

**“ASSESSMENT OF OUTCOME OF USING HIGH FLOW
OXYGEN AND T PIECE VENTILATION AMONG PATIENTS
RECEIVING MECHANICAL VENTILATION DURING WEAN
OFF PHASE”**

B.L.D.E. (DU)

**SHRI B. M. PATIL MEDICAL COLLEGE HOSPITAL AND
RESEARCH CENTRE VIJAYAPURA, KARNATAKA**



In partial fulfilment of the requirements for the degree of

DOCTOR OF MEDICINE

IN

ANESTHESIOLOGY

BY

DR. RADHIKA MILIND PATIL MBBS

Under the guidance of

DR. VIJAYKUMAR T.K MD

PROFESSOR

DEPARTMENT OF ANESTHESIOLOGY

BLDE (DU)VIJAYPURA, KARNATAKA

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation is entitled

There is real work that I did call "ASSESSMENT OF OUTCOME OF USING HIGH FLOW OXYGEN AND T PIECE VENTILATION AMONG PATIENTS RECEIVING MECHANICAL VENTILATION DURING WEAN OFF PHASE." Dr. Vijaykumar T.K. MD, professor, Department of Anaesthesiology, Shri. B M Patil Medical College, Vijayapura, oversaw and assisted me in this work.

Date:
Place: Vijayapura

Dr.Radhika Milind Patil
Department of Anaesthesiology
Shri B.M Patil Medical College and
Hospital Vijayapura

BLDE (DU)VIJAYPURA, KARNATAKA

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled **“ASSESSMENT OF OUTCOME OF USING HIGH FLOW OXYGEN AND T PIECE VENTILATION AMONG PATIENTS RECEIVING MECHANICAL VENTILATION DURING WEAN OFF PHASE”** under my direct supervision and guidance in partial fulfillment of the requirement for the degree of M.D. (ANESTHESIOLOGY)

Date:

DR. VIJAYKUMART.K MD

Place: Vijayapura

PROFESSOR

DEPARTMENT OF ANESTHESIOLOGY

BLDE (DU)VIJAYPURA, KARNATAKA

ENDORSEMENT BY THE HOD

This is to certify that the dissertation entitled **“ASSESSMENT OF OUTCOME OF USING HIGH FLOW OXYGEN AND T PIECE VENTILATION AMONG PATIENTS RECEIVING MECHANICAL VENTILATION DURING WEAN OFF PHASE”** under my direct supervision and guidance in partial fulfillment of the requirement for the degree of M.D. (ANESTHESIOLOGY)

Date:

Place: Vijayapura

DR. RENUKA HOLYACHI MD

PROFESSOR AND HOD

Department of anaesthesiology
shri. B M patil medical college,
Vijayapura

ENDORSEMENT BY PRINCIPAL

This is to certify that the dissertation entitled **“ASSESSMENT OF OUTCOME OF USING HIGH FLOW OXYGEN AND T PIECE VENTILATION AMONG PATIENTS RECEIVING MECHANICAL VENTILATION DURING WEAN OFF PHASE”** under my direct supervision and guidance in partial fulfillment of the requirement for the degree of M.D. (ANESTHESIOLOGY)

Date:

Place: Vijayapura

DR. ARVIND PATIL

PRINCIPAL

Shri B.M Patil Medical

College, Vijayapura.

COPYRIGHTDECLARATION BY THE CANDIDATE

I hereby declare that B.L.D.E (DU) Shri. B M Patil Medical college, Vijayapura shall have the right to preserve, use and disseminate this dissertation in print or electronic format for academic / research purpose.

Date:

DR. RADHIKAMILIND PATIL

Place: Vijayapura

©B. L. D. E. (DU) Shri. B M Patil medical college, Vijayapura.

ACKNOWLEDGEMENT

On completion of my post-graduation journey and this scientific document, I would like to acknowledge the immense help I received from my mentors in my department and critical care unit of BLDEDU. With privilege and respect, I would like to express my gratitude and indebtedness to my guide, Dr.

Vijaykumar T.K., professor, department of anaesthesiology, and his constant inspiration, encouragement, and loving support, which rendered in pursuit of my post-graduation studies and preparing a dissertation.

I am forever grateful to Dr. Renuka Holyachi, professor and HOD, department of anaesthesiology; Dr. Santosh Alalamath, assistant professor, department of anaesthesiology; and all faculties of Shri B M Patil Medical College, Vijayapura, for constant support and valuable suggestions throughout this journey.

I am extremely thankful to Prof. Dr. Arvind Patil, principal, B. M. Patil Medical College, Vijayapura, for permitting me to utilize resources required for the completion of my research work.

My thanks to all who are involved directly and indirectly in my journey: critical care unit staff, librarian, statistician, my postgraduate colleagues, especially Dr. Suman and Dr. Satvik, respected seniors, and beloved juniors.

I would like to express my deep-felt gratitude toward my parents and brother, Dr. Milind and Sharda, and Dr. Siddharth. Their trust and constant support and encouragement bring this journey to completion.

Last but not least, I am thankful to all my patients and attenders for their cooperation during my study.

