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Prediction of Difficult Intubation by Airway Assessment Using Ultrasound Vs Conventional Bed Side Screening Test: A Randomised Comparative Study

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Abstract

Background and aims: *To predict difficult intubation by airway assessment using ultrasound vs conventional bed side test.*

Methods*: A prospective study involving 400 patients of age 18-65 years undergoing surgical procedure requiring elective oral intubation. Patients were randomly allocated in 2 groups. In group 1 patients airway was assessed by bedside test – mallampati score, thyromental distance (TMD), neck circumference (NC) and in group 2 by ultrasonography - posterior tongue thickness, anterior neck soft tissue at the level of hyoid bone (ANS-HB), epiglottis (ANS-EP), vocal cords (ANS-VC) were recorded. Receiver operating characteristic (ROC) curve was used to find out cut off point of parameters for predicting difficult intubation. Diagnostic test was used to calculate sensitivity, specificity, negative and positive predictive value. A p value of <0.05 was considered statistically significant. Statistical analysis was done using Statistical Package for Social Sciences version 21.0.*

Results: *25 patients out of 400 patients were categorized as difficult laryngoscopy. ANS-HB (P<0.0001), ANS-VC (p< 0.0001), ANS-EP (p<0.0002) are greater in the difficult laryngoscopy group. Among this ANS-VC is the best predictor of difficult laryngoscopy with largest area on ROC curve. Whereas in bedside tests, only TMD was accurate in 93% cases in predicting difficult intubation. When TMD and ANS-VC were compared than it was found that there was no statistical difference (p-0.704).*

Conclusion: *TMD, ANS-VC, ANS-HB are good predictors of difficult laryngoscopy. Thus using both bedside and ultrasound parameters can add incremental value for prediction of difficult intubation.*

Keywords – *intubation, anesthesia, ultrasonography.*

Introduction

In anesthesia difficult intubation forms a major cause of morbidity and mortality. Most of the airway adversities have occurred when the difficult airway was not precisely anticipated. Predicting difficult airway by certain clinical tests reduce the number of unanticipated difficult tracheal intubations leading to airway catastrophes. Various bedside screening tests are used to anticipate difficult airways. **[**1**]** Despite availability of these tests, unexpected difficult intubations may occur due to their high inter-observer variability and average to fair sensitivity and specificity.**[**2**]**,**[**3**]**

Ultrasound imaging technique has emerged as a portable and non-invasive tool for airway assessment in recent times.**[**4**]** Ultrasound measurement of anterior neck soft tissue helps in predicting difficult intubation in obese patient.**[**5**]** Ultrasonographic measurement of tongue size and volume has also been studied for its possible role in causing difficult intubation.**[**6**]**,**[**7**]** Though, there are few studies depicting role of ultrasound in predicting difficult intubations but the results are very variable and confusing. Thus the primary objective of this study was to assess the predictive value of bedside tests and ultrasound parameters for difficult intubation. Whereas, the secondary objective was to compare the predictive value of best bedside parameter and best ultrasound parameters so that the best predictor of difficult intubation among the two groups can be found out.

Methods

After approval from the institutional review board and obtaining informed consent, 400 patients with ASA grade I-II between 18-65 years of age, scheduled for operative procedures requiring general anesthesia with oral intubation from Feb 2018 to Feb 2020 were randomly allocated by computer based software in 2 different groups. In group1 conventional parameters were used to assess the airway and in group 2 ultrasound measurements were recorded to assess airway. Patients with anticipated difficult airway, cervical spine pathologies and undergoing emergency procedures were excluded.

Pre-anaesthetic evaluation of the patient was done before the surgery. Patient airway assessments were done in group 1 by using conventional parameters modified mallampati score, neck circumference, and thyromental distance were noted by one investigator and in Group 2 ultrasound parameters posterior tongue thickness, anterior neck soft tissue at the level of hyoid bone (ANS-HB), epiglottis (ANS-EP) and vocal cords (ANS-VC) were observed by another investigator.

