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Original Article

Anaesthesia Section

Comparison of Ultrasound-based Diaphragmatic Thickness Fraction (DTF) with Rapid Shallow Breathing Index and DTF alone for Predicting Successful Weaning from Mechanical Ventilation: A Randomised Control Trial

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ABSTRACT

Introduction: The timing for weaning from mechanical ventilator support is crucial because both early discontinuation and delayed weaning may lead to increased morbidity and mortality as well as high medical cost. Diaphragmatic Thickness Fraction (DTF), among the various ultrasound-based diaphragmatic measurements, can not only assess the readiness to wean but also predict the simple weaning. The Rapid Shallow Breathing Index (RSBI) or Yang Tobin index is a tool that is used in the weaning of mechanical ventilation. RSBI is the ratio of Respiratory Rate To Tidal Volume in litre (RR/VT).

Aim: To estimate success of weaning process by using the ultrasound-guided DTF alone as a weaning predictor, and compare it with the index derived from the combination of both DTF% and RSBI.

Materials and Methods: This randomised control study was conducted on 100 patients admitted to Intensive Care Unit (ICU) during one year, from October 2019 to September 2020. When the patients satisfied the weaning criteria, they were given Spontaneous Breathing Trial (SBT). After SBT the ultrasound was done and RSBI were calculated. Composite Index (CI) was derived by combining DTF% and RSBI. Patients were divided in two groups. In "group C" CI was used as weaning predictor, and in "group D" DTF% alone was taken as weaning predictor. Incidence of weaning failure was noted in each group. The statistical analysis was done using Statistical Package for the Social Sciences (SPSS) Version 19.0. Chi-square test, Student's t-test, Receiver Operating Characteristic (ROC) curve, 2×2 tables were used.

Results: The mean age of the study participants was 35.27±11.88 years. The DTF% value >44.0% was found to be 95.2% sensitive, and 96.2% specific based on the ROC curve. The proportion of cases requiring reintubation was significantly higher in group D (DTF%) compared to group C (CI) (30.0% vs 12.0%). The RSBI with DTF% had a better sensitivity and specificity than DTF% alone.

Conclusion: The DTF% with RSBI is a much better predictor than DTF% alone. Sonography is subjective and has a long learning curve DTF% can be combined with RSBI to improve patient outcome.

Keywords: Diaphragm, Extubation, Inspiratory positive pressure, Tidal volume, Tracheal, Ultrasonography

INTRODUCTION

Gradual withdrawal from mechanical ventilation is termed as weaning [1]. Wrong timing of weaning and extubation can lead to weaning failure or prolonged mechanical ventilation. This can increase morbidity and mortality as well as treatment cost. Simple Weaning (SW) is defined as the process of weaning initiation to extubation at first SBT without any difficulty [2].

Dysfunction of diaphragm leads to prolongation of mechanical ventilation [3]. There may be diaphragm atrophy and dysfunction due to prolonged mechanical ventilation. Diaphragmatic dysfunction may ensue even after short duration of mechanical ventilation which in turn may lead to difficulty in weaning [4]. A study showed that diaphragmatic thickness may decrease by 6% or 7.5% per day in patients who are on mechanical ventilation [5].

The RSBI is described as the ratio of RR/VT, the value of RSBI >105 breaths/min/L indicate high probability of weaning failure while RSBI <105 breaths/min/L is the predictor of successful weaning [6].

Diaphragm ultrasound is a new tool in the armamentarium, which can detect the loss of diaphragm thickness during mechanical ventilation and a decrease in diaphragm thickness over time indicate atrophy. The right hemidiaphragm thickness can be easily and uniformly measured [7].

Low contractility of diaphragm is associated with rapid decrease in diaphragm thickness, whereas high diaphragm contractility is associated with increase in diaphragm thickness. Diaphragm thickness does not vary over time following extubating or in non ventilated patients. Patients have to be weaned off from the ventilator as early as possible but some of them found to be difficult to wean [8,9]. Diaphragm function is an important determinant of successful weaning and recovery from critical illness [10,11]. The value of diaphragmatic thickening fraction (DTF%) >36% is associated with successful weaning [12].

The aim of the study was to determine the efficacy of composite score and DTF in predicting successful weaning. The primary outcome measure was the incidence of reintubation in patients undergoing weaning trial after fulfilling weaning criteria. The secondary outcomes measures were maximum diaphragmatic thickness during full inspiration and the minimum thickness during end expiration (DTi/DTe).

