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Ultrasonography versus conventional methods (Mallampati score and thyromental distance) for prediction of difficult airway in adult patients

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ABSTRACT

Background: The poor reliability of traditional screening tools to identify a potentially difficult airway makes the difficult laryngoscopy and tracheal intubation rate remains at 1.5–13%.The hypothesis is that fat pads affect the view during direct laryngoscopy so the increasing thickness of pretracheal soft tissue or pre-epiglottic space could be strong predictors of difficult laryngoscopy as the mobility of the pharyngeal structures is impaired. Upon that, we aimed to evaluate ultrasound-measured distance from skin to epiglottis for prediction of difficult laryngoscopy in Egyptian population.

Methods: This was a prospective single blind randomized clinical study conducted on 80 patients requiring general anesthesia.Preoperatively, airway evaluation was performed using three parameters including Mallampati score, thyromental distance and ultrasound-measured distance from skin to epiglottis at the level of thyrohyoid membrane. The primary outcome was to correlate ultrasound measured distance from skin to epiglottis with difficult laryngoscopy in Egyptian population using Cormack – Lehane grading.

Results: Difficult laryngoscopy group displayed greater thickness of the ultrasound measured distance from the skin to epiglottis(2 ± 0.3 cm versus 1.7 ± 0.3 cm; p = 0.002). The cut-off point for difficult laryngoscopy was >1.85 cm with sensitivity of 80%, specificity of 70.8% and area under the receiver operating characteristic curve was 0.759. Mallampati score and thyromental distance had poor area under the curve = (0.651, 0.670 respectively).

Conclusion: Our study revealed good correlation between ultrasonograohic measurement of the skin to epiglottis distance and Cormack-Lehane grade in Egyptian population, therefore it might be considered as a predictor of difficult laryngoscopy.

Clinical trial number: NCT03799055.

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KEYWORDS
Airway ssessment; difficult laryngoscopy; distance from skin to epiglottis; Egyptian population; ultrasound

1. Introduction

Airway control is one of the main anaesthetic issues and the most important challenge in routine practice is unpredictable difficult intubation which remains a major contributor to mortality and morbidity [1]. Difficult airway does not have widely accepted standard definition, but rather is a constellation of different aspects of airway management. It can be categorized into difficult mask or supraglottic airway (SGA) ventilation, difficult SGA positioning, difficult or unsuccessful intubation of the trachea, and difficult laryngoscopy. The definition of difficult intubation also lacks consensus but is commonly derived from endpoints of laryngoscopy such as the Cormack–Lehane Grade (CLG) [2]. Due to the poor reliability of traditional protocols, algorithms and combinations of screening tools to identify a potentially difficult airway, the difficult laryngoscopy and tracheal intubation rate remains at 1.5–13%. Therefore, any tool can enhance airway assessment must be regarded as an adjunct to the traditional clinical evaluation [3]. Ultrasound (US) has recently emerged as a simple, compact, portable, noninvasive, and safe tool for rapid airway assessment and management in the operating room, emergency department, and intensive care unit [4] Ultrasound has the same efficacy of CT scan in quantifying almost all dimensions of the airway structure [2]. The hypothesis is that fat pads affect the view during direct laryngoscopy so the increasing thickness of pretracheal soft tissue or pre-epiglottic space could be strong predictors of difficult laryngoscopy as the mobility of the pharyngeal structures is impaired [5–7]. Upon that, recent studies have used anterior soft neck tissue thickness to predict difficult intubation and showed correlation between difficult laryngoscopy with different ultrasound parameters [2,8]. One of these parameters which recently had good predictive results was the ultrasonic measured distance from skin to epiglottis at level of thyrohyoid membrane(US-DSE) but with marked variation of its value [1,3,5,6,9–13]. In this regard, our main objective was to evaluate the capability of US-DSE in predicting difficult laryngoscopy in Egyptian populations. Secondary objective was to compare between US- DSE and clinical airway

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screening tests (Mallmpati score & thyromental distance) for prediction of difficult laryngoscopy.