The modified mallampati score (MMS) was specified according to the visibility of pharyngeal structures with the patient in an upright sitting position, head in neutral position, mouth wide open, and tongue protruding to its maximum without phonation . Class I is visualization of the hard palate, soft palate, fauces, uvula, and pillars. Class II is visualization of the hard palate, soft palate, fauces, and base of uvula. Class III is visualization of the hard palate and soft palate. Class IV is visualization of only the hard palate.

Thyromental distance (TMD) was measured from the mental prominence to the thyroid cartilage with the patient's neck extended fully. Neck circumference was measured at the level of thyroid cartilage.

Ultrasound parameters were obtained in supine position with patient head extended and placing the high frequency (7-15MHz) linear transducer probe (SONOSITE) in transverse view at submandibular area (fig 1). First, we noted the tongue thickness, by measuring the distance between anterior surface of mylohyoid to dorsal surface of genioglossus up to the air-mucosal interface as shown in fig 1(A). Then, the distance from skin to hyoid bone was noted. Hyoid bone was visible as a hyperechoic inverted U-shaped linear structure with posterior acoustic shadowing as shown in fig 1(B). Now the angle of the probe was slightly turned caudally and distance from skin to epiglottis was measured where epiglottis was visualised as a hypoechoic curvilinear structure as shown in fig 1(C). Its visualisation was facilitated by tongue protrusion and swallowing just inferior to the base of tongue as a mobile structure. Ultrasonographically its anterior border was demarcated by a hyperechoic pre-epiglottis space and posterior border by bright air mucosal interface. Distance from the skin to the anterior commissure of vocal cords was measured by placing the probe at the level of thyroid isthmus with probe in transverse view as shown in fig 1(D). Identification of the vocal cords was done by observing their linear movement during quiet breathing and phonation.

