were excluded. Written informed consent was obtained from all eligible patients for participation in the study and use of the patient data for research and educational purposes.

All patients underwent flexible laryngoscopy (FL) for VC assessment by the surgeons as part of a standard surgical workup in our hospital. All study patients had standard preoperative and intraoperative anaesthesia and surgical management. Patients received tracheal intubation with a single- or double-lumen tube based on the need for lung isolation.

All recruited patients underwent FL to assess VC movement immediately after extubation or within 30 min of extubation (time point T1) in the operation theatre or the post-anaesthesia care unit (PACU) under topical anaesthesia by one of the three study investigators who were experienced thoracic anaesthesiologists. Patients with tracheal extubation after the first postoperative day (POD) were excluded from the analysis. This was shortly followed by a TLUSG examination in PACU by one of the two trained investigators blinded to the findings of FL. The two anaesthesiologists who performed TLUSG had completed 25 examinations supervised by radiologists. On POD 3 or 4 in patients operated for total oesophagectomy or on POD 1 or 2 in patients undergoing mediastinoscopy (time point T2), all study patients underwent laryngoscopy under topical anaesthesia with the Hopkins® forward oblique telescope 70° (HL) by experienced otorhinolaryngologists as per the standard institutional practice. Patients also had a repeat TLUSG on the same day of undergoing HL by one of the two trained investigators blinded to direct visualisation findings. TLUSG was performed with a SonoSite M-turbo™ machine (Fujifilm Sonosite, Bothell, WA, USA) using a linear probe (6–13 MHz). VCs were examined by placing the probe over the thyroid cartilage transversely and scanning in the cephalad and caudad directions to visualise true VCs or arytenoid cartilages. Both anterior and lateral approaches were applied to get the best views. Visualisation of true VCs or arytenoid cartilages was considered a successful assessment. VCs were assessed during normal breathing and phonation (vocalisation of sound 'eee') in all three methods. VC movement was described as 'normal' when adduction and abduction were present on each side, slow adduction or abduction was noted as 'sluggish' movement and the absence of movement of the VC was recorded as 'absent'. The absent or sluggish movement was considered abnormal for analysis.

The primary outcome was the concordance between VC palsy detected by FL and TLUSG at time point T1 (within 30 min of extubation) and concordance between VC palsy seen by HL and TLUSG at time point T2 (POD 1–4). The secondary outcome was the ability to visualise the VCs by TLUSG at both time points.

Sample size calculation was performed using Package kappaSize to detect discordance (kappa of 0.8) between TLUSG and direct visualisation (null hypothesis being kappa of 0.5) at 90% power. A 30% incidence of postoperative VC palsy obtained from a prospectively maintained institutional database was used to calculate the sample size for this study of interobserver agreement. The estimated sample size was 103 sets of measurements. To account for protocol violations, the study was conducted with a sample size of 110 patients.

The degree of concordance was derived using Cohen's kappa statistics by Statistical Package for Social Sciences software version 23. The sensitivity, specificity, accuracy and positive and negative predictive values of TLUSG were also calculated. The secondary outcome of the ability to visualise VCs by TLUSG is described as a number and percentage. Gender and type of surgery were given as a number and percentage. Height, weight, body surface area and age were described as mean and standard deviation.

RESULTS

One hundred ten patients were studied [Figure 1], of which 76 (69%) were males. The mean age was 54.7 years (SD 11.82). The mean values of height, weight and body mass index (BMI) were 166.59 cm (SD 6.45), 60.26 kg (SD 12.17) and 21.65 kg/m^2 (SD 3.76), respectively, in males and 153.28 cm (SD 5.27), 52.97 kg (SD 9.59) and 22.54 kg/m^2 (SD 3.87), in females.

Table 1 shows the findings of the first and second VC assessments (time points T1 and T2, respectively). Thirty (27%) of 110 patients were observed to have VC palsy on FL, 24 of whom had left cord palsy, five had right cord palsy, and one patient had bilateral cord palsy. The incidence of VC palsy was 23% (eight in 35 patients) and 29% (22 in 75 patients) in the mediastinoscopy and oesophagectomy patients, respectively. VCs were satisfactorily visualised on TLUSG in 103 of 110 patients: all female patients and 69 (90%) of the 76 male patients. Other than the gender difference, these seven patients were not significantly different in their demographic parameters from those in whom VCs were visualised on TLUSG. Findings of FL and TLUSG matched in 89 (86.4%) out of 103 patients, and the concordance was found to be 0.69 (95% confidence interval [CI] =0.52–0.83). HL and TLUSG findings matched in 83 (94.3%) out of 88 patients in whom the VCs could be visualised, and concordance was 0.89 (95% CI = 0.77–0.98). TLUSG findings at T1 and T2 matched in all patients. The sensitivity, specificity, accuracy and positive and negative predictive values were better when compared with HL than with FL [Table 2]. None of the cases reported a difficult airway requiring multiple attempts or prolonged time for intubation. Also, there were no adverse events related to the study procedures.