2. Materials and methods

2.1. Patients

The study was performed at Benha University Surgical Hospital, Egypt .The study was conducted from June 2018 to January 2020.The study was approved by Institutional Ethical committee of Benha University Hospitals and was recorded on clinicaltrial.gov (NCT03799055,principal investigator: Baher Abdelhady). Written informed consent was obtained from each patient during the preoperative visit. We enrolled patients (18–60 years old) with an American Society of Anesthesiologists physical status classification score of I to III, scheduled for elective surgical procedure requiring endotracheal intubation and body mass index less than 40 kg/m^2. The exclusion criteria were patient refusal, unable to give consent, pre-existing airway malformations or pathology like facial or cervical fractures, maxillofacial abnormalities, cervical tumors or goiter, history of difficult or intubation, patients with tracheostomy tubes, pregnant patients and body mass index greater than 40 kg/m2. During pre-anesthetic evaluation of the patients, demographic variables were collected from each patient and clinical screening tests to predict a difficult airway were performed in the form of Mallampati score, thyromental distance and ultrasonographic measured distance from skin to epiglottis (DSE). During Mallampati score assessment, patients were seated, head held in neutral position, mouth open as wide as possible and tongue protruded out maximally and patients were instructed not to speak. Thyromental distance (in centimeters) was measured with the patient's neck fully extended with closed mouth. Distance was measured from the thyroid notch to the tip of the mentum.

2.2. Ultrasonigraphic -measured distance from skin to epiglottis (US-DSE) Figure 1

US-DSE was measured at the thyrohyoid membrane level (midway between the hyoid bone and thyroid cartilage) using the linear probe of General Electric; GE, " LOGIQ P5" ultrasound machine with frequency of 10–13 MHz in transverse plane with varying degrees of cephalad/caudal angulation when patients were in supine position with neutral head and neck without a pillow. Patients were instructed to keep their mouth closed and to breathe slowly during measurements to minimize errors during respiration. The Epiglottis was identified at the thyrohyoid membrane level as a linear hypoechoic structure . Its posterior border is delineated by a brighter linear air-mucosa interface and the anterior border is delineated by the hyperechoic pre-epiglottic space. Distance in centimeters was measured from the skin surface to the middle axis of the highest part of epiglottis through the thyrohyoid membrane.

2.3. Anesthesia

Patients were taken to the operating room and were monitored by ASA standard monitors: ECG, NIAB, pulse oximetry, capnography then after preoxygenation with

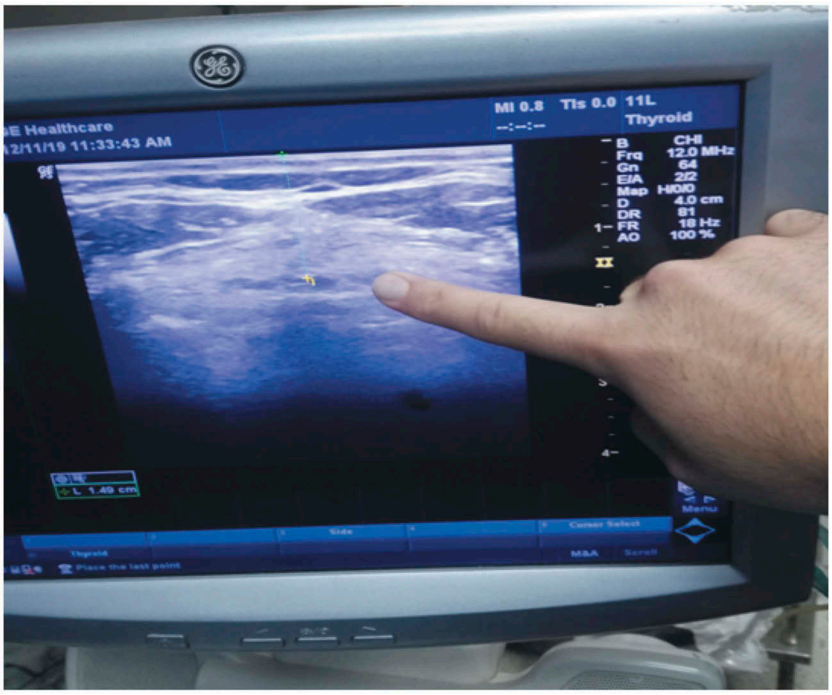

Figure 1. Utrasound measured distance from skin to epiglottis(US-DSE)at transverse view through thyrohoid membrane.(Epiglottis is pointed by index finger of the invstigator).