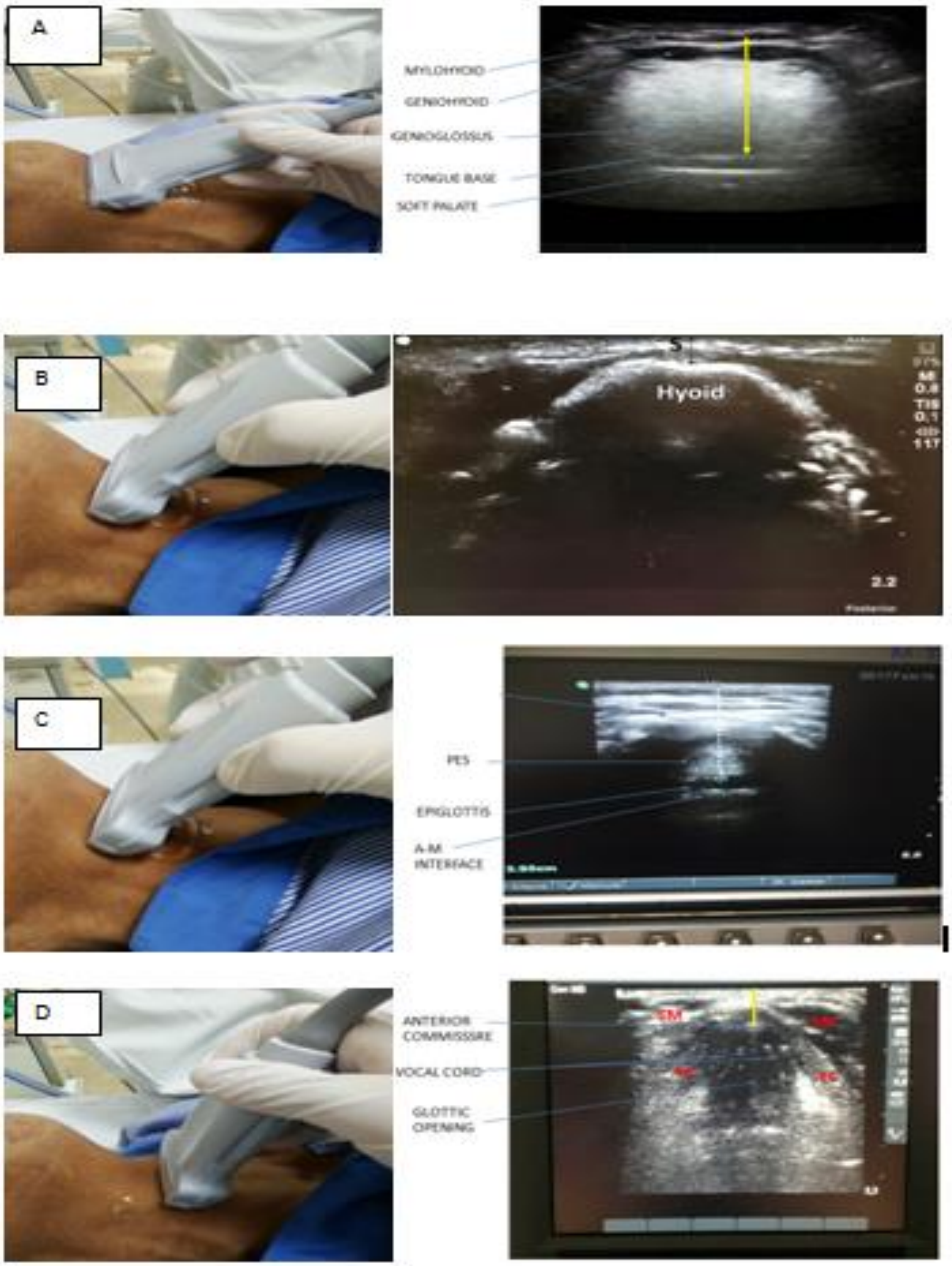


Fig 1. Ultrasound measurements of anterior neck soft tissue thicknesses, left panel: different neck levels with ultrasound probe in transverse position, Submandibular area (A),hyoid level(B), thyrohyoid level (C), vocal cord(D).

All the patients were kept nil per orally overnight before the surgery and pre-medicated with Tab ranitidine 150 mg and tab alprazolam 0.25 mg 2 hrs before the scheduled procedure on the day of surgery.

After airway assessment, patients were induced with propofol 2mg/kg, fentanyl 2-3 mcg/kg and rocuronium 0.6 mg/kg. Direct laryngoscopy was performed by same experienced senior anaesthetist in all the cases who was blinded to the findings of preoperative airway assessment to prevent observer bias and after induction, the cormack lehane's (CL) grade was noted.CL grade 1 and 2 was categorized as an easy laryngoscopy whereas grade 3 and 4 was marked as difficult one. After intubation, patients were ventilated with fresh gas flow of 2 l/min using closed circuit and further anaesthesia was maintained accordingly.

Statistical analysis

The sensitivity and specificity values for calculations were based on a previous study by Jinhong wu et al. p. Taking sensitivity and specificity as reference, the minimum required sample size with power 90%, desired precision of 20% and 5% level of significance is 182 patients per group. So sample size taken is 200 per group.

Formula used is:

