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Sonographic diaphragmatic parameters as a predictor of weaning failure in critically ill patients in need of invasive mechanical ventilation: a prospective observational cohort study

Prathmesh G. Kumbhar,[1] Manvinder Tejpal,[2] Sunaina T. Karna,[1] Pooja Singh,[1] Saurabh Saigal,[1] Vaishali Waindeskar[1]

[1]Department of Anesthesiology, All India Institute of Medical Sciences, Bhopal, Madhya Pradesh; [2]Department of Community and Family Medicine, All India Institute of Medical Sciences Bhopal, Madhya Pradesh, India

Abstract

Weaning from invasive mechanical ventilation is difficult in critically ill patients, with diaphragmatic dysfunction being a key factor. This prospective observational study aimed to estimate key sonographic diaphragmatic parameters—thickness, thickening fraction, and excursion—in critically ill patients needing invasive mechanical ventilation and evaluate their association with weaning from mechanical ventilation.

Over 18 months, adult patients needing mechanical ventilation were studied in a tertiary care hospital's medical intensive care unit. Besides the demographic and clinical parameters, the sonographic diaphragmatic thickness, thickening fraction, and excursion (DE) were measured via ultrasound at two points: before intubation and at the first spontaneous breathing trial. Patients were followed for 28 days after recruitment in the study to determine weaning outcomes, which were classified as simple or complicated (which included both difficult and prolonged). The baseline diaphragmatic parameters were compared between the outcome groups to determine clinically significant predictors of simple weaning. Out of the 70 patients enrolled in the study, final analysis was possible for 50 of them. Weaning was simple and complicated in 30 and 20 patients, respectively. DE was significant in predicting simple vs. complicated weaning ($p<0.001$). The receiver operating characteristic curve displayed the cut-off of 10.5 mm with an area under the curve of 0.986 (95% confidence interval: 0.903-1.000), with $p<0.0001$. The test demonstrated a sensitivity of 96.77% and a specificity of 100%. Patients with pre-intubation DE<10.5 mm needed more days for weaning [median (interquartile) range of 8 (7-40)] and intensive care [16.50 (10-50)] as compared to those with DE>10.5 mm [4 (2-40)] and 8.50 (5-52)], which was significant with $p<0.001$. In conclusion, pre-intubation sonographic DE of less than 10.5 mm can effectively predict complicated weaning and may be an adjunct in prognostication.

Key words: diaphragmatic dysfunction, ventilator weaning, spontaneous breathing trial, diaphragm ultrasound, diaphragmatic weakness, diaphragmatic excursion.

Correspondence to: Sunaina Tejpal Karna, Department of Anesthesiology, All India Institute of Medical Sciences Bhopal, Saket Nagar, Bhopal, Madhya Pradesh, 462020, India.
Tel.: 9540946869. E-mail: drtejpal@gmail.com

Introduction

Invasive mechanical ventilation *via* endotracheal intubation is a critical, often lifesaving intervention in intensive care units (ICUs) [1]. Weaning patients off mechanical ventilation accounts for nearly 40% of the total ventilation duration [2]. While weaning is straightforward in most cases, it poses challenges in approximately 20-25% of patients, nearly one-fifth failing their first attempt [3-5]. These failures are multifactorial, influenced by patient-specific characteristics, underlying disease pathology, and evolving physiological changes.

Accurate prediction of weaning difficulty can enhance weaning strategies and improve prognostication. Diaphragmatic ultrasound has emerged as a simple, non-invasive, cost-effective, and accessible bedside tool in the ICU, with prior studies highlighting its utility in predicting successful weaning outcomes [6]. A recent systematic review and meta-analysis further validated diaphragmatic ultrasound as a practical and economical method for predicting weaning success, identifying the diaphragmatic thickening fraction (DTF) as a particularly promising parameter [7].

However, there remains a lack of data from the Indian context, especially regarding optimal cut-off values for diaphragmatic ultrasound parameters that could aid in early prognostication of weaning difficulty, even before intubation. Therefore, this study aimed to estimate key diaphragmatic parameters—thickness, thickening fraction, and excursion—in critically ill patients needing invasive mechanical ventilation and to evaluate their association with weaning outcomes during ICU stay.