FiO2: 100% for 3 min, intravenous (IV) midazolam 1 mg and fentanyl 1 ug/kg, anesthesia was induced with injection of propofol 2 mg/kg. After muscle relaxation with injection of rocrounium 0.8 mg/kg IV and ventilation with oxygen and isoflurane 1.5% for 3 min, direct laryngoscopy was done by attending anesthesiologist (with more than 2 years of experience post-qualification) using an appropriate size curved Macintosh blade, and the Cormack–Lehane (CL) laryngoscopic grade was noted. The correct positioning of the endotracheal tube was confirmed via capnography and bilateral auscultation of lungs. The intubating anesthesiologist was not involved in preoperative clinical and sonographic airway assessment. Therefore, he was blinded to the findings of preoperative airway evaluation. Anaesthesia was maintained by isoflurane, booster doses of rocrounium and fentanyl as needed. At the end of surgery, patient was extubated with a train-of-four ratio 0.9 or greater with sugammadex 2 mg/kg.

2.4. Statistical analysis

The collected data was revised, coded, tabulated using Statistical package for Social Science (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp.). Data were presented and suitable analysis was done according to the type of data obtained for each parameter. Mean, Standard deviation (± SD) were used for numerical data. Frequency and percentage were used for non-numerical data. Student T Test was used to assess the statistical significance of the difference between two study group means. Chi-Square test was used to examine the relationship between two qualitative variables. Correlation analysis was used to assess the strength of association between two quantitative variables. The kappa statistic was calculated to estimate agreement between the methods. The strength of agreement of kappa coefficients was guided by the boundaries suggested by Landis and Koch [14]. The ROC Curve (receiver operating characteristic) provides a useful way to evaluate the sensitivity and specificity for quantitative diagnostic measures that categorize cases into one of two groups. The optimum cut off point was defined as that which maximized the AUC value. The area under the ROC curve (AUC) results were described as that by Ludemann et al. [15]. Regression analysis: Logistic, linear regression analyses were used for prediction of risk factors, using generalized linear models. N.B: p is significant if <0.05 at confidence interval 95%.

Sample size was calculated using G Power software version 3.1.9.2 Based on previous studies by J. Pinto, et al (2016).Power and alpha were adjusted at 95% and 5% respectively, a minimum of 15 patients were required for difficult group and 65patients for easy group .At the end of the study, the patients were classified as GROUP A and GROUP B based on the Cormack-Lehane classification of laryngoscopic view. GROUP A: Easy intubation group and GROUP B: Difficult intubation group.

3. Results

During the study period, 231 patients were screened for eligibility. Of these, 92 met the inclusion criteria. 12 were subsequently excluded due to a not achievable ultrasonographic visualization of the epiglottis. Accordingly, 80 patients aged between 18 and 60 years (39) males and (41) female completed the study. Using the Cormack-Lehane grade during direct larygnoscopy, the patients were divided in two groups, 65 patient in the easy group and 15 patients in the difficult group. (50) patients with a Cormack–Lehane grade 1, (15) patients with a Cormack–Lehane grade 2, (7) patients with a Cormack–Lehane grade 3,and (8) patients with a Cormack–Lehane grade 4. Patient demographics are showen in Table 1. Airway evaluation parameters, including Mallmpati score, TMD and US-DSE are shown in Table 2. Regarding the ultrasound measurements, patients with difficult laryngoscopy showed significantly greater thickness of DSE (2 ± 0.3 cm vs 1.7 ± 0.3 cm; p = 0.002). Regarding classic pre-intubation screening tests, statically significant differences were found in the Mallmpati score, which was higher in patients with DL (p = 0.044) and the TMD, which was shorter in these patients (4.3 ± 1.4 cm vs 5 ± 1.1 cm, p = 0.033). ROC curve of clinical airway assessment and ultrasound airway assessment was conducted for discrimination between easy and difficult laryngoscopy