01.	INTRODUCTION	13
02.	AIMS AND OBJECTIVES OF STUDY	14-15
03.	REVIEW OF LITERATURE	16-35
04.	TOPICS SPECIFIC TO STUDY	36-42
05.	MATERIALS AND METHODS	43-47
06.	RESULT	48-56
07.	DISCUSSION	57-59
08.	CONCLUSION	60-61
09.	BIBLIOGRAPHY	62-65
10.	ANNEXURE	66-81
11.	MASTER CHART	82-84

LIST OF IMAGES

1.	ANDREAS VESALIUS	18
2.	SIR WILLIAM MACEWEN	19
3.	MACEWEN ENDOTRACHEAL TUBES	20
4.	SIR IVAN WHITESIDE MAGILL	21
5.	19 TH CENTUARY NEGATIVE PRESSURE VENTILATORS	22
6.	ICU SETUP DURING WORLD WAR II AND BOSTON CHILDREN HOSPITAL ICU	23-24
7.	FIRST GENERATION VENTILATOR	25
8.	SECOND GENERATION VENTILATOR	26
9.	THIRD GENERATION VENTILATOR	28

LIST OF GRAPHS AND CHARTS

Serial number	Name	Page number
1.	WEANING CRITERIA	39
2.	WEANING PROTOCOL FROM MV	40
3.	INDICATORS OF WEANING FAILURE	41
4.	INTERVENTION FLOW CHART OF STUDY	46
5.	DEMOGRAPHIC DETAILS TABLE AND BAR GRAPH	49
6.	LENGTH OF STAY AND DAYS OF MV BEFORE SBT TABLE AND BOXPLOT	50
7.	ABG ANALYSIS OF BOTH GROUP TABLE AND LINE GRAPH	51-52
8.	REASON OF INTUBATION IN BOTH GROUP TABLE AND PIE CHART	53-54
9.	POST EXTUBATION ABG ANALYSIS OF BOTH GROUP TABLE AND BAR GRAPH	55-56

ABBREVIATIONS

1. HFO: high flow oxygen
2. NIV: non-invasive ventilation
3. ICU: intensive care unit
4. COPD: chronic obstructive pulmonary diseases
5. HFNC: high flow nasal cannula
6. SBT: spontaneous breathing trial
7. WOB: work of breathing
8. PSV: pressure support ventilation
9. PEEP: positive end expiratory pressure
10. CPAP: continuous positive airway pressure
11. COT: conventional oxygen therapy
12. MV: mechanical ventilator

INTRODUCTION

Delay extubation is highly associated with mortality and morbidity. Timely discontinuation from mechanical ventilation is very crucial in critically ill patients. High flow oxygen therapy gives more physiological advantages and improves conditions like hypoxemic respiratory failure, post-operative respiratory failure, palliative care, hypercapnic respiratory failure, acute exacerbation of COPD, and pre-intubation oxygenation.

With this study, we might reduce the days on mechanical ventilation and bring back to normal respiration hence saving the high cost of ventilators.

High-flow oxygen system is more comfortable and easily tolerable and improves the efficacy of ventilation by reducing dead space carbon dioxide accumulation hence can be used in the wean-off phase to overcome respiratory failure whereas use of t-piece during spontaneous breathing is commonly used during weaning from mechanical ventilation. Among both method outcome is specific but the rate of reintubation after HFNC is significantly less and tolerance is more.

Main objective of this study is to overcome weaning failure by comparing HFO and T –piece during weaning phase.

AIMS AND OBJECTIVES

AIM OF STUDY

To study the effect and outcome of high-flow oxygen and T-piece in respiratory failure patients receiving mechanical ventilation

OBJECTIVES OF STUDY

Primary objectives

To overcome weaning failure within 48 hours of mechanical ventilation.

Secondary objectives

To overcome weaning failure within 72 hours after starting mechanical ventilation and account of Total no. of reintubation within seven days after extubation. To reduce the length of ICU, stay and to study themortality in a patient receiving T- piece ventilation and ventilation through an HFO during wean off phase.

REVIEW OF LITERATURE

Mechanical ventilation is very crucial mode of treatment of either critically ill patient or terminally ill patient.

Mechanical ventilation has four phases i.e. Intubation, ventilation, spontaneous breathing trial and extubation.

History of endotracheal intubation: first description about tracheostomy appears in ancient Hindu script around 2000BC and Egyptian documents around 1500BC. **Andreas Vesalius**⁽¹⁾ the anatomist and physician from Brussels, Belgium in 1543 reported first endotracheal intubation in animal.



FIG.1 Andreas Vesalius (Born: 31 dec 1514 - Died: 15 oct 1564)

In the earlier years of 1870 Trendelenburg from Germany performed first endotracheal intubation in human being. **William MacEwen** in 1878 executed the first elective endotracheal intubation for anaesthetic purpose. He did it with packing of hypopharynx, from leaking of blood and debris. he described 2 additional cases of endotracheal intubation lasting for 36 hours. He was the first who did it first for long time intubation. Later **Rosenberg** and **Kuhn** administered cocaine as a local anaesthetic to blunt the cough reflex during intubation. Intubation and tracheostomy widely used during world war-I