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Materials and Methods

This prospective observational cohort study was conducted in a tertiary care hospital in Central India from 1 August 2021 to 31 December 2022. Before the study was conducted, the Institutional Ethical Committee (IHEC PGR/2021/PG/Jan/04) approved it. Informed consent was obtained from all participants or, in cases where the patient could not provide consent due to critical illness, from their legally authorized representatives.

The study included adult patients (aged >18 years) admitted to the medical ICU who required invasive mechanical ventilation. Exclusion criteria were: i) pre-existing diaphragmatic injury, phrenic nerve palsy, and surgery of the diaphragm, ii) any local pathology preventing ultrasonographic examinations in the right subcostal area, iii) presence of multiorgan dysfunction or pre-existing myopathy, and iv) mortality within 48 hours of ICU admission (Figure 1).

Patient enrolment commenced upon the recognition of the need for invasive mechanical ventilation. The following data were collected: i) demographic data – age, gender, weight, and height; ii) clinical data – patient history, comorbidities, substance use (*e.g.*, smoking, alcohol, tobacco), and provisional diagnosis; iii) physiological parameters – key vital signs, neurological status assessed using the Glasgow Coma Scale, and nutritional status evaluated

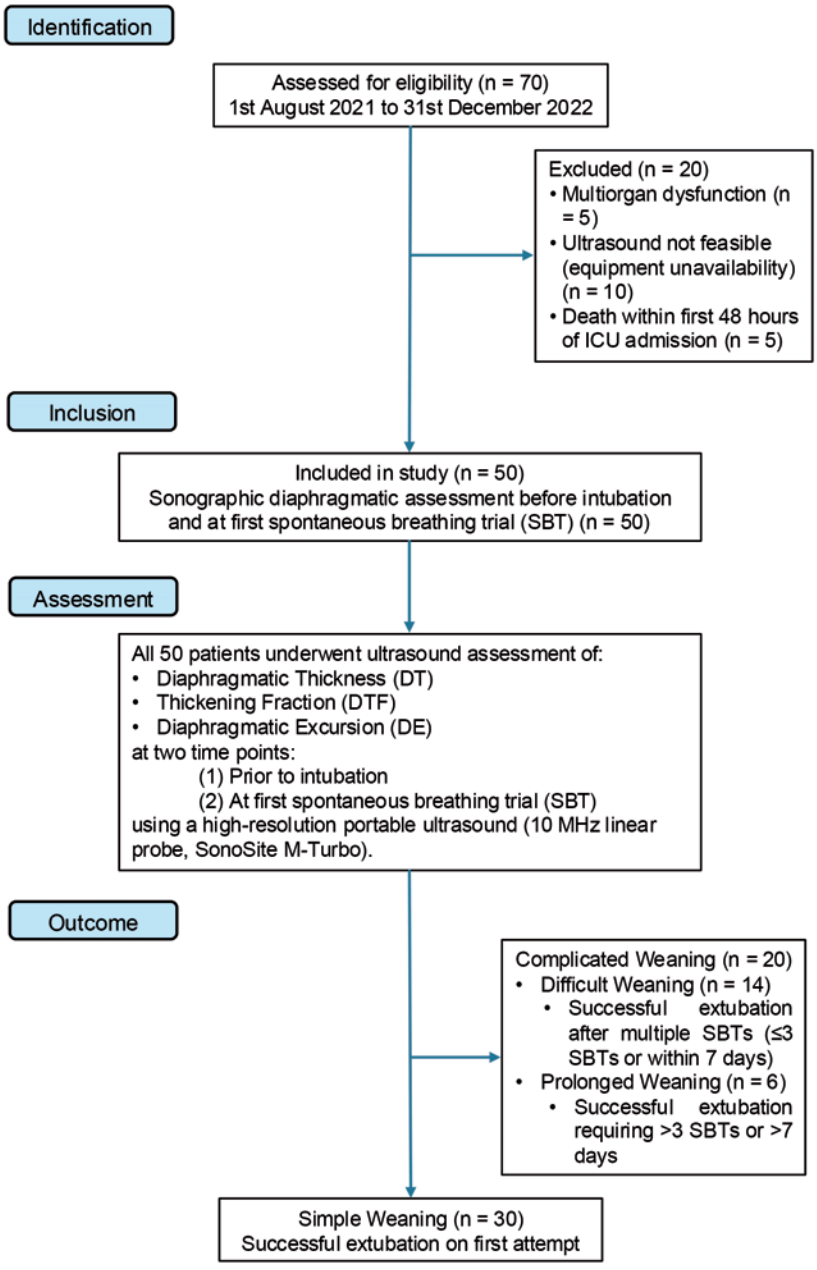


Figure 1. Flowchart of methodology.

