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Research Article

Weaning Protocol, Comparison of T-Tube and Continuous Positive Airway Pressure (CPAP) In Omdurman Teaching Hospital, Police Hospital, and Military Hospital- Khartoum -Sudan Duration: April 2010 _ February 2012.

Dr. Khalid A.M. Eltayib[1*], Dr. Einas Siddik Shaheen[2]

[1*]Anesthesiologist, Sudan Medical Specialization Board – Sudan, khalidgady@gmail.com
[2]Physicain, Khartoum Teaching Hospital –Sudan, einassiddik@gmail.com

Abstract
This study compares two methods of spontaneous breathing trials—T-tube and Continuous Positive Airway Pressure (CPAP)—to assess their effectiveness in weaning patients from mechanical ventilation. Conducted in Omdurman Teaching Hospital, Police Hospital, and Military Hospital in Sudan, —between April 2010 and February 2011. The research involved 64 patients who had been on mechanical ventilation for over 48 hours and were deemed ready for weaning based on clinical criteria. Patients were randomly assigned to undergo a 2-hour trial of spontaneous breathing using either a T-tube (Group A, n = 32) or CPAP (Group B, n = 32). Success in the trial was followed by extubation, with patients monitored for 48 hours for reintubation and associated outcomes.
Of the T-tube group, 78.1% (25/32) successfully completed the trial and were extubated, while 21.9% (7/32) failed. Among those extubated, 18.7% (6/32) required reintubation, leaving 59.4% (19/32) successfully extubated after 48 hours. In the CPAP group, 84.4% (27/32) were successfully extubated, with a failure rate of 15.6% (5/32). Reintubation was required for 12.6% (4/32) of the CPAP group, resulting in a successful extubation rate of 71.8% (23/32) after 48 hours. Although the difference in successful extubation rates was not statistically significant (59.4% vs. 71.8%, p = 0.10), the failure rate during the trial was significantly higher in the T-tube group (21.9% vs. 15.6%, p = 0.02). ICU mortality among reintubated patients was significantly higher compared to successfully extubated patients (23% vs. 4.5%, p = 0.004).
While the CPAP method showed slightly better outcomes, both T-tube and CPAP trials were effective methods for discontinuing ventilatory support in suitable patients. Further studies are recommended to refine and optimize these weaning techniques.

***Author of Correspondence: Email:** *khalidgady@gmail.com*

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Introduction

Discontinuing ventilatory support and achieving successful extubation is a crucial step in the recovery of patients who were mechanically ventilated due to critical illnesses. Identifying patients who are ready for spontaneous breathing is essential to avoid premature extubation or unnecessary delays. A critical challenge lies in distinguishing patients capable of maintaining immediate spontaneous ventilation from those who require a gradual transition.

Traditional weaning criteria, such as vital capacity, maximal inspiratory pressure, and minute ventilation,

often lack accuracy in predicting extubation readiness. Among the newer metrics, the Rapid Shallow Breathing Index (RSBI), expressed as the frequency-to-tidal volume (f/VT) ratio, has gained prominence due to its simplicity and reliability.

Evidence suggests that a 2-hour T-tube trial of spontaneous breathing is effective for selecting patients ready for extubation. However, extubation failure rates following T-tube trials—defined as the need for reintubation—range between 15% and 19%. Doubts persist about whether this method is the most appropriate for all patients. The added work of breathing imposed by the endotracheal tube during a T-tube trial may exceed the tolerance of certain patients, leading to trial failure.

In contrast, pressure support ventilation (PSV) can offset the additional workload associated with the endotracheal tube. Typically, a pressure level of 7–8 cm H2O is sufficient to simulate the effort required after extubation. While T-tube trials may increase trial failure rates, the reduced workload provided by PSV could lead to extubation in patients with marginal respiratory reserve, potentially increasing reintubation rates.

This study evaluated whether the rate of successful extubation differs significantly between T-tube trials and pressure support ventilation. By comparing these two methods, we aimed to shed light on their efficacy and suitability for patients transitioning off mechanical ventilation.