MATERIALS AND METHODS

The randomised control trial was conducted in a tertiary level critical care unit at King George's Medical University, Lucknow, Uttar Pradesh, India, from October 2019 to September 2020. The study was started after obtaining an Institutional Ethical Committee (IEC) approval (IRB NO- ECR/262/Inst/UP/2013/RR-16).

Inclusion criteria: After written and informed consent from next to kin, total 100 adult patients aged ≥18 years, of either gender and admitted to critical care unit, on mechanical ventilation longer than 24 hours were included in this study using consecutive sampling method.

Exclusion criteria: Any patient with any pre-existing diaphragm disease, patients with increased intra-abdominal pressure, phrenic nerve palsy and any breach in skin in subcostal area thus preventing diaphragm ultrasound examinations were excluded from study.

Sample size calculation: For sample size calculation, the study by Samanta S et al., was taken [2]. It was calculated by using the minimum sensitivity of among various diaphragm parameters used in prediction of simple weaning using the formula:

$$n=\frac{z^2_{\alpha}S_n(100-S_n)}{pe^2}$$

Where Sn=72%, the minimum sensitivity of diaphragm parameter (reference), p=50%, the expected minimum level of AUROC, e=0.2, error factor, Type I error (level of significance) α=0.05, Power of study=80%, Then minimum sample size required to be n=39 per group. A total of 100 patients were aimed for the study, assuming 10% dropouts from the study.

It was ensured that before undergoing their first SBT the patients were afebrile, conscious oriented and alert, co-operative, with stable haemodynamic without or minimum vasopressor support and P/F ratio >200 at FiO_2 <50% with Positive End Expiratory Pressure (PEEP) ≤5 cmH_2O and RR of <30 breaths/minute. The SBT was given in the form of pressure support ventilation of 8 cmH_2O with PEEP of 5 cmH_2O with Negative Pressure Trigger (NPT) of 2 cmH_2O. All patients who successfully tolerated the Pressure Support Ventilation (PSV) trial with NPT of 2 cmH_20 were subsequently randomised in two groups (group C=50, group D=50), using computer generated random number. Patients in both groups were considered for extubation according to group allocation (group C and D) as above. Any patient whose condition deteriorated with application of PSV at NPTs during SBT was excluded from study and managed as per attending consultant's decision.

Measurement of Diaphragm Thickness

Diaphragm thickness measurements were taken at PSV at 2 cmH_2O NPT. A minimum period of 15 to 20 minutes was used to achieve steady-state of ventilation during PSV. After achieving steady-state ventilation, diaphragmatic measurements were taken. The right side of hemidiaphragms was accessed via the intercostal spaces. With the patient in the semi-upright position, a linear high frequency (7-18 MHz) transducer of SonoScape S30 ultrasound was used to measure diaphragm thickness at the zone of opposition. The diaphragm thickness was measured by putting the probe at the anterior axillary line in the longitudinal plane, between 7th and 9th intercostal space. The liver window was used to visualise diaphragm. The normal diaphragm was visualised between two echogenic lines, which represent the parietal pleura and the peritoneal membrane. The measurements of diaphragm thickness were noted during full inspiration and expiration. The DTF (%) was calculated as the difference between DTi and DTe divided by DTe×100 by using following formula [13].

$$DTF\ (\%)=\frac{DTi-DTe}{DTe}\times 100$$

DTF% diaphragm thickening fraction

DTi diaphragmatic thickness at end of inspiration

DTe diaphragmatic thickness at end of expiration

The ultrasounds were done by the intensivist. Average of three readings taken at least three different times each lasting 10-15 min was ensured to avoid intra-observer variability to less than 10% and establish reproducibility.

Rapid Shallow Breathing Index (RSBI)

The RSBI was calculated at PSV at 2 NPT cmH_2O using formula i.e.

RSBI=respiratory rate/tidal volume (litre) [14].

Group D (DTF% group): In this group, all patients were extubated according to diaphragmatic thickness fraction (DTF%). Any patients with DTF (%) ≥36% were extubated. While patients with DTF (%) <36% were excluded from study and management was decided as per attending consultant.

Group C (composite score group): In this group, all patients were extubated according to CI including DTF% and RSBI. The DTF% and RSBI were scored arbitrary to drive composite score, as shown in [Table/Fig-1].