FIG.2 Sir William MacEwen

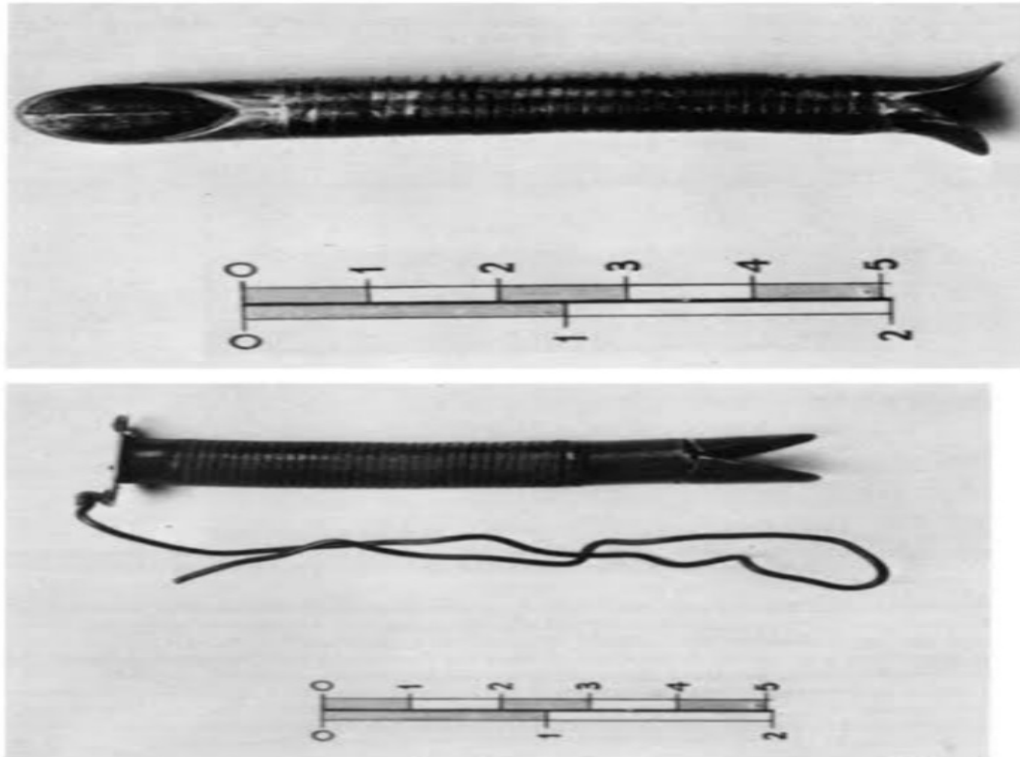


Fig. 3. Other tubes designed by Sir William MacEwen for the same purposes as detailed in the caption to Fig. 2. Wellcome Institute—by courtesy of the Trustees.

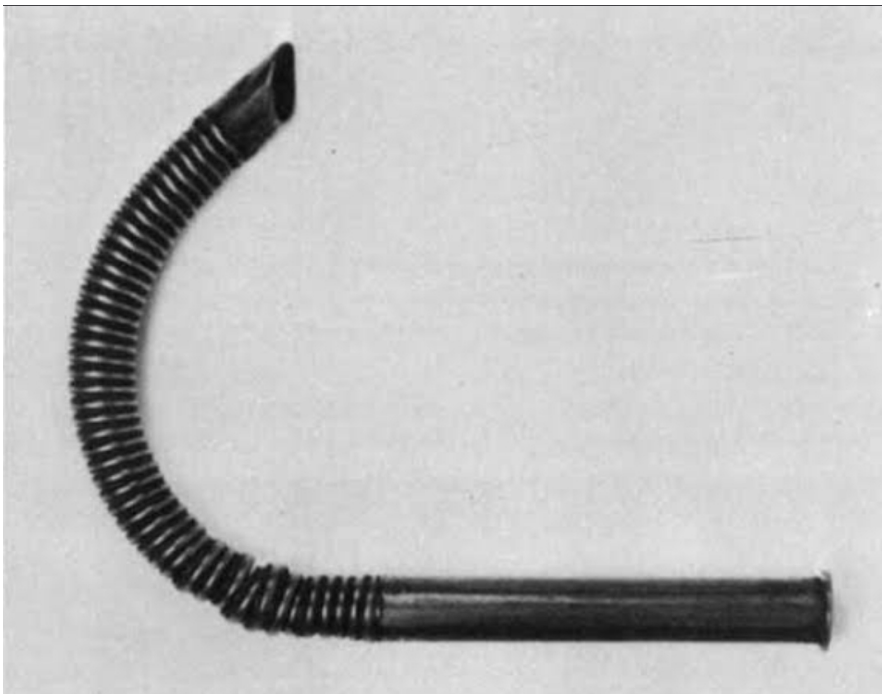


FIG.3 MacEwen endotracheal tubes

Sir Ivan Magill ⁽³⁾ is one of the most innovative and well-known figures in modern anaesthesia. he pioneered new equipment and techniques that contributes most valuable

advancement in older anaesthetic practices. He has designed Magill's forceps, Magill's laryngoscope and endotracheal tubes. Magill's bought the first orange tube from football shop and found curve is needed for endotracheal tube. He tried both nasal and oral route and noted that nasal route is more useful and gives the confidence in freedom of airway and the impossibility of blood getting into trachea.

He was the one who promoted anaesthesia as a specialised field in medicine and he was key person in the foundation of association of anaesthetist in 1932 and diploma in anaesthesia in 1935.



FIG.4 Sir Ivan Whiteside Magill

Mechanical ventilator is the most important component of mechanical ventilation after endotracheal intubation. It is of two type i.e. invasive and non-invasive. Long back in olden times in 1780 **Chaussier** introduce first non-invasive mechanical apparatus for positive-pressure NIV, a bag and mask manual ventilator.

In 1838, physician from the Scotland **John Dalziel** first demonstrated full body type “tank ventilator” which was a type of negative pressure ventilator. It was made up of an air tight box and patient had to maintain sitting position inside. Negative pressure was created by pumping air in and out of the box manually. This device had pressure gauge to measure negative pressure.

In 1904 **Sauerbrach** ⁽²⁾ Evendeveloped a negative pressure operating ventilator with patients’ body inside and head out of the chamber. This was designed in such a way that surgeon can performed surgery while also in the chamber.patients’ lower body was encased in the sac so that blood accumulation can be prevented in abdomen and lower limbs.