Study Rationale

The objective of this study was to identify the optimal method for conducting spontaneous breathing trials prior to extubation. To achieve this, we compared two groups of patients: Group A, undergoing T-tube trials, and Group B, receiving Continuous Positive Airway Pressure (CPAP) with a pressure support of 8 cm H2O. The percentage of patients in each group who remain successfully extubated and off mechanical ventilation for 48 hours was evaluated.

Additionally, the study also identified patients at higher risk of requiring reintubation within the first 48 hours and analyzed the impact of reintubation on mortality rates. By exploring these outcomes, we aimed to provide evidence-based recommendations to improve weaning protocols and optimize patient care.

Objectives of the Study

General Objective: To evaluate and compare the clinical characteristics, respiratory function parameters, and outcomes of spontaneous breathing trials conducted with T-tube and Continuous Positive Airway Pressure (CPAP).

Specific Objectives:

- To determine the success rate of spontaneous breathing trials in each group after 48 hours.
- To assess the incidence of weaning failure in each group.
- To evaluate the incidence of reintubation within the first 48 hours post-extubation in each group.
- To analyze the mortality rate associated with weaning trials in each group.
- To compare the incidence of regurgitation and aspiration between the two groups.

Research Methodology

This prospective, randomized, multicenter study was conducted at Omdurman Teaching Hospital, Police Hospital, and Military Hospital in Sudan. The study population included patients who had been mechanically ventilated for more than 48 hours and were deemed ready for weaning based on standard criteria. Patients were randomly assigned to one of two groups for a 2-hour spontaneous breathing trial:

- **Group A**: T-tube trial.
- **Group B**: CPAP trial with pressure support set to 7 cm H2O.

Inclusion Criteria Patients were eligible for the study if they met the following conditions:

- Mechanically ventilated for more than 48 hours.
- Resolution of the underlying cause of respiratory failure.
- Adequate gas exchange (PaO_2 > 60 mmHg) with $FiO_2 \leq 0.4$ and PEEP ≤ 5 cm H_2O.
- Glasgow Coma Scale (GCS) score > 13.
- Core temperature < 38°C.
- Hemoglobin level ≥ 10 g/dl.
- No use of vasoactive or sedative drugs.
- Physician agreement on patient readiness for weaning.

Exclusion Criteria Patients were excluded if:

1. They did not meet the inclusion criteria.
2. They had a tracheostomy, as it reduces the work of breathing and simplifies weaning.

Methods

Once written consent was obtained, patients were divided into Group A or Group B. Spontaneous breathing trials commenced after patients fulfilled the weaning criteria listed above. Each patient was first allowed to breathe spontaneously for 3 minutes on the same FiO_2 settings used during mechanical ventilation. Following this, patients underwent either a T-tube trial or CPAP trial (with 7 cm H_2O pressure support) for 2 hours, provided they met two of the following conditions:

- Maximal inspiratory pressure < -30 cm H_2O.
- Tidal volume > 5 ml/kg.
- Respiratory rate < 35 breaths per minute.
- Rapid Shallow Breathing Index (RSBI, calculated as f/T.V in liters) < 105.

During the 2-hour trial, vital signs—heart rate (HR), respiratory rate (RR), blood pressure (BP), and oxygen saturation (SpO_2)—were recorded every 15 minutes. Signs of poor tolerance, such as agitation, anxiety, tachypnea (RR > 35 breaths/min), tachycardia (HR > 140 bpm), systolic BP > 200 or < 80 mmHg, and SpO_2 < 90%, were considered indicators of trial failure.

Patients who failed the trial were resumed on mechanical ventilation.

Patients who tolerated the trial were extubated and placed on oxygen via face mask, with close observation over 48 hours. If reintubation was required during this period, the cause (e.g., upper airway obstruction, hypoxemia, hypercapnia) was documented. Patients were followed until hospital discharge or death. Successful extubation was defined as no need for reintubation within 48 hours of extubation.

Sampling and Sample Size The study included 64 patients, equally divided into two groups (32 patients per group). Systematic random sequencing was used for assignment (e.g., the first patient was placed in Group A, the second in Group B, the third in Group A, and so on).