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using the Nutritional Risk in Critically Ill score; iv) ICU Severity Scores – illness severity was assessed using the Sequential Organ Failure Assessment score and the Acute Physiology and Chronic Health Evaluation II score [8,9]

Sonographic assessment of diaphragmatic parameters

A high-resolution portable ultrasound device (SonoSite M-Turbo, Fujifilm Sonosite, Inc., Bothell, USA) with a 10 MHz linear array transducer was used to evaluate the diaphragm. The right hemidiaphragm was visualized by placing the transducer perpendicular to the chest wall at the zone of apposition between the diaphragm and the rib cage, along the mid-axillary line between the 8th and 10th intercostal spaces. All assessments were performed with the patient's head end elevated between 20° and 40°.

Diaphragmatic parameters were measured at two key time points: (i) prior to intubation and (ii) at the time of the first spontaneous breathing trial (SBT). The following three parameters were recorded (Figure 2).

i. Diaphragmatic thickness (DT): measured at end-expiration (tDe) and end-inspiration (tDi) during normal tidal breathing using B-mode ultrasound. Three images were acquired for each respiratory phase on the right side and averaged to reduce intra-observer bias. Thickness was measured from the center of the pleural line to the center of the peritoneal line using the ultrasound system's calliper function.
ii. DTF: calculated using the formula (tDi-tDe)×100/tDe. This measurement was derived from the B-mode measurements during tidal breathing.
iii. Diaphragmatic excursion (DE): assessed using M-mode ultrasound. The transducer was placed at the same site for thickness measurement. DE was recorded as the vertical distance (in mm) between end-expiration and end-inspiration on the M-mode tracing.

The first SBT was initiated when standard weaning criteria were met: fraction of inspired oxygen (FiO_2) <0.5, positive end-expiratory pressure <5 cm H_2O, partial pressure of oxygen in arterial blood (PaO_2)/FiO_2 ratio >200, stable hemodynamics, and a conscious, alert, and oriented patient with a Rapid Shallow Breathing Index (RSBI) <105.

Weaning outcomes and follow-up

Weaning outcomes were classified into two categories.

i. Simple weaning: successful extubation on the first attempt, without difficulty or need for reintubation.
ii. Complicated weaning: this category included both difficult and prolonged weaning.

Difficult weaning: failure of the initial weaning attempt, followed by successful extubation within three SBTs or 7 days of the first SBT.

Prolonged weaning: failure of at least three weaning attempts or needing more than 7 days to achieve successful extubation after the first SBT.

Follow-up: all patients were followed until the 28th day of recruitment in the study, which coincided with ICU admission to assess survival status, total duration of invasive mechanical ventilation, and length of ICU stay. The time to ventilator liberation was defined as the number of days from endotracheal intubation to successful discontinuation of mechanical ventilation. If the patient was discharged from intensive care to the ward, the follow-up was continued till 28 days of recruitment in the study.

Statistical analysis

Statistical analysis was performed using IBM SPSS software, version 22 (IBM, Armonk, NY, USA). Continuous variables were summarized as mean (standard deviation) for normally distributed data and median (interquartile range) for non-normally distributed data. Categorical variables were expressed as frequencies and percentages, *i.e.*, n (%).

Associations between categorical variables were assessed using the Chi-square test or Fisher's exact test, as appropriate. The unpaired *t*-test or Mann-Whitney U test was used to compare continuous variables between two groups based on data distribution. Correlations between continuous variables were examined using Pearson's or Spearman's correlation coefficient, depending on normality.

