MMJ

Malta Medical Journal, 2024; 36(4)
http://mmsjournals.org/index.php/mmj/42

ORIGINAL ARTICLE

The Effects of a Weaning Protocol in ITU

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Background

Protocol driven ventilator discontinuation procedures have reduced ventilator days for patients in Intensive Care Unit (ITU) and are associated with better patient prognosis. In order to improve successful extubations, a weaning protocol was created for the Mater Dei Hospital (MDH) ITU using evidence-based criteria.

Aim

The purpose of this audit was to assess whether implementation of a mechanical ventilation weaning protocol had an impact on successful extubations as well as improved clinician and nursing knowledge regarding weaning.

Method

A prospective study was carried out to assess successful extubations before and after implementation of a ventilation weaning protocol. Adult patients who were ventilated for more than 7 days were included in the study. A questionnaire about mechanical ventilation and weaning was distributed to ITU physicians and nurses before and after implementation of the weaning protocol.

Results

We could not find any statistically significant differences in weaning success after the introduction of the weaning protocol. Information retention did not improve after usage of the protocol.

Conclusion

The introduction of an ITU weaning protocol at Mater Dei Hospital did not increase the number of successful extubations. Despite enhanced staff perception of weaning, a mechanical ventilation questionnaire did not improve retention of knowledge.

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INTRODUCTION

Mechanical ventilation is a standard of care in ITU, with respiratory support being necessary most commonly after respiratory, cardiac or neurological impairment. However invasive mechanical ventilation is a double-edged sword, with the possibility of ventilator-induced lung injury (VILI) or ventilator associated pneumonia (VAP), which increases with the duration of mechanical ventilation. According to the International Nosocomial Infection Control Consortium the overall rate of VAPs is 13.6 cases per 1000 ventilator days[1] with prolonged ventilation leading to a greater risk of ventilator dependency and death.[2] Indeed such risk is not constant but higher in the first week of mechanical ventilation.[3]

It is therefore ideal to wean patients as quickly as possible while still achieve successful extubation and discontinuation of mechanical ventilation. Weaning is the process of reducing ventilatory support to a point where a patient can breathe spontaneously unassisted. Weaning practices differ in different centres and countries as demonstrated by Burns et al[4] where 142 international ITUs utilised various directives, daily screening, ventilator modes and clinician roles in weaning.

Weaning success can be categorized into the following three groups[5]:

- Simple – ventilator discontinued after first assessment and weaning attempt
- Difficult – patients who fail their first weaning attempt and require up to seven days of ventilation
- Prolonged – ventilator discontinued after more than seven days from initial assessment

About 20% of mechanically ventilated patients require a more gradual and prolonged weaning process.[5] Causes for this are several, and include cardiac dysfunction, neuromuscular weakness and endocrine issues.

Previous studies have demonstrated that there is no superior method for weaning patients. Instead focus has shifted to implementation of weaning protocols that guide medical and nursing staff according to established practices.[6]

This research aims to assess the feasibility and impact of a new weaning protocol in our local ITU. We also sought to assess clinician and nursing knowledge regarding weaning and improve such knowledge.

The weaning protocol introduced in the Intensive Therapy Unit at Mater Dei Hospital was the result of an extensive literature review of best practices. We also considered local practices and needs. It was not intended for patients who were on short-term ventilation, had severe obesity or had suffered a spinal cord injury. Criteria were set when the clinician was guided to start the weaning process.

The protocol included patients with either a tracheostomy or an endotracheal tube. It also provided the following two alternative weaning processes: gradual pressure support reductions (PS) or the use of tracheostomy masks if a tracheostomy was present. The complete protocol is shown in **Digital Supplemental File 1**.

MATERIALS & METHODS

A prospective study of weaning practices was carried out before and after implementation of a ventilation weaning protocol in the Intensive Therapy Unit (ITU) at Mater Dei Hospital (MDH) from February 2020 to November 2021. Approval for the study was sought and obtained by University Research and Ethics Committee of the University of Malta (031220194123) as well as the Mater Dei Data Protection Office.