Data Collection Data was gathered using an observational checklist and recorded by the researcher and ICU staff.

Data Analysis

The collected data was analyzed using the SPSS statistical program.

Results

Patient Distribution and Baseline Characteristics

Of the 64 patients, 32 were assigned to the T-tube group (Group A) and 32 to the CPAP group (Group B). Both groups were comparable in terms of baseline characteristics, indications for mechanical ventilation, and respiratory functional parameters measured before the trials (Tables 1 & 3). No statistically significant differences were observed between the two groups in any of these baseline measures.

Outcomes of Spontaneous Breathing Trials

- **T-Tube Group (Group A):**
  - 25 patients (78.1%) successfully completed the trial and were extubated.
  - 7 patients (21.9%) failed the trial and required continued mechanical ventilation.
  - Among the extubated patients, 6 (18.7%) required reintubation within 48 hours.
  - Ultimately, 19 patients (59.4%) remained successfully extubated after 48 hours (Table 2).
- **CPAP Group (Group B):**
  - 27 patients (84.4%) successfully completed the trial and were extubated.
  - 5 patients (15.6%) failed the trial and required continued mechanical ventilation.
  - Among the extubated patients, 4 (12.6%) required reintubation within 48 hours.
  - A total of 23 patients (71.8%) remained successfully extubated after 48 hours (Table 2).
- **Statistical Comparisons:**
  - The difference in the percentage of patients who remained successfully extubated after 48 hours was not statistically significant (T-tube: 59.4% vs. CPAP: 71.8%; $p = 0.10$).
  - However, the trial failure rate was significantly higher in the T-tube group compared to the CPAP group (21.9% vs. 15.6%; $p = 0.02$).

Respiratory Parameters

Baseline respiratory parameters, including the ratio of PaO_2 to FiO_2, tidal volume, respiratory rate, RSBI, and maximal inspiratory pressure, were similar between the two groups (Table 3). None of the comparisons showed statistically significant differences (all p-values > 0.05).

Reintubation and Mortality

- ICU mortality rates were significantly higher among reintubated patients (23%) compared to successfully extubated patients (4.5%; $p = 0.004$).
- Patients reintubated due to respiratory failure had a mortality rate of 30%, whereas those reintubated for other reasons (e.g., upper airway obstruction, aspiration) had a lower mortality rate of 7%.

Weaning Outcomes and Predictive Factors

- Comparison of successfully extubated and reintubated patients revealed significant differences in age, duration of ventilator support, PaO_2/FiO_2 ratio, respiratory frequency, tidal volume, and RSBI (Table 4).
- Patients who failed the trial exhibited higher RSBI values and lower tidal volumes compared to successfully extubated patients ($p < 0.001$ for both).

Changes in Physiological Parameters During the Trial

- Patients who failed the trial exhibited significantly higher increases in respiratory frequency, heart rate, and systolic blood pressure, as well as greater drops in oxygen saturation, compared to the extubated groups ($p < 0.01$ for all parameters, Figure 2).
- No significant differences were observed between successfully extubated patients and reintubated patients for these physiological changes.

TABLE (1)

CHARACTERISTICS OF THE STUDY POPULATION AT BASELINE ACCORDING TO METHODS USED TO PERFORM THE SPONTANEOUS BREATHING TRIAL

Characteristic:-	T-Tube Group	CPAP Group	p Value
Sex:-			
Male, n (%)	20(62.5%)	18(68.7%)	0.24
Female, n (%)	12(37.5%)	14(31.3%)	0.34
Median age, yr (25th-75th percentiles).	52(24-670	49(19-65)	0.47
Median time of ventilator support before trial of spontaneous breathing, days (25th-75th percentiles).	4(2-6) days	4(3-7) days	0.23
Reason for mechanical ventilation:-			
Myasthenia gravis, n (%)	1(1.8%)	0(00)	0.23
CVA, n (%)	6(9.3%)	4(6.4%)	0.46
Pulmonary edema, n (%)	4(6.2%)	5(6.4%)	0.18
Postoperative state, n (%)	3(4.7%)	4(6.4%)	0.54
Severe Pneumonia, n (%)	4 (6.2)	5 (7.8)	0.39
Multiple traumas, n (%)	5(7.8%)	5(7.8%)	0.67
ARDS, n (%)	4(6.4%)	5(7.8%)	0.96
Heart failure, n (%)	2(3.2%)	1(1.8%)	0.23
Bronchial Asthma, n (%)	3(4.7%)	2(3.2%)	0.92
Alcoholic encephalopathy (%)	0(00)	1(1.8%)	0.83