Receiver operating characteristic (ROC) curve analysis was plotted to identify the optimal cut-off value for those sonographic parameters showing statistically significant associations with weaning outcomes. A parameter was considered statistically significant if

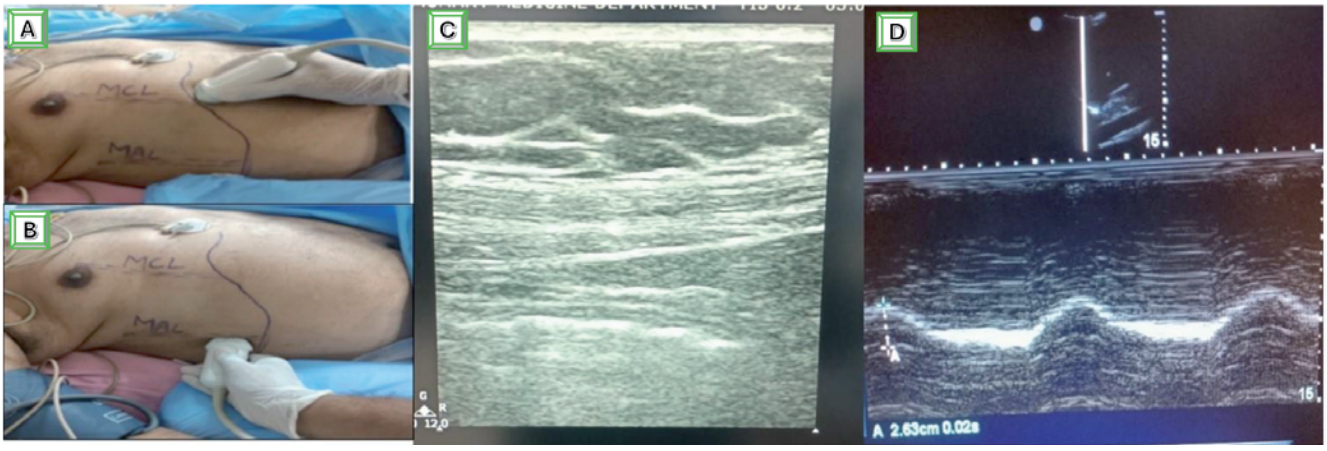


Figure 2. Diaphragm ultrasound (USG). A) Probe position for measurement of diaphragmatic thickness; B) USG B-mode frozen image of diaphragm showing diaphragmatic thickness; C) probe position for measurement of diaphragmatic excursion; D) USG M-mode frozen image of diaphragm showing diaphragmatic excursion.

the area under the curve (AUC) exceeded 0.50 and the p-value was less than 0.05.

Sample size estimation

The sample size was calculated using the online tool at riskcalc.org for prediction models based on ROC analysis. A previous prospective observational study in mechanically ventilated Indian patients had reported an AUC of 0.809 for the DE as a predictor of complicated weaning (incidence: 0.14) [10]. Assuming a power of 80% and accounting for a 20% dropout rate, the minimum required sample size was estimated to be 50 patients.

Post hoc power analysis

After the study, a post hoc power analysis was conducted using the calculator at clincalc.com. The mean DE was 13.42±0.9 mm in the simple weaning group (n=30) and 10.23±0.95 mm in the complicated weaning group. With an alpha (type I error) of 0.05, the calculated power of the study was 100%.

Results

Participant flow and baseline characteristics

Of the 70 patients initially enrolled in the study, 20 were excluded for the following reasons: five developed multiorgan dysfunction, ultrasound assessment was not performed in ten cases due to equipment unavailability, and five patients died within the first 48 hours of ICU admission. Thus, the final analysis was performed on 50 participants.

The study cohort comprised 62% males and 38% females, with a mean age of 43.04±16.9 years and a mean BMI of 25.31±4.9 kg/m^2. Comorbidities were present in 21 patients (42%). Substance use was reported in 23 patients (46%): 11 were smokers, nine consumed alcohol and one was a tobacco chewer. The most common indication for ICU admission was respiratory illness (13/50), followed by metabolic disorders (11/50), hepatic conditions (9/50), and poisoning (9/50), enumerated in Table 1.

Table 2 presents the clinical and diaphragmatic ultrasound parameters (both pre-intubation and at the first SBT.

Weaning outcomes

Among the 50 patients, 30 (60%) achieved simple weaning, while 20 (40%) experienced complicated weaning, 14 with difficult weaning and 6 with prolonged weaning. Statistically significant differences in outcome variables were observed across these groups (Table 3).