$$n \geq \frac{p_C(1-p_C)+p_E(1-p_E)}{\delta_0^2}(Z_\alpha + Z_\beta)^2$$

with

$p_C =$ Ultrasound parameters sensitivity

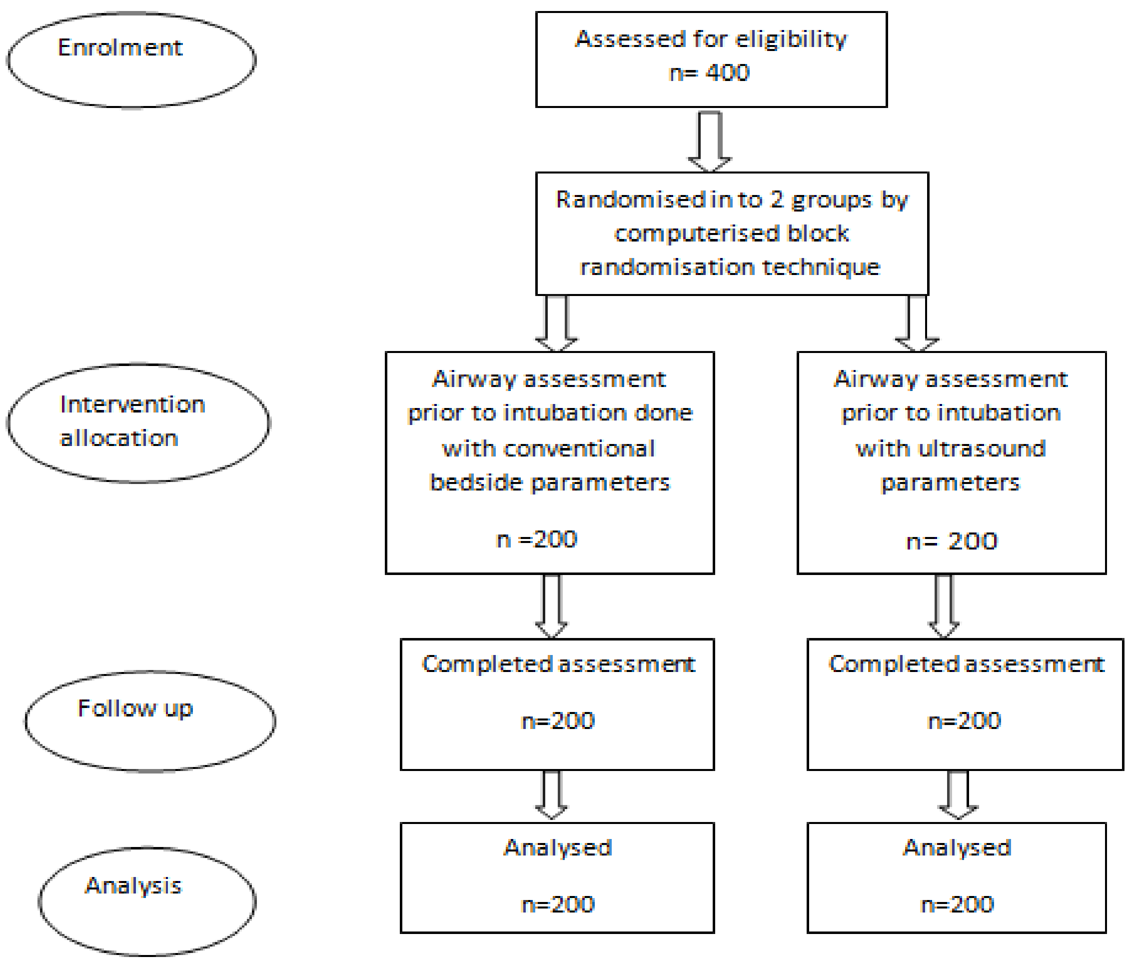
$p_E =$ Conventional bed screening test sensitivity

$\delta_0 = p_E - p_C$

Where $Z\alpha$ is value of Z at two sided alpha error of 5% and $Z\beta$ is value of Z at power of 90% .