TABLE (2):-Distribution of the study population according to the method used in the trial and the outcome of the trials.

No of patients	Extubated after 2 hours	reintubated	Successful after 48 hours	Failure with trial
T tube group	25(78.1%)	6(18.7%)	19(59.4%)	7(21.7%)
CPAP group	27(84.4%)	4(12.6%)	23(71.8%)	5(15.6%)
P. value	0.16	0.23	0.14	0.03

TABLE (3)

RESPIRATORY PARAMETERS MEASURED DURING THE FIRST THREE MINUTS AFTER DISCONTIN UATION OF VENTILATOR SUPPORT AND PRIOR TO THE TRIAL

Respiratory Parameters	T-Tube Group	CPAP Group	p Value
	Median (25th-75th Percentiles)	Median (25th-75th Percentiles)	
Ratio of Pa_{O2} to FI_{O2}*	260(225-329)	245 (225-325)	0.23
Tidal volume, ml	410 (350-540)	450 (358-555)	0.07
Respiratory rate breaths/min	27 (21-35)	25 (19-32)	0.46
RSBI (f/VT ratio)†	76 (48-89)	69 (46-81)	0.48
Maximal inspiratory pressure, cm H_2O	−27 (−23 -−35)	−25 (−22 -−35)	0.42

TABLE(4):-
COMPARISON OF THE STUDY POPULATION ACCORDING TO THE OUTCOME OF THE SPONTA NEOUS BREATHING TRIAL

Parameters	Successfully Extubated (*n = 52*)	Reintubated (*n = 10*)	Trial Failure (*n = 12)*	p Value
	Median (25th-75th Percentiles)	Median (25th-75th Percentiles)	Median (25th-75th Percentiles)	
Age, yrs	56 (24-67)	61 (45-65)	63 (54-67)	0.005*
Duration of ventilator support before trial of spontaneous breathing, days	3 (2-5)	4 (3-7)	5 (3-7)	0.02†
Ratio of Pa_{O2} to FI_{O2}	269 (228-337)	234 (233-314)	212 (193-310)	0.03‡
Respiratory frequency, breaths/min	23 (20-26)	25 (21-27)	30 (22-35)	0.001†
Tidal volume, ml	420 (380-582)	405 (350-430)	350 (290-385)	0.001†
f/VT ratio	67 (45-86)	92 (64-102)	102 (78-108)	0.001†
Maximal inspiratory pressure, cm H_2O	−25 (−20-−36)	−25 (−25-−35)	−28 (−25-−37)	0.48

* Significant difference for the comparison of successfully extubated with reintubated patients.
†Significant difference for the comparison of trial failure group with each of the other two groups.
†Significant difference for the comparison of successfully extubated and trial failure groups.