Correlation of diaphragmatic sonographic parameters with weaning outcomes

DE measured before intubation was the most significant predictor of weaning outcomes of the three ultrasonographic parameters evaluated. A strong association was found between DE and the categorization into simple *vs.* complicated weaning, with p<0.001 (Table 4).

The ROC curve analysis yielded a DE cut-off of 10.5 mm, with an AUC of 0.986 (95% confidence interval: 0.903-1.000; p<0.0001). The diagnostic performance of this threshold was as follows: sensi-

Table 1. Indications of intensive care admission in the study participants.

Indication	Diagnosis at time of ICU admission	Number of study participants
		13
Respiratory illness	Carbon dioxide narcosis with old pulmonary tuberculosis	2
	Acute respiratory failure with tuberculosis	2
	Pneumonia	3
	Acute exacerbation of chronic obstructive pulmonary disease	6
		8
Metabolic disorders	Diabetic ketoacidosis	5
	Diabetic Ketoacidosis with pre-renal AKI	1
	Alcoholic encephalopathy	1
	Uremic encephalopathy	1
		8
Hepatic disorders	Pyogenic liver abscess with sepsis	2
	Hepatic encephalopathy grade III	6
		12
Infectious aetiology	Dengue fever with sepsis	1
	Resolved melioidosis with PDR urosepsis	2
	Dengue with haemorrhagic shock	3
	Scrub typhus	3
	Right upper limb cellulitis	1
	UTI with sepsis	2
		9
Poisoning	Organophosphate	3
	Paracetamol	2
	Metformin	1
	Phenyl	1
	Snake bite	2

AKI, acute kidney injury; ICU, intensive care unit; PDR, pan drug resistant; UTI, urinary tract infection.

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tivity 96.77%, specificity 100%, positive predictive value 58.48%, negative predictive value 96.7%, and overall accuracy 82.00% (Figure 3).

Based on this DE cut-off, statistically significant differences were observed in ventilator-free days, ICU stay duration, and total hospital stay (Table 5).

Table 2. Clinical, Respiratory and diaphragmatic parameters before intubation and at the time of first spontaneous breathing trial.

Parameters (mean ± standard deviation)	Before intubation	At the time of first SBT
GCS	9.50±1.02	13.38±1.56
NUTRIC score (out of 9)	4.26±0.75	4.70±0.76
SOFA score	10.30±2.68	3.58±2.26
APACHE-2	31.94±9.43	22.46±8.08
Respiratory parameters		
PaO_2/FiO_2 ratio	205.24+46.38	351.90+79.76
ROX index	9.73±5.35	13.73±4.32
RSBI	-	56.67±22.50
SpO_2 (%)	92.40±3.98	98.32±1.62
FiO_2	0.45±0.07	0.36±0.03
RR (breaths/min.)	26.74±10.24	21.44±4.55
Diaphragmatic parameters		
Diaphragm thickness – inspiration (cm)	0.76±0.15	0.76±0.21
Diaphragm thickness – expiration (cm)	0.42±0.10	0.42±0.13
Thickening fraction (%)	0.50±0.08	0.52±0.14
Diaphragm excursion (mm)	12.22±1.89	12.21±1.81

GCS, Glasgow Coma Scale; SBT, spontaneous breathing trial; NUTRIC, Nutrition Risk in Critically Ill; SOFA, Sequential Organ Failure Assessment; APACHE II, Acute Physiology and Chronic Health Evaluation II; PaO_2, partial pressure of oxygen in the arterial blood; FiO_2, fraction of inspired oxygen; ROX, Respiratory rate-Oxygenation Index; RR, respiratory rate; RSBI, Rapid Shallow Breathing Index; SpO_2, peripheral oxygen saturation.

Table 3. Outcome parameters in simple, difficult and prolonged weaning groups.

Characteristics	Simple weaning (n=30, 60%)	Difficult weaning (n=14, 28%)	Prolonged weaning (n=6, 12%)	p
Number of spontaneous breathing trials	2.33±0.48	4.50±0.52	6.17±0.75	<0.001
Days needed for weaning	4.17±0.83	7.21±1.67	27.33±11.89	<0.001
No. of ventilator days	6.17±2.44	9.64±3.08	25.17±12.01	<0.001
Duration of ICU stay (days)	8.70±2.83	13.57±4.11	34.00±13.75	<0.001

Values are presented as mean ± standard deviation. Comparison between groups was done using appropriate statistical tests (one-way analysis of variance); $p<0.05$ was considered statistically significant. ICU, intensive care unit.