The MS Excel® and SPSS® 21.0 software packages were used for data entry and analysis. The results were averaged (mean ± standard deviation [SD]) for each parameter for continuous data. The Chi-square test was used to determine whether there was a statistical difference between the patients with easy and difficult intubations. The predictive value of the tests was assessed by calculating the sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV) and accuracy. To assess the optimal cut-off scores, a relative operating characteristics (ROC) curve was plotted and the area under the curve was calculated to assess the prognostic accuracy. Randomization technique used was computerized block randomization in which blocks of size four was considered -that is, for every four patients randomized two were observed by conventional bed side tests and other two were observed by ultrasound. Now there were six different ways to evenly distribute these four patients between two groups: 1) AABB, 2) ABAB, 3) ABBA, 4) BAAB, 5) BABA, 6) BBAA. Now to randomly select among these six different blocks, random number generating function RANDBETWEEN() was used with lower limit as 1 and upper limit as 6. Blocks were generated according to the generated number like if 5 was generated then BABA sequence was used and so on. In this way patients were randomized using excel and study became selection unbiased.

Consort flow chart



Result

Total of 400 patients (175 males, 225 females) were included in this study. The demographic characteristics are included in table 1. There were 25 difficult intubations (6.25%) observed in this study of which 6 difficult intubations were observed in conventional group and 19 in ultrasound group. In our series of cases, bougie was used as a first line aid in difficult intubation and in all the cases it was successful. The demographic characteristics age, gender, height, weight, and body mass index (BMI) were comparable in both the groups (Table 1)

Characteristics	Conventional bedside group n=200	Ultrasound group n=200	P value
Age (in yrs)	46.24 ± 12.72	46.98 ± 12.85	0.571
Gender (%)	Male – 40.5% Female - 59.5%	Male - 47% Female -53%	
Height (in meters)	1.64 ± 0.06	1.64 ± 0.09	0.364
Weight (in kgs)	70.1 ± 12.04	70.68 ± 15.35	0.691
BMI (kg/m^2)	26.05 ± 3.98	26.29 ± 4.87	0.58

Table 1. (Demographic characteristics)

Airway evaluation parameters including MMP score, TMD, NC, posterior tongue thickness, ANS-HB, ANS-EP and ANS-VC are shown in table 2 and fig 1. The thickness of anterior neck soft tissue at the level of hyoid, epiglottis and vocal cord measured by ultrasound was more in the difficult intubation group except posterior tongue thickness which showed a poor strength of association with difficult intubation. Mallampati score (kappa 0.112) and neck circumference (kappa -0.019) showed a poor strength of association with prediction of difficult intubation whereas thyromental distance came out to be fair predictor of difficult intubation with kappa value of 0.302. (Table 2).

PARAMETERS	Easy (n= 375)	Difficult (n=25)	Kappa
MMP			0.112
MMP 1 AND 2	187 (93.5%)	5(2.5%)	
MMP 3 AND 4	7(3.5%)	1(0.5%)	
TMD			0.302
TMD ≥6.5 cm	180 (90.00%)	2 (1.00%)	
TMD < 6.5 cm	14 (7.00%)	4 (2.00%)	
NC			-0.019
NC ≥ 42 cm	4 (2.00%)	2 (1.00%)	
NC < 42 cm	190 (95.00%)	4 (2.00%)	
Post tongue thickness			0.176
post tongue ≤5.1cm	151 (75.50%)	11 (5.50%)	
post tongue >5.1cm	30 (15.00%)	8 (4.00%)	
ANS HB			0.681
ANS HB≤1.22 cm	173 (86.50%)	4 (2.00%)	
ANS HB>1.22 cm	8 (4.00%)	15 (7.50%)	
ANS EP			0.365
ANS EP≤2.48 cm	161 (80.50%)	8 (4.00%)	
ANS EP>2.48 cm	20 (10.00%)	11 (5.50%)	
ANS VC			0.657
ANS VC≤0.9 cm	170 (85.00%)	3 (1.50%)	
ANS VC>0.9 cm	11 (5.50%)	16 (8.00%)	

Table 2 Data are presented as number of patients as percent. MMP – modified mallampati score, TMD – thyromental distance, NC – neck circumference, ANS HB – anterior neck soft tissue at the level of hyoid bone, ANS-EP- anterior neck soft at the level of epiglottis, ANS VC - anterior neck soft tissue at the level of vocal cord.