Adult patients (> 18 years) who were ventilated for more than 7 days were included in the study. Patients were excluded for the following reasons: <7 days ventilated, <18 years, BMI >40, spinal cord injury or COVID pneumonia/ARDS.

Data collected included the following: reason for admission, length of stay in ITU, number of days mechanically ventilated, number of failed extubations, complications after failed extubations, type of airway, method of weaning, use of spontaneous breathing trial, neurological or respiratory problems, presence of delirium and mortality.

Prior to the launch of the new weaning protocol, a questionnaire about mechanical ventilation and weaning was distributed to physicians and nurses working in ITU at MDH. After training of staff, the same questionnaire with the addition of three questions was re-distributed after implementation of the protocol to assess information retention and adherence. The questionnaire is described in **Digital Supplemental File 2**.

The primary outcome was the number of successful extubations before and after the implementation of the weaning protocol. The secondary outcomes included information retention by ITU staff, the total

ventilator days and mortality rate before and after implementation of the protocol.

Statistical Analysis

Data was transcribed into an MS Excel® file (Microsoft Washington US). Statistical analysis was performed with R (version 3.5.1), using R Studio (Version 1.1.442). A p-value of 0.05 was taken as significant. Univariate analysis was performed initially, using parametric or non-parametric tests where appropriate. The data was first checked for normality and skewness using visual methods, and other tests such as Shapiro's test of normality. When appropriate, t-tests, Mann-Whitney U tests, Kruskal-Wallis test and chi-squared tests were used for univariate analysis.

RESULTS

A total of 82 patients were recruited into this study. The demographics of both groups were similar, with the patients enrolled before the introduction of the protocol being non-significantly older. The majority of both groups were admitted to ITU for medical reasons (59% of all patients). This is shown in Table 1. Patients spent a median of 22 days (IQR: 14 – 38) in ITU, with a median of 17.5 days (IQR: 11.25 – 26] spent on a mechanical ventilator.

Following the introduction of the protocol, more patients were weaned with a tracheostomy mask, but this was not statistically different (Before: 45% vs After: 50%, p = 0.67). As shown in Table 2, there were no differences between outcomes in the two groups.

Table 1 Demographic data of patients enrolled in study before and after the implementation of a weaning protocol

	Pre-Protocol (n=40)	Post-Protocol (n=40)
Median Age (years)	62.5 [IQR: 50.75 - 73]	57 [IQR: 42 - 65.25]
Male (n / %)	30 (75%)	26 (65%)
Reason for admission (medical)	24 (60%)	24 (60%)
Underlying Respiratory Conditions	8 (20%)	5 (13%)
Neurological Problems	17 (43%)	16 (40%)

Questionnaire Responses

The questionnaire was distributed to 232 nurses and anaesthetists, see Table 3. In the pre-protocol phase, 61 participants answered the questionnaire. 61% of the participants were nurses whereas 39% were ITU doctors. The majority of participants had worked in ITU for more than 5 years.

Most participants (77%) could recognize signs that would prevent initiating weaning; however, far less (33%) could recognize the signs and symptoms that would halt weaning once started. 90% of participants knew the definition of the rapid shallow breathing index; however, only 31% knew the significance of its value. A minority of participants (21%) knew about a spontaneous breathing trial with far less (15%) knowing how to carry it out. Despite this, 49% of participants knew when a spontaneous breathing

Table 2 Differences in outcomes between the two study groups

	Pre-Protocol (n=40)	Post-Protocol (n=40)	p value
Median duration of ITU stay (days)	23 [IQR: 12.75 - 38]	21.5 [IQR: 15.25 - 37]	
Median duration of MV (days)	17 [IQR: 11.5 - 27.5]	18 [IQR: 11.25 - 21]	p = 0.97
Number of failed extubations	9 (23%)	13 (33%)	p = 0.46
Number of VAPs	5	4	
Airway type (tracheostomies)	23 (58%)	26 (65%)	
Tracheostomy mask weaning	18 (45%)	21 (53%)	
Pressures support weaning	22 (55%)	19 (47%)	
Delirium	8 (20%)	10 (25%)	
Mortality	17 (43%)	11 (28%)	p = 0.16