- Tracheostomy was performed in 3 of the 6 reintubated patients in the T-tube group and 4 of the 4 reintubated patients in the pressure support group.
- In patients who tolerated the trial of spontaneous breathing there were no differences between T-tube and pressure support groups regarding ICU mortality (8.8 versus 5.8%, p = 0.25), in-hospital mortality (15.1 versus 15.6%, p = 0.90), median length of stay in the intensive care unit (10 d versus 12 d, p = 0.33), and median length of stay in hospital (24 d versus 28 d, p = 0.33).
- Age, days receiving mechanical ventilation prior to spontaneous breathing trial, Pa_{O2}/FI_{O2} ratio, respiratory frequency, tidal volume, f/VT ratio, and maximal inspiratory pressure are shown and compared according to weaning outcome in Table(4).
- Changes in respiratory frequency, heart rate, systolic blood pressure, and oxygen saturation during the spontaneous breathing trial are shown in Figure (2). When the trial failure group was compared with each of the other two groups, that group had significantly higher incremental areas under the curve for respiratory frequency, heart rate, and systolic blood pressure, and significantly lower incremental area for oxygen saturation. However, patients who were reintubated were not different from those who were successfully extubated.
- Ninety percent of the patients were reintubated because of respiratory failure, and the remaining patients needed reintubation because of other causes such as: - signs of upper airway obstruction, cardiac arrest, gastric aspiration, supraventricular tachycardia, aspiration and pneumonia.
- ICU mortality among patients requiring reintubation was significantly higher than mortality in successfully extubated patients 24% versus 4.5%, p = 0.004).
- Patients requiring reintubation because of respiratory failure had a mortality rate of 30%, whereas mortality was 7% (in patients needing reintubation because of other causes.

Discussion

This study provides valuable insights into the effectiveness of spontaneous breathing trials using T-tube and pressure support ventilation (CPAP) for discontinuing ventilatory support in critically ill patients. Four key findings emerged from our analysis:

1. Spontaneous breathing trials over 2 hours demonstrated a high success rate in weaning patients from mechanical ventilation.
2. The percentage of patients successfully extubated after these trials was 6.3% higher with CPAP (pressure support of 7 cm H_2O) compared to T-tube circuits.
3. Neither respiratory functional parameters measured in the first three minutes before the trial, nor clinical characteristics or changes in clinical variables during the trial, allowed accurate prediction of reintubation within 48 hours post-extubation.
4. Reintubation was associated with a significant increase in mortality.

Predictive Weaning Criteria

Various predictive criteria, including the rapid shallow breathing index (f/VT ratio), have been used to identify patients ready for extubation. The f/VT ratio is regarded as the most reliable parameter due to its simplicity and accuracy. However, despite favorable pre-trial parameters, spontaneous breathing may become less

effective over time. This highlights the importance of performing brief tests to evaluate the ability to maintain spontaneous ventilation, although the optimal approach to conducting such trials remains uncertain.

Our findings align with previous studies, which reported successful extubation rates of 75% and reintubation rates of 15–19% after 2-hour trials with T-tube circuits. The resistive workload imposed by the endotracheal tube is notable, as work of breathing may increase by 27–240% depending on tube diameter and flow rate. Pressure support ventilation has been shown to reduce this additional workload, potentially improving breathing efficiency and oxygen consumption during weaning.

Comparison of T-Tube and Pressure Support Ventilation

Pressure support ventilation has distinct advantages, such as compensating for the endotracheal tube's imposed workload and reducing respiratory muscle oxygen consumption. While previous studies have demonstrated comparable weaning outcomes between these methods, our study shows a marginally higher success rate with CPAP during spontaneous breathing trials. This suggests that CPAP may alleviate the respiratory burden imposed by the T-tube system, allowing some patients to successfully complete the trial.

However, the observed difference in extubation success rates (6.3%) may not constitute a clinically significant impact, given our predefined threshold for relevance (20%). Larger sample sizes may help clarify whether this difference translates into meaningful improvements in patient care.

Reintubation and Associated Mortality

Reintubation significantly increased ICU mortality rates in our study, emphasizing its critical impact on patient outcomes. Patients reintubated due to respiratory failure experienced higher mortality rates (30%) compared to those reintubated for other reasons (7%). These findings are consistent with prior observations and underscore the importance of strategies aimed at reducing reintubation rates.

While neither respiratory parameters nor clinical evolution during the trials predicted extubation failure, other post-extubation factors—such as cardiac failure, restless sleep, use of sedatives, respiratory muscle weakness, or psychological factors—may play a crucial role. Future studies focusing on these aspects could provide deeper insights into the determinants of reintubation and strategies to mitigate associated risks.

Clinical Implications and Cost Considerations

Our results suggest that CPAP may offer an effective alternative to T-tube trials, with the added advantage of being widely available in most ICUs, eliminating the need for specialized equipment such as humidification systems and connectors. However, no financial analyses were conducted, and future investigations should address cost-efficiency comparisons between these methods.