Table 4. Comparison of Clinical and Diaphragm parameters between simple and complicated weaning.

Parameters	Simple weaning (n=30)	Complicated weaning (n=20)	p
Diaphragm thickness – inspiration (cm)	0.76±0.20	0.77±0.23	0.74
Diaphragm thickness – expiration (cm)	0.41±0.13	0.43±0.14	0.63
Thickening fraction (%)	0.54±0.15	0.49±0.11	0.17
Diaphragm excursion (mm)	13.42±0.90	10.23±0.95	<0.001
PaO_2/FiO_2 ratio	362.23±61.07	336.39±101.46	0.266
RSBI	48.86±14.61	68.39±27.19	0.002

Values are presented as mean ± standard deviation; PaO_2, partial pressure of oxygen in the arterial blood; FiO_2, fraction of inspired oxygen; RSBI, Rapid Shallow Breathing Index; $p<0.05$ was considered statistically significant.

Table 5. Comparison of outcome parameters based on diaphragmatic excursion.

Outcome parameters	DE>10.5 (n=38)	DE<10.5 (n=12)	p
Number of spontaneous breathing trials	2.82±1.14 2.00 (2-7)	5.25±0.87 5.00 (4-7)	<0.001
Days needed for weaning°	4.00 (2-40)	8.00 (7-40)	<0.001
No. of ventilator days°	6.00 (3-40)	10.00 (8-40)	0.001
Ventilator free days°	2.00 (0-40)	2.50 (0-40)	0.091
Duration of intensive care unit stay (days)°	8.50 (5-52)	16.50 (10-50)	<0.001
Duration of hospital stay (days)°	13.50 (7-67)	21.00 (14-65)	0.002

°Values are expressed as median (interquartile range). Comparison between groups was performed using the Mann-Whitney U test; $p<0.05$ is considered statistically significant. DE, diaphragmatic excursion.

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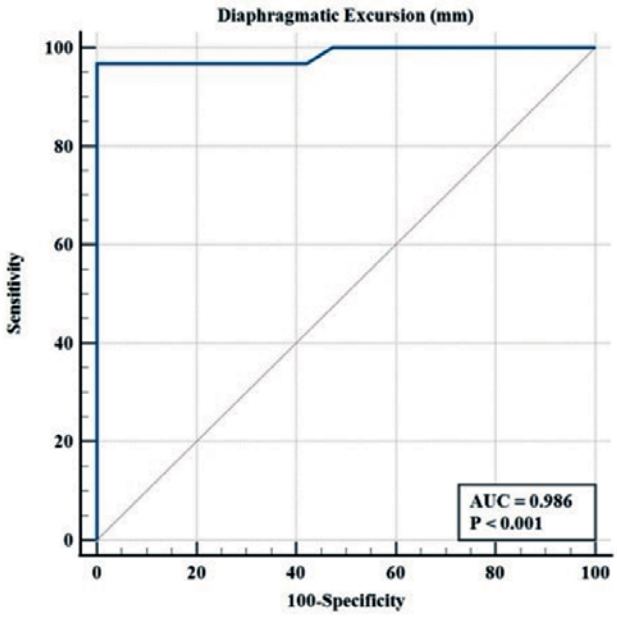


Figure 3. Receiver operating curve of Diaphragmatic excursion values. The area under the curve (AUC) for diaphragmatic excursion was 0.986 with 95% confidence interval (0.903-1.000), which was statistically significant (p<0.0001).

Survival outcomes

All 50 patients survived up to day 28, resulting in a 28-day survival rate of 100% in the study cohort.

Discussion

In this prospective observational cohort study involving 50 critically ill patients aged 18-65 years from central India who required invasive mechanical ventilation, we observed the following key findings.

Ultrasonographic diaphragmatic parameters, including diaphragmatic thickness, thickening fraction, and DE, were feasible to measure before intubation. The mean diaphragmatic thickness at inspiration and expiration was 0.76±0.15 cm and 0.42±0.1 cm, respectively. The mean thickening fraction was 50±8%, and the mean DE was 12.22±1.89 mm. These values remained relatively unchanged at initiating the first SBT.