Negative pressure ventilation clinically gotmore attention during World War II when outbreaks of poliomyelitis happened worldwide in 19930-1960with the development of iron lung, designed by **Drinker** and **Shaw**, manufactured and sold by **Emerson**.Initial ICUs set up with this machine managed dozens of peoples of all ages requiring negative ventilation.

Boston’s children hospital developed chambers such that it can accumulates 4 childrensimultaneously in itand allowed to nurse them at a time from inside the chamber.

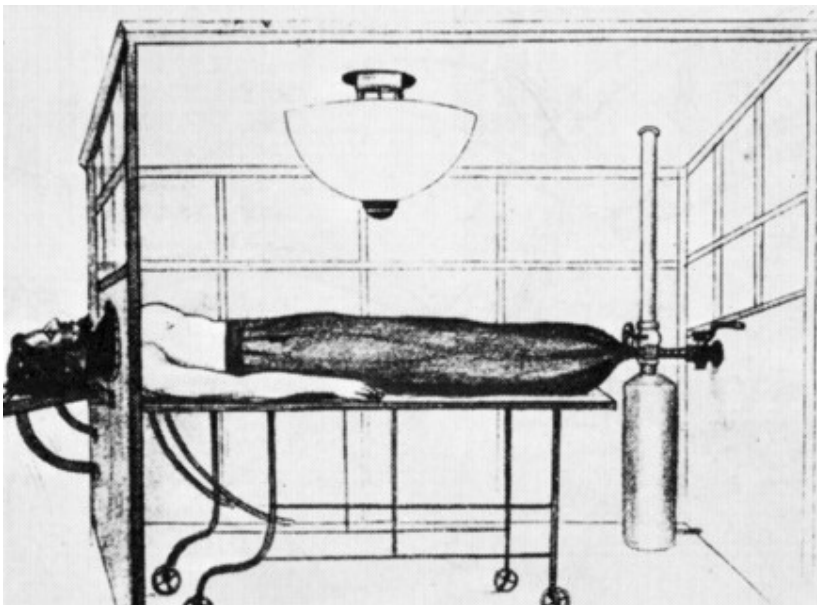


FIG.5 19th century Negative pressure ventilator

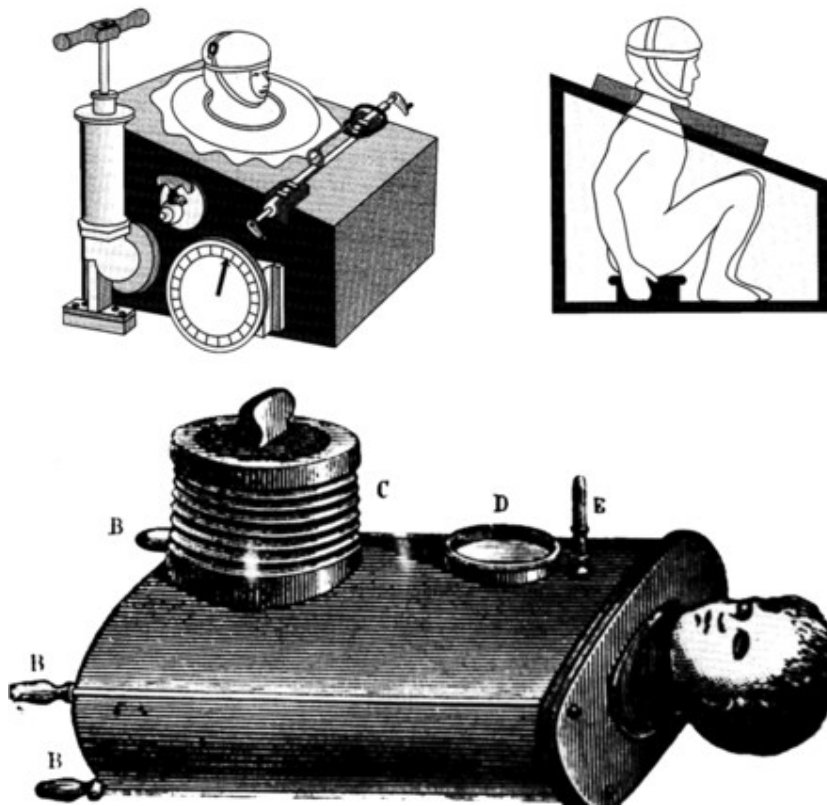


FIG.6 ICU SETUP OF WORLD WAR II DURING POLIOMYELITIS OUTBREKS

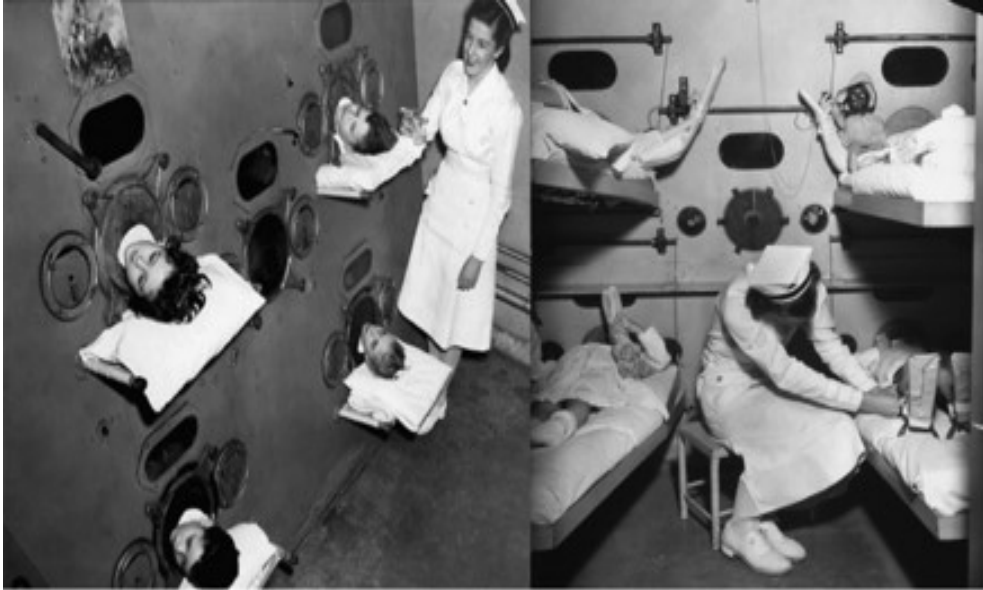


FIG.7 BOSTONS CHILDREN HOSPITAL – MULTIPERSON VENTILATOR 1950

Over the time numerous other types of ventilators has come up with varying success, such as “raincoat”, “chest cuirass”.

In late 60's new trend has come with several new factor. Volume targeted ventilators begin to appear and second jet aviation at the close of second world war led to development of small compact intermittent positive pressure breathing devices. Negative pressure ventilator is difficult to use because of their size, heavy weight and cumbersome and it is difficult to avoid leaking of excess gases which causes major effect on patient like cooling of body.

Bag and mask manual ventilator should be provided with positive pressure ventilator was introduced in 1780 by **Chaussier** and bellow with mask introduced by **fell** and **Drager's pulmator** was introduced for the first time in 1911.this has been saved thousands of lives by using unique pneumatically operated positive pressure device.

FIRST GENERATION ICU VENTILATORS