Limitations

This study involved patients with a favorable pre-trial clinical course, which may explain the relatively low mortality rates observed. Additionally, while we found a strong association between reintubation and mortality, causality cannot be inferred, as reintubation may result from severe clinical events already associated with high mortality risk. The sample size limits our ability to detect smaller but potentially meaningful differences between the groups.

Conclusion

In conclusion, both T-tube and CPAP trials are effective methods for weaning ventilated patients. While CPAP demonstrates a marginal advantage in trial success rates, further studies with larger sample sizes are needed to determine its clinical relevance and cost-effectiveness. Identifying factors influencing reintubation and implementing targeted interventions remain critical for improving patient outcomes and reducing mortality rates.

Conclusion

1. The 2-hour spontaneous breathing trial is an effective method for discontinuing mechanical ventilation, demonstrating a high success rate.
2. Both T-tube and Continuous Positive Airway Pressure (CPAP) are viable options for weaning patients who meet the weaning criteria, with no significant statistical differences in successful extubation rates after 48 hours between the two groups.
3. The failure rate of extubation was significantly higher in the T-tube group compared to the CPAP group, suggesting that CPAP may be a more favorable method for reducing trial failures.
4. While pre-trial respiratory function parameters, such as the Rapid Shallow Breathing Index (RSBI), did not differ significantly between the groups, RSBI during the trial emerged as a reliable predictor of difficulties and failures in the trial.
5. Reintubation was strongly associated with higher mortality rates compared to patients who were successfully extubated. Patients requiring reintubation due to respiratory failure faced significantly higher mortality rates compared to those reintubated for other reasons.

This study highlights the importance of individualized approaches to weaning, incorporating clinical parameters and available ICU resources, to optimize patient outcomes and minimize risks.

Recommendations

1. Future Research: Further studies are needed to evaluate the comparative effectiveness of different weaning methods, focusing on both their advantages and limitations. Larger multicenter trials are essential to establish evidence-based protocols.

2. Adoption of Spontaneous Breathing Trials: The use of 2-hour spontaneous breathing trials should be incorporated into routine weaning protocols for discontinuing mechanical ventilation, given its demonstrated effectiveness.

3. Preference for CPAP: CPAP is recommended over the T-tube for weaning, as it reduces the work of breathing, is more comfortable for patients, and is readily available on most ventilators in ICUs.

4. Training and Familiarity: ICU staff should receive adequate training on the selected weaning method, ensuring familiarity and expertise in managing and monitoring patients during weaning trials.

5. Patient-Centered Approach: The choice of weaning method should be individualized based on the patient's specific clinical needs and comfort, ensuring optimal outcomes while minimizing risks of failure.

By addressing these recommendations, ICUs can improve the success rates of weaning and extubation, ultimately enhancing patient recovery and reducing the risk of complications.

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APPENDIX
DATA COLLECTION SHEET

Patient group: - A_____B_____ Age:-_____ sex: - M___ F____

Cause of M.V_____ Duration of M.V:- <48 HRS___ >48hrs___

- Pre-weaning parameters:-

1. Maximal inspiratory pressure: - < 30cmH2O_____ >30cmH2O_____
2. Tidal volume: - < 5ml/kg_____ >5ml/kg_____
3. R.R :- <35 b/min_____ > 35b/min_____
4. Rapid shallow breathing index (RSBI) :- < 105_____ >105_____
5. PaO2/FiO2 ratio:- <200_____ >200 :_____

- **The first 2 hours vital signs:-**

Time	15min	30min	45min	60min	75min	90min	105min	120min
HR								
RR								
BP								
SPO2								

- Failure of the trial:-

Time:-_____ the cause:-_____

- Extubation after 2 hrs: YES:_____ NO: _____
- Reintubation in the first 48 hrs after Extubation:-

YES: _____ NO:_____

- Cause of Reintubation:-_____
- Outcome after Reintubation:- DEATH:-_____DISCHARGE: ____