Table 3 *Questionnaire responses pre- and post-protocol implementation*

	Pre Protocol			Post-Protocol		
Question	**Total Correct (n/%)**	**Nurses**	**Doctors**	**Total Correct (n/%)**	**Nurses**	**Doctors**
4	47 / 77%	26	21	54 / 74%	29	25
5	8 / 13%	2	6	11 / 15%	3	7
6	20 / 33%	12	8	20 / 28%	11	9
7	50 / 82%	33	22	64 / 88%	37	27
8	10 / 16%	3	7	21 / 29%	5	16
9	4 / 7%	2	2	15 / 21%	8	7
10	9 / 15%	1	8	10 / 14%	1	9
11	15 / 25%	6	9	20 / 27%	8	12

trial should be performed. An overwhelming 87% of participants felt a protocol would improve the rate of successful extubation.

After implementing the protocol, the questionnaire was re-sent to assess information retention as well as user feedback. 73 participants responded with the majority being nurses (60%) and those that worked in ITU for more than 10 years (37%).

Information retention did not improve after usage of the protocol. However, overall attitude towards weaning was positive. This was evident in the second survey, which had additional questions regarding staff usage of the protocol. 82% of participants felt more comfortable with weaning after the introduction of the protocol. 83% felt it was easy to use while 67% of participants felt there has been an improvement in weaning from the ventilator.

DISCUSSION

Advanced age, more complex surgery and higher expectations have led to prolonged ventilatory weaning becoming an ever-increasing problem in most ICUs.[7] However there is a paucity of large prospective trials to help guide intensivists in decision-making for individual patients.

Multiple factors have been identified as potential contributors to prolonged ventilatory weaning such as positive fluid balance, neuromuscular diseases, advanced age and cardiac dysfunction. The relative frequency and degree of contribution of each individual factor among cohorts of patients requiring prolonged ventilation has not been defined.[7] Individual weaning predictors lack precision to guide clinical decisions; weaning strategies should thus incorporate non-physician-implemented protocols that utilize daily SBTs of progressively increasing duration after a certain level of ventilatory support reduction has occurred.[7]

Balas et al introduced an ABCDE bundle in nearly 200 patients in a single ICU, and compared ventilator outcomes in patients both pre and post implementation.[3] Patients who followed the ABCDE bundle underwent SBTs more frequently and experienced less mechanical support, more ventilator free days and less delirium. This effect was not small; patients in the post-implementation phase had 3 days less of mechanical ventilation. This occurred even in patients who initially failed an SBT.

One may also note the study by Jubran et al who attempted to assess the difference in outcomes between a gradual pressure-support reduction or use of a tracheostomy mask.[8] Patients included in this study had to undergo a trial period without mechanical support for a maximum of five days. Interestingly out of 500 patients enrolled, 160 passed this trial period with no further intervention.This shows how often mechanical support is weaned too slowly, and how simple clinical assessments may improve outcomes.

Prior to implementation of the weaning protocol in ITU at MDH, weaning practices varied between different specialists. There was no continuity to the weaning process, which may have led to increased ventilation duration.

Multiple studies have highlighted that clinical protocols reduce ventilation times.[9] Our experience does not support this, as there were no significant differences between the two groups. We postulate that our study was not powered enough to find such differences. Initially a larger number of patients were going to be enrolled, but this was hindered by the number of COVID patients

in ITU, which were excluded from this study. It is also possible that the education campaign might have failed to achieve its goals.

We also found that an educational campaign consisting of a PowerPoint presentation was not effective in collective data retention.