Score	1	2	3
DTF at 2 NPT (%)	>36	36	<36
RSBI at 2 NPT (breaths/min/L)	<105	105	>105

[Table/Fig-1]: Composite score.
Composite Score (DTF% Score+RSBI Score): minimum 2 and maximum 6; DTF: Diaphragmatic thickness fraction; RSBI: Rapid shallow breathing index; NPT: Negative pressure triggers

All patients with composite score <5 were extubated. The patients had composite score of ≥5 were excluded from the study and managed as per attending consultant. If any patient in either group, showed decrease in consciousness, increased work of breathing (respiratory rate >35 breaths/min, use of accessory muscle, unstable haemodynamic) were considered for reintubation. Reintubation within 48 hours of extubation was considered as weaning failure. The independent intensivist who took decisions for reintubation was unaware of group allocation. All the patients who could be successfully weaned from mechanical ventilator were monitored for the next 72 to 96 hrs. The patients who were haemodynamically stable, alert, oriented and without oxygen support, they were shifted to their respective ward/department.

STATISTICAL ANALYSIS

The SPSS version 19.0 software was used for analysis. The values are represented in number (%) and mean±SD. Chi-square test, Student's t-test, ROC curve, 2*2 tables were used.

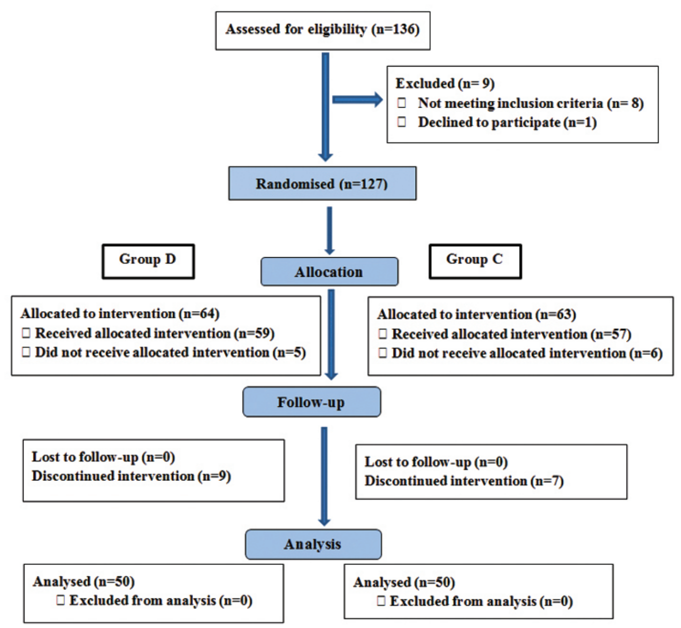
RESULTS

Total 136 patients of age 18-66 years were screened for eligibility for this study. Total 127 patients, fulfilling the inclusion criteria, were randomised in two groups. During weaning process 11 patients did not tolerate SBT. After group intervention, 16 patients were excluded from final analysis as they were extubated without Lung Ultrasound (LUS). They had to be extubated as patients were off sedation and it was not justified to wait for intervention. There was not enough time to perform LUS. Among these 16 patients, one patient was self-extubated before intervention [Table/Fig-2].

The demographic profile and baseline clinical variable of the both groups were comparable. The mean age was 33.30±10.44 and 37.24±12.98 in group C and D, respectively [Table/Fig-3]. The distribution of patients requiring either medical or surgical problems were found to be equal in both groups [Table/Fig-4].

Statistically significant difference was noted in values of DTi and DTF in both the groups [Table/Fig-5]. The number of patients who required reintubation within 48 hours, were significantly more in group D, in comparison to group C [15 (30%) vs 6 (12%), p-value:0.027] [Table/Fig-6].

The patients who required reintubation, n=21, DTF%=39.66±3.68d had significantly lower DTF% than who did not require reintubation n=79, DTF%=76.36±19.20, (p-value <0.0001) [Table/Fig-7].



[Table/Fig-2]: CONSORT diagram.

S. No.	Parameter	Mean±SD Group C (n=50)	Mean±SD Group D (n=50)	Mean±SD Total (N=100)
1	Age (years)	33.30±10.44	37.24±12.98	35.27±11.88
	(Range)	18-66	20-62	18-66
	't'=-1.673; p=0.098			
2	Gender	No. (%)	No. (%)	No. (%)
	Female	26 (52.0)	30 (60.0)	56 (56.0)
	Male	24 (48.0)	20 (40.0)	44 (44.0)
	χ^2=0.649 (df=1); p=0.420			

[Table/Fig-3]: Between group comparison of demographic variables.