To further assess the roles of ultrasound parameters in predicting difficult intubations, the ROC curves were drawn using Medcalc software with laryngoscopy CL grade 3 and 4 as difficult laryngoscopy as shown in table 3. As determined by the youden index, the optimal cut off values (with sensitivity and specificity in parentheses) for MMP, TMD, NC, posterior tongue thickness, ANS-HB, ANS-EP and ANS-VC were 2 (16.67%. 96.39%) ,6.5 (66.67%, 92.78%), 42 (66.67%. 2.06%) , 5.1 (42.11%, 83.43%), 1.22 (78.95%, 95.58%), 2.48 (57.89%, 88.95%), 0.9 (84.21%, 93.92%) respectively as shown in table 3. p values of ANS-HB, ANS-EP, ANS VC were under 0.0002 except posterior tongue thickness denoting that all ultrasound parameters except posterior tongue thickness can be good predictor of difficult intubation.

	ROC (AUC)	Sensitivity	95% CI	Specificity	95% CI	PPV	95% CI	NPV	95% CI	P value
Post Tongue thickness	0.543	42.11	20.3 - 66.5	83.43	77.2 - 88.5	21.1	9.6 - 37.3	93.2	88.2 - 96.6	0.6192
ANS-HB	0.903	78.95	54.4 - 93.9	95.58	91.5 - 98.1	65.2	42.7 - 83.6	97.7	94.3 - 99.4	<0.0001
ANS-EP	0.748	57.89	33.5 - 79.7	88.95	83.5 - 93.1	35.5	19.2 - 54.6	95.3	90.9 - 97.9	0.0002
ANS-AC	0.906	84.21	60.4 - 96.6	93.92	89.4 - 96.9	59.3	38.8 - 77.6	98.3	95.0 - 99.6	<0.0001

Table 3 - AUC, sensitivity, specificity, 95% confidence interval, PPV - positive predictive value, NPV – negative predictive value, p value of ultrasound parameters.

Discussion

There are several traditional indices of predicting difficult airway, but none of them proved to be 100% sensitive and specific. Therefore, after proper airway examination prior to surgery, anaesthesiologist should be ready to deal with it, using different intubation aids. Various bedside tests are available to help anticipate difficult airway. These include neck circumference, BMI, abnormalities of upper teeth, retrognathia, ability to move the lower teeth in front of upper teeth, mouth opening and modified mallampati score, thyromental distance and sternomental distance. These tests have average to fair sensitivity and specificity and high inter-observer variability. Use of ultrasound in airway examination has been a recent technological advance in the field of anaesthesia as it is safe, non-invasive and gives real time dynamic images.**[5]**,**[4]**,**[8]** Ultrasound imaging allows anaesthesiologist in evaluation of complex anatomy.**[9]**

In our study of 400 patients, we compared the role of conventional bedside test (mallampati score, thyromental distance, and neck circumference) versus ultrasound measurements in predicting difficult laryngoscopy in indian population. In our study, demographic parameters such as age, height, weight and BMI were comparable between both the groups.

The prevalence of difficult intubation in our study was 6.25% of which only 0.5 % of cases require additional operator which was comparable to 5.8% in meta-analysis of thirty five studies (50,760 patients) conducted by Shiga et al.[3]

Modified mallampati score reflect size of the tongue relative to the oral cavity. Thyromental distance reflects the length of the neck; whereas neck circumference and ultrasound measurements reflect anterior neck soft tissue thickness.

Several studies showed that mallampati score is inadequate if done alone to predict difficult airway.[10] Our study result also confirmed this conclusion that modified mallampati score with a sensitivity of 16.67%, specificity of 96.39% and positive predictive value of 12.50% and kappa value of 0.112 showed a poor strength of association with prediction of difficult intubation.