(Figure 2). Mallampati score as well as thyromental distance had poor AUCs (AUC = 0.651, 0.670 respectively). The optimal cutoff values (with sensitivity and specificity in parentheses) for MS and TMD to predict difficult laryngoscopy were over 2 (93.%, 26.2) and less than 4.4 cm (53.3%, 80%), respectively. While DSE had fair AUC (AUC = 0.759) with cut-off point of >1.85 cm with sensitivity of 80% and specificity of 70.8% (Table 3). So, DSE had a better predictive power than any of the involved pre-intubation screening tests (Mallmpati score and thyromental distance) to predict a difficult laryngoscopy. Logistic regression analysis was conducted for prediction of difficult laryngoscopy, using age, gender, BMI, ASA, Mallampati score, TMD, DSE as risk factors. Older age, higher BMI, Mallampati score and DSE were associated with risk of difficult laryngoscopy in univariable analysis. However, according to the multivariate analysis, the inclusion of these new parameter (DSE) in the clinical practice may significantly improve our ability to anticipate a DL (Table 4).

4. Discussion

Ultrasound has become an important tool in the operating theatre and critical care settings for various

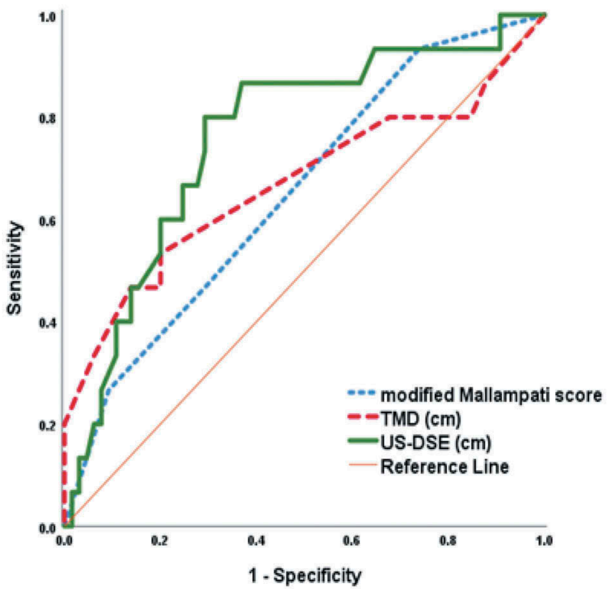

Figure 2. ROC curve of clinical airway assessment and ultrasound airway assessment for discrimination between easy and difficult larvngoscopy.

Table 1. Patient demographics.

		Group (A) (Easy)		Group (B) (Difficult)		
		N = 65		N = 15		*P-value*
Age (years)	Mean ± SD	40.2	±12.3	48.9	±9.6	**0.012**
Males	N, %	30	46.2%	9	60%	0.334
Females	N, %	35	53.8%	6	40%	
BMI (kg/m^2)	Mean ± SD	29.4	±2.4	32	±4.4	**0.002**
ASA 1	N, %	33	50.8%	6	40.0%	0.205
11	N, %	32	49.2%	8	53.3%	
111	N, %	0	0%	1	6.7%	

BMI: Body Mass Index, ASA: American Society of Anesthesiologists physical status classification score, SD: Standard deviation.

Table 2. Preoprative airway evaluating parameter.

			Group (A) (Easy)		Group (B) (Difficult)		
			N = 65		N = 15		*P*-value
Mallampati score	I	N, %	17	26.2%	1	6.7%	**0.044**
	II	N, %	29	44.6%	7	46.7%	
	III	N, %	13	20%	3	20.0%	
	IV	N, %	6	9.2%	4	26.7%	
Thyromental Distance	<6 cm	N, %	57	87.7%	13	86.7%	0.914
	>6 cm	N, %	8	12.3%	2	13.3%	
		Mean ± SD	5	±1.1	4.3	±1.4	**0.033**
US-DSE (cm)		Mean ± SD	1.7	±0.3	2	±0.3	**0.002**

US-DSE: ultrasound measured distance from skin to epiglottis, SD: Standard deviation, N: number.

diagnostic or therapeutic purposes over the last decade. The use of ultrasound in airway management is relatively recent [5]. There are several conventional methods for prediction of difficult laryngoscopy, but none of them are 100% sensitive and specific with no established standard parameters for predicting a difficult laryngoscopy [5]. Many authors have used ultrasound for prediction of difficult laryngoscopy, but to date, there has been low agreement and little evidence about which ultrasound parameters are the best predictors. US-DSE has been shown to be useful in prediction of

Table 3. Performance characteristics of clinical airway assessment and ultrasound airway assessment for discrimination between easy and difficult laryngoscopy.