Ventilators for positive-pressure invasive ventilation were introduced in the 1940s and 1950s⁽⁴⁾ primarily providing volume-control ventilation without patient-triggered capabilities. The Morch ventilator was a basic, single-circuit piston device placed under the patient's bed, equipped with a monitor and alarm, but requiring manual respiratory rate counting and separate tidal volume measurement. The inspiratory and expiratory ratio was fixed.

In contrast, the more advanced Engstrom ventilator, with a double-circuit, functioned as both an anaesthesia machine and an ICU ventilator. It featured airway pressure and tidal volume monitoring, and allowed for more precise respiratory rate settings, but still relied on machine-triggered inspiration with a 1:2 inspiratory/expiratory ratio. The Emerson postoperative ventilator was a middle-ground option, offering volume-controlled ventilation with machine-triggered inspiration, adjustable inspiratory/expiratory ratios, and pressure and volume monitoring.

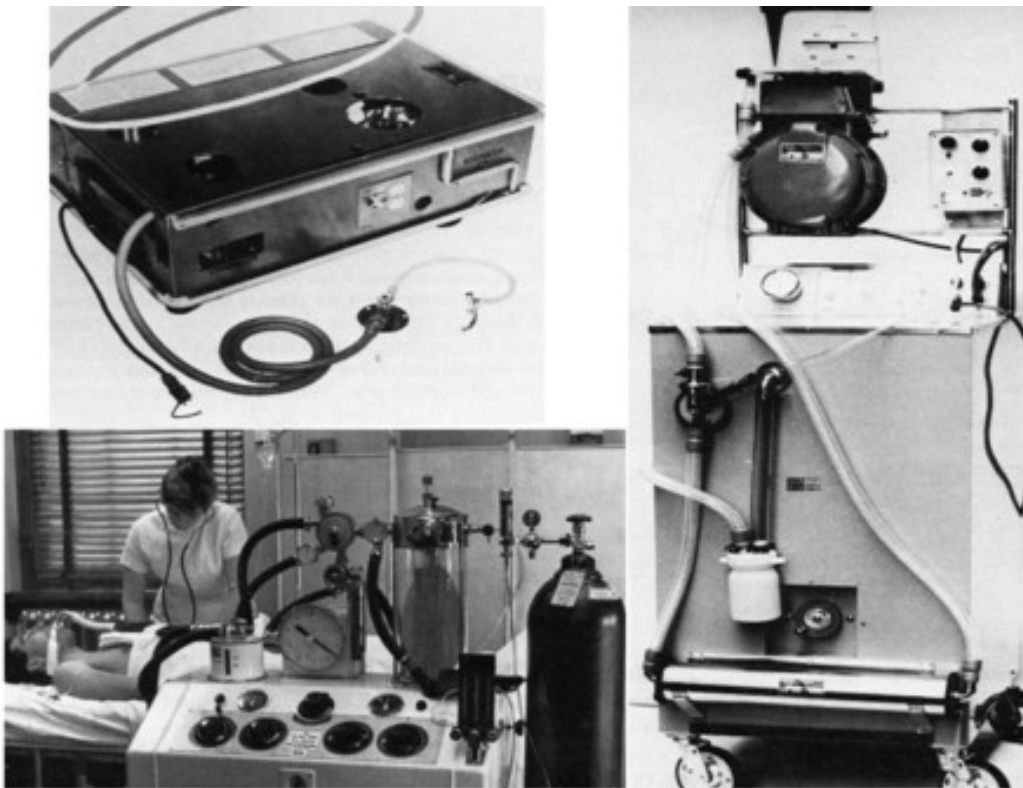


FIG.8 FIRST GENERATION ICU VENTILATOR

SECOND GENERATION ICU VENTILATORS

The second generation of ICU ventilators were different from first generation in many aspects. Simple monitors were incorporated into the ventilator itself. Monitoring of tidal volume and respiratory rate was visible on monitor but most unique feature was patient triggered inspiration. This was also supported with alarm setting for high pressure and respiratory rate. It was the first ventilator of this kind. Soon after the introduction of this generation of ventilators, intermittent mandatory ventilation (IMV) was introduced into adult ventilation. Downs et al published the first case series using IMV in 1973. He used an external secondary IMV gas flow system introduced into the ventilator circuit. Later ventilators of this generation added demand valves, and IMV became synchronized intermittent mandatory ventilation (SIMV). The introduction of the Servo 900C at the end of this generation introduced into clinical practice pressure-support and pressure-control ventilation.