Whereas neck circumference when used alone showed a sensitivity of 66.67% and specificity of 2.06% and positive predictive value of 2.06% and kappa value of -0.019 which depicts a very poor strength of association. In this study, after intragroup comparison of bedside screening tests, thyromental distance came out to be the best predictor of difficult intubation with highest area under the curve on ROC Curve. In a meta-analysis of thirty five studies, Shiga T et al concluded that combination of mallamapati score and thyromental distance is most useful bedside test with a positive likelihood ratio of 9.9, 95% CI 3.1-31.9 and combination of tests adds some incremental diagnostic value in comparison to the value of each test alone.[3]

In our study, we have four ultrasound parameters, posterior tongue thickness, ANS-HB, ANS-EP and ANS-AC. 162 patients had tongue thickness ≤ 5.1 cm and 38 patients had tongue thickness >5.1 cm. The result showed that it is a poor predictor (sensitivity of 42.11%, specificity of 83.43% and p value 0.619 and kappa value of 0.176) and it has poor strength of association with prediction of difficult intubation.

Accordingly, ANS – HB was measured in all patients of whom 88.5% had ANS-HB ≤ 1.22 cm and 11.5% had > 1.22 cm. Statistical analysis showed that ANS-HB is a good predictor of difficult intubation (sensitivity of 78.95%, specificity of 95.58% and p value of < 0.0001).

ANS – EP was measured in all patients of whom ANS-EP has a cut-off> 2.48 cm (sensitivity of 57.89%, specificity of 88.95% and p value of 0.0002). It was found to have a fair strength of association with prediction of difficult intubation.

Whereas, ANS –AC has a cut-off > 0.9cm (sensitivity of 84.21%, specificity of 93.92% and p value of < 0.0001). Intragroup comparison of ultrasound parameters showed that ANS-AC is the best predictor of difficult intubation with largest area under the curve on ROC curve.

The similar study conducted in china mainland in 203 patients by Jinhong Wu et al to determine if ultrasound measurements of anterior neck soft tissue thickness at hyoid bone (DSHB), thyrohyoid membrane (DSEM), and anterior commissure (DSAC) levels can be used to predict difficult laryngoscopy. There were 28 patients who came out to be difficult on direct laryngoscopy. DSHB, DSEM, DSAC, and mallampati were greater in the difficult laryngoscopy group (P<0.0001). The areas under the ROC curve (AUCs) of mallampati, DSHB, DSEM, and DSAC were significantly larger compared with the reference line (P<0.0001). **[**11**]**

Finally, best of difficult intubation predictors among the two groups, namely bedside versus ultrasound parameters, were compared. Therefore, TMD and ANS-AC were compared then it was found that TMD was accurate in 93% of cases and ANS –AC was accurate in 92.5% of cases in predicting difficult intubation but there was no statistical difference (p value - 0.704).So, we conclude that, as there was no statistical difference between TMD (conventional bedside test) and ANS-AC (ultrasound parameter), any of these can be used for airway assessment. But definitely further studies are still needed to evaluate new ultrasound parameters and combination of ultrasound parameters and bedside tests, so as to find new and reliable predictors of difficult airway.

Several limitations exist in our study. Glottis exposure by placing laryngoscope is a very complicated procedure, and many subjective and objective factors such as the provider's skills and experience, airway secretions, and abnormalities of anatomical structures are involved in this procedure. The investigators were not totally blinded to the study purpose, and some clinical signs might indicate the possibility of difficult laryngoscopy, which can cause some bias during ultrasound measurements.

Conclusion

Anterior neck soft tissue thicknesses measured by the ultrasound at the level of hyoid bone, epiglottis and vocal cords are independent predictors of difficult intubation. When used alone these commonly used bed side screening tests have poor to moderate predictive power. Therefore combinations of these bedside screening tests with ultrasound parameters can add up some incremental value in diagnosing difficult laryngoscopy.

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