	Mallampati score	Thyromental Distance	US-DSE
AUC	0.651	0.670	0.759
Cut off value (cm)	>2	<4.4	>1.85
Sensitivity (%)	93.3	53.3	80
Specificity (%)	26.2	80	70.8
PPV (%)	22.6	38.1	38.7
NPV (%)	94.4	88.1	93.9

AUC, area under ROC curve, PPV, positive predictive value, NPV, negative predictive value.
US-DSE: ultrasound measured distance from skin to epiglottis.

difficult laryngoscopy with significant results in several studies [1,3,6,7,8,9,10,11,12,25]; however, those results are seemingly contradictory and surprisingly, some of that studies were conducted in the same country. In this trial, we found a high correlation with the ROC curves between US-DSE and Cormack–Lehane score at direct laryngoscopy and it may be useful to predict a difficult laryngoscopy (DL). Our results showed that US-DSE cut off point for difficult laryngoscopy was >**1.85 cm** with sensitivity of 80% and specificity of 70.8%. Our findings are consistent with those of Wu [3] and Nazir [13] who found out approximately the same cut-off point. Nazir's [13] study was conducted on 90 Indian patients with 19 diffficult laryngoscopies and showed that US-DSE with cut off point **1.77 cm** was able to predict difficult laryngoscopy with sensitivity of 78.9%, and specificity of 76.3%. Wu's [3] study was conducted on a Chinese Han population and included 203 patients with 28 difficult laryngoscopies. The study showed that US-DSE had cut-off point of **1.78 cm** for difficult laryngoscopy with sensitivity of 100.0% and specificity of 66.3%. However, these results are much lower than that of the other authors. Mirunalini's [9] study included 150 Indian patients with 11dificult laryngoscopies. Mirunalini demonstrated that the US-DSE has cutoff point of **2.33 cm** for difficult laryngoscopy with sensitivity of (100%) and specificity of (99.3%) in contrast to Nazir's [13] cutoff point which was **1.77 cm.** Shi et al [10] study included 71 Chinese patients and showed that US-DSE had cutoff point for difficult laryngoscopy group was **2.36 cm** with specificity of 96.43% and sensitivity of 60% in contrast to Wu's [3] cutoff point which was **1.78 cm**. Adhikari's [6] study included African-American population (51 patient). Six patients were categorized as difficult laryngoscopy. US-DSE cut off point for difficult laryngoscopy was **2.8 cm**. Falcetta's [5] study, included 301 adult Italian patients with 28 difficult laryngoscopy patients. The study showed that US-DSE had cut-off value of **2.54 cm** with sensitivity of 82% and specificity of 91%. Pinto's [1] study was conducted on Portuguese population and included 74 adult patients with 17 difficult laryngiscopies. Pinto et al [1] concluded that US-DSE of **2.75 cm** could be used as a cut off point for difficult laryngoscopy with sensitivity of 64.7% and specificity of 77.1%. In 2020,

Table 4. Regression analysis for prediction of difficult laryngoscopy.

	Univariable				Multivariable			
	P	OR	95% CI		*p*	OR	95% CI	
Age	**0.014**	1.039	1.008	1.071	0.096	1.032	0.994	1.072
Gender	0.334	0.729	0.384	1.385				
BMI	**0.008**	1.175	1.044	1.322	0.088	1.132	0.982	1.305
ASA	0.259	1.417	0.774	2.593				
Mallampati score	**0.047**	1.421	1.004	2.012	0.109	1.458	0.919	2.313
Thyromental Distance	0.066	0.77	0.582	1.017				
US-DSE	**0.003**	4.958	1.719	14.3	**0.003**	6.573	1.88	22.982

OR, odds ratio, CI, confidence interval., BMI:Body Mass index, ASA: American Society of Anesthesiologists physical status classification score, US-DSE: ultrasound measured distance from skin to epiglottis