In the late 1970s a publication by Hewlett et al provided a brief look into the future of ventilator modes. As illustrated, they were the first to demonstrate the concept of closed-loop ventilation. Although their approach to mandatory minute ventilation was purely mechanical, it did function as a closed-loop controller and provided a model for many of the modes of today. The main drawback with this system was that the patient could breathe the entire minute volume with a very rapid and shallow breathing pattern, but it did provide the first form of closed-loop control.

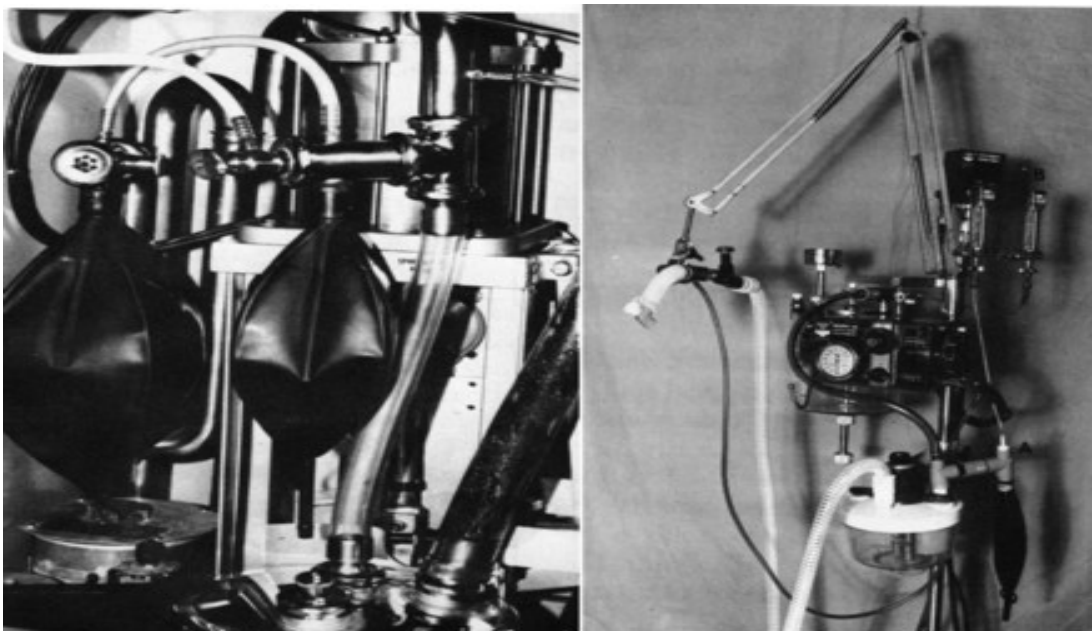


FIG .9

SECOND GENERATION ICU VENTILATOR

THIRD GENERATION ICU VENTILATOR

Third-generation ICU ventilators, such as the Puritan Bennett 7200, Bear 1000, Servo 300, and Hamilton Velour, ⁽⁴⁾ were notable for their microprocessor control, which enabled advanced gas delivery and monitoring methods. These innovations significantly improved gas delivery systems and made them more responsive to patient demand through flow-triggering. This generation of ventilators included features like pressure support, pressure control, volume control, and synchronized intermittent mandatory ventilation (SIMV). They provided volume ventilation, pressure ventilation, and pressure support during spontaneous breaths. These ventilators were also equipped with numerous alarms and monitors, continuously checking the patient's condition and ventilator functions. They introduced pressure, flow, and volume waveforms, as well as pressure-volume and flow-volume loops.

Stock et al. pioneered airway pressure release ventilation (APRV) using these ventilators. Their high-flow circuit incorporated a solenoid valve and two PEEP valves, enabling high continuous positive airway pressure (CPAP) with periodic reductions to facilitate ventilation. The solenoid allowed customization of the inspiratory-expiratory time ratio and the frequency of low CPAP drops.

These advancements represented a significant leap in ICU ventilator technology, enhancing patient support and monitoring capabilities



FIG.10 THIRD GENERATION VENTILATOR

FOURTH GENERATION ICU VENTILATOR

Modern ICU ventilators ⁽⁵⁾ are the most advanced and versatile mechanical ventilators. Many advanced ventilators, including ICU ventilators, are available worldwide. Sub-acute, transport, home-care, and non-invasive ventilators are also available. Tertiary care centres worldwide employ these ventilators.

REVIEW OF LITERATURE

Brochard et al. (1994) and Esteban et al. (1995, 1997)⁽⁸⁾ compared different weaning techniques, including T-piece trials, CPAP, and pressure support ventilation (PSV). Their findings suggested that PSV reduces work of breathing (WOB) more effectively than T-piece trials, while CPAP may provide benefits in reducing airway collapse and intrinsic PEEP.