S. No.	Variables	Group C (n=50) No. (%)	Group D (n=50) No. (%)	Total (N=100) No. (%)
1	Type of Intervention			
	Medical	15 (30.0)	15 (30.0)	30 (30.0)
	Surgical	35 (70.0)	35 (70.0)	70 (70.0)
	χ^2=0.0 (df=1); p=1.000			
2	Type of illness			
	Sepsis	8 (16)	7 (14)	15 (15)
	CNS	12 (24)	18 (36)	30 (30)
	CVS	7 (14)	3 (6)	10 (10)
	Respiratory	11 (22)	8 (16)	19 (19)
	Others	12 (24)	14 (28)	26 (26)
	χ^2=3.494 (df=4); p=0.479			
3	Co-existing illness			
	None	35 (70.0)	33 (66.0)	68 (68.0)
	COPD	6 (12.0)	5 (10.0)	11 (11.0)
	Diabetes mellitus	6 (12.0)	5 (10.0)	11 (11.0)
	Hypertension (HTN)	0	3 (6.0)	3 (3.0)
	HTN+Diabetes	1 (2.0)	4 (8.0)	5 (5.0)
	Hypothyroid	1 (2.0)	0	1 (1.0)
	Other	1 (2.0)	0	1 (1.0)
	χ^2=7.041(df=6); p=0.317			

[Table/Fig-4]: Group comparison of patients' clinical characteristics.
CNS: Central nervous system; CVS: Cardio vascular system; COPD: Chronic obstructive pulmonary disease

In the study population (n=100), the DTF% value >44% {based on 'The Closest to (0, 1) Criteria'} showed 95.2% sensitivity, 96.2% specificity with area under ROC curve as 0.977 [Table/Fig-8]. All patients who were weaned off in group C were transferred to ward in the next 3-4 days. While in group D, three patients stayed in ICU longer than four days after weaning.

S. No.	DT	Group C (n=50) Mean±SD	Group D (n=50) Mean±SD	Student 't' test 't'	Student 't' test 'p'
1	DTi (mm)	7.85±1.98	6.57±1.52	3.641	<0.001
2	DTe (mm)	4.65±1.15	3.91±0.76	3.793	<0.001
3	DTF (%)	69.18±20.95	68.14±24.68	0.227	0.902

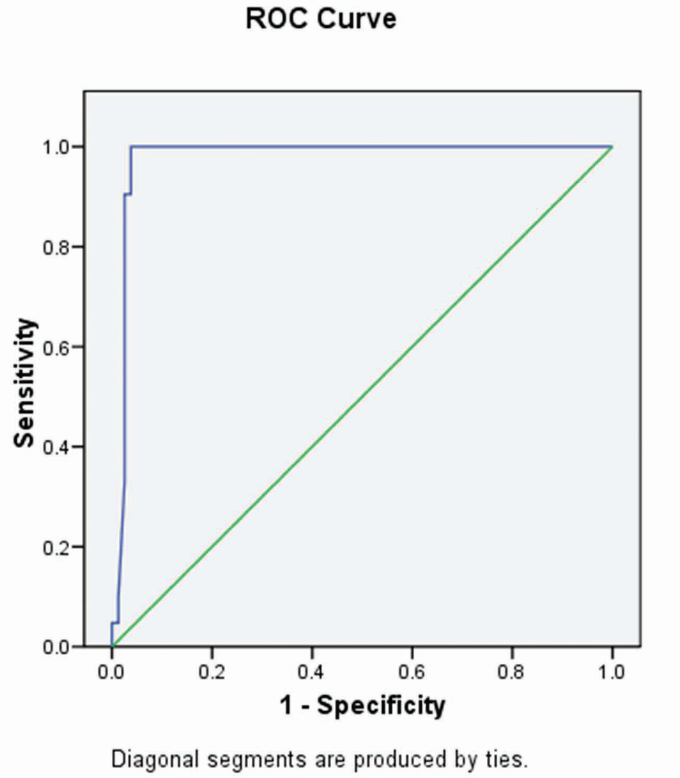
[Table/Fig-5]: Diaphragmatic thickness at -2 cmH_2O negative pressure triggers in both groups.

Reintubation	Group C (n, % out of 50)	Group D (n, % out of 50)	Total (N, % out of 100)
Not required	44 (88.0)	35 (70.0)	79 (79.0)
Required	6 (12.0)	15 (30.0)	21 (21.0)

[Table/Fig-6]: Between group comparison of requirement of reintubation.
χ^2=4.882 (df=1); p=0.027

	Intubation	n	Min	Max	Mean	SD
DTf% (both group C+D)	Not required	79	32.8	134.4	76.36	19.20
	Required	21	28.8	44.4	39.66	3.68
	Total	100	28.8	134.46	68.66	22.78
	't'=8.687; p<0.0001					

[Table/Fig-7]: Requirement of reintubation in group C and group D.



Area under curve	SE	'p'	95% CI Lower bound	95% CI Upper bound
0.977	0.016	<0.001	0.946	1.007

[Table/Fig-8]: ROC curve table.