Martínez-García's [11] study included 16 difficult laryngoscopy (32%) of 50 Spanish patients. They established that DSE ≥ **3 cm**, could predict a DL with sensitivity of 56.3% and specificity of 88.2%. On the other hand, more confliction was noted in Parameswari's [12] results which were inconsistent with the results of all authors especially with Mirunalini [9] and Nazir [13] as their studies were in India, also. Parameswari's [12] study was conducted on Indian 130 patients with 12 difficult laryngoscopy patients. The study showed that patients with skin to epiglottis distance **<1.8 cm** were predicted to be difficult and those with distance >18 mm were predicted to be easy with sensitivity of 75% and specificity of 63.6%. In light of the above, there are marked and significant variations in the results of studies that can be due to the absence of specific ultrasound scanning protocols and variations in ultrasound experience among investigators. In addition, the experience of the person who performs laryngoscopy as well as non application of external laryngeal pressure may influence the CL as Martínez-García et al. [11] suggested. Also, it could be related to demographics of the groups and anthropometric differences among different populations and different races. Kajekar et al. [17] postulated the difference between observations is due to the difference in the fat distribution between ethnic groups . This postulation was supported by previous studies using magnetic resonance imaging to prove that [18–20]. Furthermore, this postulation was considered in Komatsu's [21] study in which obese Caucasian and African American patients were included. Komatsu's [21] study showed that ultrasound measured pretracheal tissue thickness (The distance from the skin to the anterior aspect of the airway at the level of vocal cords anterior to the thyroid cartilage) had no significant difference between easy and difficult laryngoscopy patients; however, the study of Ezri et al. [7] showed marked and significant difference in the same parameter between the two laryngoscopy groups but in Middle Eastern Israeli obese patients. Komatsu et al. [21] explained that difference between those two studies by the variation of the fat distribution between ethnic groups. There is no doubt that the lack of homogeneity in methodology and the limited number of publications currently makes it difficult to establish recommendations. Finally, we can say that the results of the studies carried out in Western countries are almost in line with each other. However, regarding Eastern countries, the results of published studies are more conflicting.

Regarding the clinical airway screening tests, Mallampati score and thyromental distance have been reported to be good predictors by many, but were found to be of limited value by others. This significant variation could be attributed to demographics of the groups and anthropometric differences among different populations and different races as well as variations in DSE. We found significant association between Mallampati score and difficult intubation and between thyromental distance and easy intubation as we found that Mallmpati score had AUC = 0.651 which was close to the results published by Nazir [13] (AUC = 0.637) and Andruszkiewicz [22] (AUC = 0.645) while thyromental distance had AUC = 0.67 which was close to the results published by pinto [1] (AUC = 0.662). However, as two recent systematic reviews [23,24] pointed out that the most frequently performed tests like Mallampati score and measurement of thyromental distance have limited to moderate accuracy and have inconsistent capacity to discriminate between patients with difficult and easy airways . In fact, it remains elusive to accurately anticipate airway difficulties, with up to 93% of difficult intubations being unexpected and most often when a difficult intubation is predicted, it does not occur [25].

Our study has several limitations. Small sample size and the fact that there is one race only. In addition, ultrasonographic evaluation of a single parameter as it is very simple to obtain. Furthermore, ultrasonographic measurements were obtained by one investigator which can cause some bias. We could not control factors such as experience of anesthesia providers, equipments used for laryngoscopy and number of intubation attempts. Furthermore, optimal sniffing position and external laryngeal manipulation which were not considered in our study protocol, can affect glottis exposure and CL as the components of best performance of laryngoscopy consist of the optimal sniff position, complete muscle relaxation, skilled laryngoscopist and external laryngeal manipulation if needed. Future research should address these limitations. Achieving a larger sample size combined with a formalized ultrasound scanning protocol and specifying the measurements to be obtained as well as appropriate technique in attaining the measurements would enhance predictive value and maximize results accuracy. In other word, standardized studies are required to link this diagnostic modality with difficult intubation or refuse it.

In summary, our study revealed a strong correlation between sonographic measurement of DSE and a difficult laryngoscopy as well as being better than clinical airway tests (Mallmpati score and thyromental distance) for discrimination between easy and difficult laryngoscopy. Therefore, inclusion of this new parameter in the clinical practice may significantly enhance our ability to anticipate a DL. Further studies are required to clarify whether ultrasonographic evaluation of DSE could deliver significant clinical progress.

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Disclosure statement

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