DISCUSSION

This single-centre, single-arm study was conducted to understand if TLUSG would be a good alternative to direct visualisation for postoperative VC assessment in patients undergoing thoracic surgery, both in

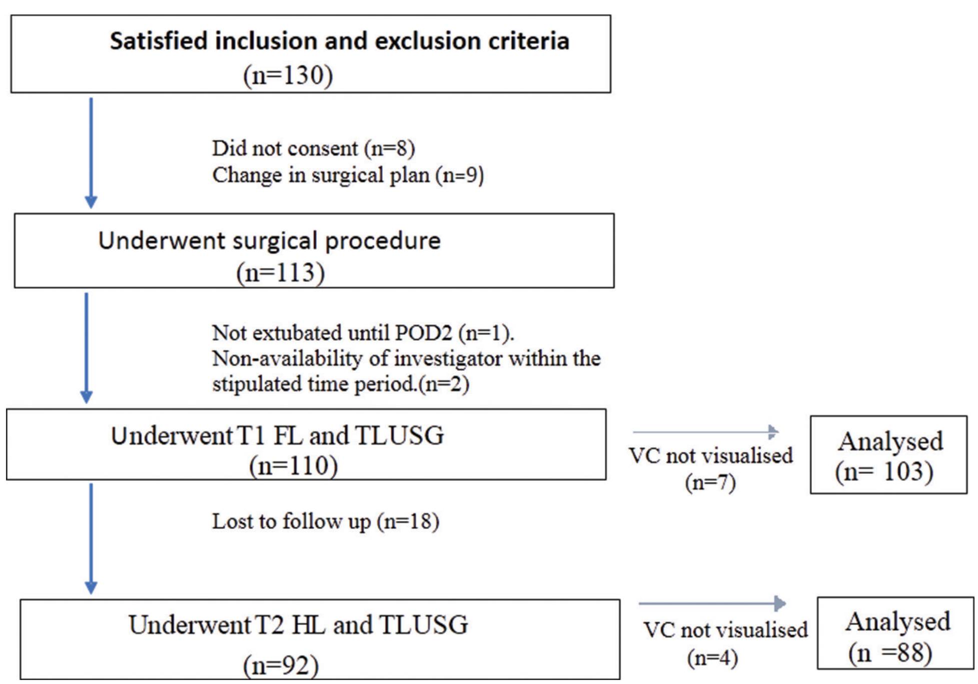

Figure 1: Study schema. FL = flexible laryngoscopy, HL = laryngoscopic examination with Hopkins endoscope, POD = postoperative day, TLUSG = translaryngeal ultrasonography, VC = vocal cord

Table 1: Comparison of translaryngeal ultrasonography findings with laryngoscopic examination with flexible laryngoscopy and Hopkins endoscope for vocal cord assessment at time points T1 and T2

	TLUSG				Cohen's kappa coefficient (95% CI)
	Normal (*n*)	VC palsy (*n*)	NV (*n*)	Total (*n*)	
FL (T1) (*n*=110)					
Normal	66	11	3	80	0.69 (0.52-0.83)
VC palsy	3	23	4	30	
Total	69	34	7	110	
HL (T2) (*n*=92)					
Normal	51	1	1	53	0.89 (0.77-0.98)
VC palsy	4	32	3	39	
Total	55	33	4	92	

CI=Confidence interval, HL=Laryngoscopic examination with Hopkins endoscope, NV=Not visualised, time-point T1=Within 30 min of extubation, time-point T2=Postoperative day 1–2 for mediastinoscopy or postoperative day 3–4 for oesophagectomy, TLUSG=Translaryngeal ultrasonography, VC=Vocal cord, *n*=Numbers