DE was significantly greater in patients who experienced simple weaning (13.42±0.9 mm) compared to those with complicated weaning (10.23±0.95 mm; p<0.001).

A DE cut-off value of ≥10.5 mm correlated strongly with improved outcomes, including fewer SBTs required, reduced ventilator days, and shorter ICU stays. DE predicted simple weaning with a sensitivity of 96.77% and a negative predictive value of 90.9%.

Weaning from mechanical ventilation remains challenging. Funk *et al*. reported simple, difficult, and prolonged weaning rates of 59%, 26%, and 14%, respectively, among 257 intubated patients [11]. Similarly, Kaur *et al*. noted a 30% rate of SBT failure [12]. Our findings align closely with these studies, showing 60%, 28%, and 12% rates for simple, difficult, and prolonged weaning, respectively.

Previous studies have identified DE as an effective predictor for successful weaning, with suggested DE cut-off values typically ranging between 10 and 14 mm [13-15]. Samanta *et al*. demonstrated the utility of DTF, identifying a cut-off of >25.5% during T-piece trials [16]. A recent systematic review and meta-analysis confirmed that diaphragm excursion and thickening fraction are reliable predictors of weaning outcomes [17,18]. Menis *et al.* also highlighted the significance of DE in tracheostomized patients, showing marked differences between successful and failed weaning attempts [19].

Shamil *et al*. evaluated the diaphragmatic RSBI (D-RSBI) compared to the conventional RSBI, finding superior diagnostic performance for D-RSBI [20]. In our study, conventional RSBI and DE independently correlated with weaning outcomes, underscoring DE's utility as a practical bedside tool.

Demoule *et al*. studied the utility of operator-independent continuous ultrasound monitoring of DE to predict successful weaning from mechanical ventilation. They observed that a DE value of <1.1 cm, 2 minutes after the onset of SBT, predicted weaning failure with a sensitivity of 0.83 and a specificity of 0.68 [21]. Their findings further reinforce the predictive value of DE, even when measured early during the weaning trial.

Although previous research has indicated significant diaphragmatic atrophy with prolonged mechanical ventilation, particularly within the first 3 days, our study cohort demonstrated stable diaphragmatic parameters from intubation to the first SBT despite varying durations of mechanical ventilation [22]. This stability might be attributed to assisted ventilation modes, avoidance of muscle relaxants, judicious sedation for ventilator synchrony, early nutritional interventions, and prompt initiation of weaning efforts. Assisted ventilation modes preserve diaphragmatic function by reducing atrophy [23].

The strengths of our study include a standardized protocol for patient positioning and ultrasonographic technique, minimizing variability and enhancing reproducibility. Furthermore, unlike studies that relied on single-point measurements at the initiation of weaning, we evaluated diaphragmatic parameters before intubation and at the time of the first SBT, allowing earlier prognostication.

Nevertheless, our study has limitations. Its observational design inherently restricts causative inferences. Further medications like steroids act as a confounder by contributing to diaphragmatic weakness as well as delayed weaning, which was not specifically analyzed in our study. Additionally, the small sample size and heterogeneity of critical illnesses limit the generalizability of the findings. Future studies should focus on validating these results in larger cohorts and specific subgroups of critical illness. Diaphragmatic ultrasonography should be considered an adjunctive prognostic tool during intubation.

Conclusions

Our findings reinforce DE as a reliable and sensitive predictor of successful weaning in critically ill patients. Given its non-invasive nature, wide availability, and robust predictive capability, diaphragmatic ultrasonography should become integral to critical care management strategies, particularly in resource-limited settings such as India, where relevant clinical data remain sparse.

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Conflict of interest: the authors declare that no conflict of interest is present.

Ethics approval and consent to participate: the study protocol was approved by the Institutional Human Ethics Committee- Post Graduate Research (IHEC-PGR) of All India Institute of Medical Sciences, Bhopal. The study approval number is IHEC-PGR/2021/PG/Jan/04 dated 21/08/28. The committee assessed the planned project as ethically unobjectionable.

Informed consent: written informed consent was obtained from a legally authorized representative(s) to publish anonymized patient information in this article. The manuscript does not contain any individual person's data in any form.

Patient consent for publication: consent was given by all study participants for publication of anonymized data.

Availability of data and materials: the datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

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