However, **Epstein (2002)** argued that T-piece trials provide a better assessment of spontaneous breathing ability, as they expose patients to unassisted ventilation. Despite this, T-piece trials have been associated with higher respiratory muscle workload, which could lead to fatigue and weaning failure (**Jubran & Tobin, 1997**).

Jubran & Tobin (1997) and Parthasarathy & Tobin (2000)⁽⁹⁾ found that higher PTP values correlate with increased respiratory muscle workload, potentially leading to weaning failure. The Pressure-Time Product (PTP) and Respiratory Muscle Workload. PTP is an important measure of the metabolic work and oxygen consumption of respiratory muscles (Bellemare & Grissino, 1982). It quantifies oesophageal (PTP_{es}) and transdiaphragmatic (PTP_{di}) pressure over time, providing insight into patient effort and potential fatigue. Studies by **Tobin (1994)** emphasized that patients with high PTP during weaning are at risk of respiratory fatigue, necessitating ventilatory support. However, excessive support, particularly with high levels of PSV, can lead to ventilator-induced diaphragmatic dysfunction (VIDD) (**Powers et al., 2013**), making careful titration essential.

Comparative Effects of CPAP, PSV, and T-Piece on PTP and Weaning Success: CPAP and Pressure-Time Product: CPAP has been shown to reduce inspiratory effort by maintaining airway patency and reducing intrinsic PEEP (**Strickland & Marini, 1998**). However, its ability to lower PTP depends on factors like airway resistance (RL) and lung compliance (CL) (**Hess, 2001**).

PSV and Respiratory Muscle Workload: Several studies suggest that low-level PSV (5 cm H₂O) can significantly reduce PTP compared to T-piece trials, as it provides assistance proportional to inspiratory effort (**Brochard et al., 1994**). However, excessive PSV may lead to over-assistance, which can delay diaphragmatic recovery and weaning success (**Powers et al., 2013**).

T-Piece and Work of Breathing: T-piece trials, which provide no additional support, are commonly used to assess true spontaneous breathing ability (**Epstein, 2002**). However, they increase PTP compared to PSV and CPAP, leading to greater inspiratory muscle effort (**Jubran & Tobin, 1997**). This increased workload may be beneficial for assessing readiness but also poses a risk of fatigue and failed extubation.

Existing literature highlights the effects of CPAP, PSV, and T-piece trials on respiratory muscle workload, with PSV generally reducing PTP the most and T-piece leading to the highest inspiratory effort. However, limited studies have directly compared these modes using PTP as a primary outcome during weaning. This study aims to fill this gap by systematically comparing CPAP (0 and 5 cm H₂O), PSV (5 cm H₂O), and T-piece in intubated patients recovering from acute respiratory failure, focusing on their effects on PTP, breathing patterns, lung mechanics, and hemodynamic responses.

Spontaneous Breathing Trials (SBT) and Weaning Strategies The T-piece trial is one of the most commonly used methods for conducting SBTs before extubation.

Esteban et al. (1995, 1997), T-piece trials allow for an accurate assessment of a patient's ability to sustain spontaneous breathing without ventilatory assistance. However, some studies suggest that the increased respiratory effort associated with T-piece trials may lead to muscle fatigue and failed extubation.

Jubran & Tobin, 1997 Alternatively, PSV-assisted SBTs have been proposed as a strategy to reduce the work of breathing (WOB) while still allowing for the assessment of spontaneous breathing capability.

Thille et al. (2020)⁽¹⁰⁾ conducted a post-hoc analysis of a multicentre trial and found that PSV-assisted SBTs increased extubation success rates among high-risk patients compared to T-piece trials. Their findings suggest that a gradual reduction in ventilatory support, rather than abrupt removal (as in T-piece trials), may improve weaning outcomes.

Burns et al. (2018) highlighted that patient who failed a T-piece trial often had higher respiratory muscle workload and greater risk of reintubation. This suggests that PSV may offer a more protective transition by supporting weakened respiratory muscles while still testing spontaneous breathing capability. Pressure Support Ventilation (PSV) vs. T-Piece in Weaning. The debate between PSV and T-piece trials continues in clinical practice. Brochard et al. (1994) first demonstrated that PSV reduced WOB during weaning compared to T-piece trials. More recently, **Thille et al. (2020)** found that patients at high risk of extubation failure benefitted more from PSV-assisted SBTs than from T-piece trials.

Key findings include PSV provides partial support, reducing respiratory muscle workload while still assessing the patient's ability to breathe independently. T-piece exposes patients to unassisted breathing, making it a more challenging trial, which may be beneficial for low-risk patients but problematic for high-risk patients. High-risk patients (e.g., those with chronic respiratory disease, prolonged mechanical ventilation, or cardiac comorbidities) may have a higher chance of extubation success with PSV than with T-piece trials. However, some studies suggest that PSV trials might overestimate readiness for extubation by providing more support than the patient will receive post-extubation (Epstein, 2002). This discrepancy raises concerns about PSV potentially leading to premature extubation in some cases.

Xu et al. (2018)⁽¹¹⁾ examined the effects of HFNC in comparison to COT and NIV. Their key findings include: HFNC significantly reduced reintubation rates compared to COT (OR 0.46, 95% CI 0.33–0.63, $p < 0.00001$). HFNC did not show a clear advantage over NIV in preventing reintubation when used after extubation. When used as a primary mode of support, HFNC lowered the risk of treatment failure compared to COT. These findings suggest that HFNC is an effective post-extubation support strategy, especially for preventing reintubation in high-risk patients. However, its role compared to PSV-based weaning strategies remains an area of ongoing research. High-Flow Nasal Cannula (HFNC) as a Post-Extubation Strategy: Post-extubation support plays a crucial role in preventing reintubation. HFNC has emerged as an alternative to conventional oxygen therapy (COT) and NIV for patients at risk of extubation failure. A systematic review and meta-analysis.