Prolonged ventilatory weaning mostly deals with those patients who have failed their first SBT; even though traditional weaning methods are still in widespread use, novel strategies have been introduced over recent years. New ventilation methods such as automatic tube compensation (ATC), adaptive support ventilation (ASV), mandatory minute ventilation (MMV) as well as pressure support-based automatic weaning systems are being gradually implemented in daily ICU practice; however, their impact on prolonged ventilatory weaning outcomes remains to be established.[10] This is one of the main reasons why they have not yet been included in the weaning protocol.

Automated closed loop systems for prolonged ventilatory weaning are also being steadily introduced in modern ICUs. These rely on specialised computer software which can adapt the ventilator's mechanical support to the patients' needs and hence facilitate their ability to breathe spontaneously with the aim of finding the optimal timing for weaning. The latest pooled evidence (adult and paediatric) indicates that automated closed loop systems reduce the mean duration of weaning by 32%.[11] However there is substantial heterogenicity present in the systems and protocols used across the trials. Even though more high-quality evidence is needed to fully appreciate the role of these systems in a mixed ICU, such automated protocols might be considered for our next weaning protocol update.[11]

A common clinical observation is that patients wean more rapidly from mechanical ventilation following tracheostomy. Even though theoretical considerations to explain this are not fully validated, some of its advantages are associated with optimisation of positioning, superior secretion removal, the ability to eat and speak, less laryngeal damage, better oral hygiene as well as sedation discontinuation.[12] The work of breathing is reduced by decreasing both artificial airway resistance and dead space.[13] These advantages are greatest in patients with long intubation times since tube coating with biofilm develops, further increasing airway resistance. Importantly the return to ventilation via the natural airways after decannulation is associated with an increase in the work of breathing[14], a fact that should be borne in mind when considering the timing of decannulation.

SUMMARY BOX

Known Findings

- Risk of VILI or VAPs increases with the duration of mechanical ventilation.
- Previous studies have demonstrated that there is no superior method for weaning patients.
- The focus has shifted to implementing weaning protocols to guide clinicians.

New Findings

- No statistically significant difference in weaning success after introduction of the weaning protocol.
- Information retention did not improve after usage of the protocol.
- Overall attitude towards weaning patients from mechanical ventilation was positive.

When dealing with difficult-to-wean patients, factors other than ventilatory protocols can impact weaning success; proper nutrition, physiotherapy as well as venue selection have all been implicated as potential contributors to successful weaning.[15] A recently discovered major contender as a contributor to weaning failure is the presence of underlying cardiovascular dysfunction. Early identification and prompt treatment of patients who are at high risk for weaning failure of cardiac origin is crucial in allowing the heart to tolerate more effectively the burden of weaning.

There are a number of limitations to our study, primarily that the population size of the study was small, and this may have reduced the power necessary to detect significant differences. The COVID-19 pandemic started during the post-implementation phase of the protocol. Since this population had particular lung pathology and were not included in the pre-implementation phase, data collection was interrupted until COVID numbers reduced. Furthermore there is no automated data collection in our unit, which means that such an observational study cannot be done retrospectively. This reduces bias, but also is more labour-intensive.

With regards to the impact of the educational campaign, staff retention of information did not improve after protocol implementation. There was a delay in sending the post-implementation

questionnaire, due to a number of protocols being introduced during the COVID pandemic. The long duration between teaching sessions and re-assessment could have had an impact on information retention. Furthermore there was a great turnover of nursing and medical personnel during this period. Since the questionnaires were anonymous, we could not match the pre- and post-responses.

The introduction of the weaning protocol should not be considered as a failure, however. It has helped junior doctors and nurses better assess patients during the weaning process. We would consider improving on the educational campaign by using interactive training sessions and providing feedback to staff on protocol use.

CONCLUSION

The introduction of an ITU weaning protocol at Mater Dei Hospital did not increase the number of successful extubations. Despite enhanced staff perception of weaning, a mechanical ventilation questionnaire did not improve retention of knowledge.

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