Table 2: Comparison of efficacy of TLUSG with flexible laryngoscopy and laryngoscopic examination with Hopkins endoscope for vocal cord assessment

	TLUSG versus FL (*n*=103)	TLUSG versus HL (*n*=88)
Sensitivity (%)	88	89
Specificity (%)	85	98
Positive predictive value (%)	67	97
Negative predictive value (%)	95	96
Accuracy (%)	86	94

FL=Flexible laryngoscopy, HL=Laryngoscopic examination with Hopkins endoscope, TLUSG=Translaryngeal ultrasonography

terms of accuracy and visualisation. TLUSG had a high sensitivity, specificity, positive predictive value, negative predictive and accuracy compared to our current standard of HL; however, the accuracy was lower when TLUSG was compared to the post-extubation FL. VCs were assessable with TLUSG in most patients.

The results of our study are comparable to the published literature, most of which are related to TLUSG for VC assessment in patients with thyroid disease, with endoscopic laryngoscopy as the standard arm.[5-7] A systematic review by Kim *et al.* included 17 studies evaluating VC function in patients undergoing thyroid surgery and found that TLUSG had a pooled sensitivity of 0.91, pooled specificity of 0.97 and a pooled negative predictive value of 0.99, suggesting excellent overall diagnostic accuracy.[5] In this review, the studies which reported a low sensitivity had certain factors which could explain their results, such as the timing of the study (the early 2000s when USG technology was still new), the inclusion of obese patients with difficult landmarks and inadequate training of USG operators.[8]

Our study showed a lower concordance of TLUSG with FL than with HL. There are several possible reasons for this. First, even though experienced operators performed FL in our study, false movement of VC while gagging and coughing during the procedure could have resulted in errors in reporting VC movement during the first assessment. Also, residual effects of anaesthetic agents could have affected VC movement during FL to a greater extent as it was performed immediately after extubation in the operating room in most cases. As TLUSG was performed in PACU, there was more time for recovery from anaesthesia, which could have changed the findings on TLUSG. Performing FL 1–2 h after extubation could have reduced the errors.

Our study was conducted in oesophagectomy and mediastinoscopy patients as they are at a higher risk of VC palsy, and early detection in the immediate postoperative period could prompt interventions to decrease pulmonary morbidity, which is the most common cause of mortality after major thoracic surgery.[9] In our study, the incidence of VC palsy was higher than that described in the literature.[1-3] This could be related to the aggressive lymph node dissection practised in our institute.

Regarding the secondary endpoint, in our study, VCs were visualised in all females and around 90% of male patients. Our visualisation rates were much higher than those reported in the literature. We used both anterior and lateral approaches for the USG scan, which could have led to better results in our patients. In some studies, the lateral approach or application of gel pads has been described to improve visualisation in male patients.[10-12] Also, in our study group of patients undergoing oesophagectomy and mediastinoscopy, the surgical incision was distant to the site of application of TLUSG, unlike thyroid surgeries where subcutaneous air pockets at the surgical site could have hampered imaging. Lastly, we cannot discount the effect of race on the anatomical factors impacting USG visualisation.

Though our sample size was modest, we had a high incidence of VC palsy, which increases the validity of the results regarding the accuracy of TLUSG in detecting VC palsy. The study's limitations are that the VC examination findings, both by direct visualisation and TLUSG, were based on only one observation by one of the investigators, leading to a higher risk of operator error. We did not objectively quantify the VC dysfunction by measuring the vocal fold displacement velocity. Another limitation is that we did not blind assessors to patient voice quality to prevent bias in assessment.

TLUSG offers several benefits over direct visualisation methods such as FL. It can be done at the bedside, requires no sedation or topical anaesthesia of the airway and can be repeated as frequently as needed with minimum inconvenience and risk to the patient and the operator. Our study adds to the emerging evidence supporting TLUSG by demonstrating its feasibility and accuracy in an extended spectrum of patients. Whether the point-of-care TLUSG used in thoracic surgery in the early postoperative period for diagnosing and later monitoring VC function leads to improved outcomes is a subject for future studies.

CONCLUSION

TLUSG is an effective noninvasive alternative to direct visualisation for postoperative VC assessment in patients undergoing mediastinoscopy and oesophagectomy.

Study data availability

De-identified data may be requested with reasonable justification from the authors (email to the corresponding author) and shall be shared after approval as per the authors' institution policy.

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Conflicts of interest

There are no conflicts of interest.

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