DISCUSSION

In the ICU, weaning a patient from mechanical ventilation is of great importance. Timely extubation of the patient depends upon precise assessment and intelligent prediction of patient's respiratory strength which decreases the possibility of weaning failure and associated morbidity. Weaning failure is defined as either the failure of SBT or the need for reintubation within 48 hours following extubation [15]. The USG has the advantage of being non invasive diagnostic method, which is free of radiation and easily available bed side in ICUs. As the diaphragm is the key muscle of respiration, the diaphragmatic thickness measurements are used to assess the diaphragm function. Measurement of DTF% by ultrasound is an important tool for predicting the weaning success or failure. Diaphragmatic thickness can be measured by M or B mode but B mode is mainly used for diaphragmatic thickness (DT) measurement. Diaphragmatic thickness tends to reduce by 6% or 7.5% per day in mechanically ventilated patients. Patients with diaphragmatic dysfunction showed greater difficulty in weaning than patients without [16].

In the study, it was found that composite score (DTF% with RSBI) was a better predictor of successful weaning than DTF% alone. Previous studies considered DTF% as a weaning predictor and concluded with different cut-offs of DTF% [17]. Ali ER et al., reported the cut off values for diaphragmatic ultrasound predicting successful weaning to be DTF >30 [18]. Tanaka MA et al., reported the cut-off values for DTF associated with weaning failure- 25.9% on right diaphragm and, 23.1% on left side [19]. None of the studies predicted a cut-off that could be used as weaning protocol. This is primarily because ultrasound is an operator dependent modality which differs person to person. RSBI gained most accuracy for predicting success of extubation among all non ultrasound ventilator weaning indices. This study planned to evaluate a composite score for predicting weaning in which RSBI and DTF% both were included.

A study conducted by Pirompanich P et al., compared composition of DTF% and RSBI with RSBI alone for weaning predictions. They concluded that composite of DTF% and RSBI is better than RSBI alone. They also reported that combination of right DTF% of more than or equal to 26% and RSBI less than or equal to 105 had an accuracy of 88.2%, sensitivity of 92.0%, specificity of 77.8%, positive predictive value of 92.0%, and negative predictive value of 77.8 [14].

In this study sensitivity, specificity, positive predictive value and negative predictive value of composite score (DTF%+RSBI) were 100.0%, 88.6%, 54.5%, 100.0%. It was found that sensitivity and specificity of DTF% >44% for extubation success were 95.2% and 96.2%. Similarly, DiNino E et al., conducted a prospective study and they took DTf% as a weaning predictor. They found the combined sensitivity and specificity of Δtdi%≥30% for extubation success was 88% and 71%, respectively [15]. The results of meta-analysis by Li C et al., reported sensitivities for diaphragm excursion (DE) and diaphragm thickness fraction (DTF) were 0.786 and 0.893, and specificities were 0.711 and 0.796, respectively [20]. The study conducted by Gok F et al., to compare DTf and RSBI for successful weaning, found the cut-off values of 64 for RSBI, 27.5 for DTF, 1.3 cm for the DE, and 6.5 for the LUS scores [21].

Before the use of thoracic ultrasound in ICU, RSBI was the best clinical indicator for assessment of readiness to wean. But in the current scenario sonography provides the opportunity of real time assessment of diaphragm function. The study included both these parameters in consideration, and showed that the successful weaning rate was 84% when extubation was based on composite score, while it was 70% with DTF alone. The study concludes that when the ultrasonographic evaluation of diaphragm was accompanied by RSBI the chances of weaning failure were less.

Limitation(s)

It was a single centre study. The patients could not be studied with respect to the disease severity. It was not possible in this study as this would require a larger sample size. Independent trigger sensitivity for each patient group could not be individually tested. Inter-observer variability was also not taken into account.

CONCLUSION(S)

Point-of-care ultrasound examination to assess diaphragm function is a clinically viable option and has good reproducibility. This can help clinicians in deciding when a patient is weaning-ready during critical care. The DTF alone is a good predictor of successful weaning, but the sensitivity increases when combined with RSBI. Addition of RSBI to composite score results in better predictability for successful extubation and can assure the intensivist that the chances of reintubation are much less. As the calculation of RSBI is simple and require no additional cost or expertise, it may be a good addition in armamentarium of an intensivist, who is going to weaning the mechanically ventilated patient. The study concluded that composite score would be much better predictor than DTf% alone for weaning from mechanical ventilation.

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- Manual Googling: Mar 30, 2022
- iThenticate Software: May 25, 2022 (17%)

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