The literature highlights the importance of selecting an appropriate SBT method based on patient risk factors: T-piece trials provide a stricter test of spontaneous breathing but may lead

to higher muscle fatigue and reintubation risk in high-risk patients. PSV-assisted SBTs offer a more gradual transition from ventilatory support, which may be more effective in high-risk patients (**Thille et al., 2020**). HFNC is emerging as an effective post-extubation support strategy, particularly for reducing reintubation rates compared to COT (Xu et al., 2018).

Despite these insights, more studies are needed to determine the optimal combination of weaning strategies (PSV vs. T-piece) and post-extubation support (HFNC vs. NIV) for different patient populations.

This review of literature suggests that PSV may be superior to T-piece for SBTs in high-risk patients, as it reduces respiratory effort while still assessing spontaneous breathing ability. Additionally, HFNC appears to be a promising post-extubation support strategy, particularly for reducing reintubation risks. However, further studies are needed to refine patient selection criteria for these weaning approaches to ensure optimal outcomes.

Post-Extubation Oxygen Therapy: Importance and Challenges. The period following extubation is crucial, as respiratory muscle fatigue, airway obstruction, and secretion management issues can contribute to post-extubation respiratory failure and reintubation (Epstein, 2002). HFNC has gained attention as a superior alternative to COT due to its ability to: Deliver heated, humidified oxygen at high flow rates, reducing airway dryness and resistance (Frat et al., 2015). Generate a mild positive airway pressure, improving lung recruitment and reducing work of breathing (**Dewan & Bell, 1994**). Better match the patient's inspiratory demand, minimizing hypoxemia and respiratory distress (**Sztrymf et al., 2011**).

High-Flow Nasal Cannula (HFNC) vs. Conventional Oxygen Therapy (COT) in Low-Risk Patients. A multicentre randomized controlled trial (RCT) in Spain (2012-2014) analysed 527 patients at low risk for reintubation to compare HFNC and COT for 24 hours post-extubation. The study found that HFNC significantly reduced reintubation rates within 72 hours (4.9% vs. 12.2%; absolute risk reduction: 7.2%; $p = 0.004$). Postextubation respiratory failure was also lower in the HFNC group (8.3% vs. 14.4%; absolute difference: 6.1%; $p = 0.03$). Time to reintubation was similar between groups (19 hours vs. 15 hours; $p = 0.66$). No adverse events were reported, reinforcing HFNC's safety in this population. These findings align with **Xu et al. (2018)**, whose meta-analysis of 18 RCTs demonstrated that HFNC reduced extubation failure rates compared to COT, particularly in high-risk patients. **Implications for Clinical Practice:** While HFNC has proven benefits, its routine use in low-risk patients remains debated.

Advantages: Reduced reintubation rates, better oxygenation, and improved patient comfort. **Cons:** Higher costs and the need for specialized equipment compared to standard oxygen therapy. Despite these concerns, this study provides strong evidence that HFNC should be considered even in low-risk populations to prevent avoidable reintubation and ICU complications. The literature consistently supports HFNC over COT in reducing post-extubation failure and reintubation risks. While previously studied in high-risk patients, this study confirms its benefits in low-risk patients as well. Future research should explore cost-effectiveness and optimal HFNC protocols to guide broader implementation in ICUs. **High-Flow Nasal Cannula (HFNC) in Post-Extubation Management. Mechanism and Benefits of HFNC:** HFNC delivers heated, humidified oxygen at high flow rates (up to 60 L/min), providing several physiological advantages over conventional oxygen therapy (COT) and NIV. **WOB:** HFNC matches inspiratory demand better than standard oxygen, reducing air

hunger and effort required to breathe (Sztrymf et al., 2011). Mild Positive Airway Pressure: While not as strong as CPAP or NIV, HFNC generates a low level of positive end-expiratory pressure (PEEP), improving lung recruitment and preventing atelectasis (Dewan & Bell, 1994). Airway Humidification and Secretion Clearance: Heated, humidified oxygen prevents airway dryness, reduces inflammation, and improves mucus clearance, leading to less secretion retention (Frat et al., 2015)⁽¹³⁾ Improved Oxygenation and CO₂ Clearance: The high flow rate reduces dead space ventilation, leading to better CO₂ washout and more effective oxygen delivery (Spoletini et al., 2015).

2. HFNC vs. Conventional Oxygen Therapy (COT) After Extubation Xu et al. (2018) conducted a systematic review of 18 randomized controlled trials (RCTs, n = 4,251 patients) comparing HFNC to COT and NIV in adult ICU patients. Their findings include: HFNC significantly reduced reintubation rates compared to COT (Odds Ratio [OR] 0.46; 95% CI 0.33–0.63; p < 0.00001). HFNC reduced extubation failure rates (OR 0.43; 95% CI 0.25–0.73; p = 0.002). HFNC was superior to COT in preventing postextubation respiratory failure, particularly in high-risk patients. Compared to NIV, HFNC reduced intubation rates when used as primary support but showed no clear advantage in post-extubation use. Similarly, a Spanish multicentre RCT (2012–2014, n = 527) focused on low-risk patients found that reintubation within 72 hours was lower with HFNC (4.9% vs. 12.2%; p = 0.004). Post-extubation respiratory failure was lower with HFNC (8.3% vs. 14.4%; p = 0.03). Time to reintubation was not significantly different (19 hours vs. 15 hours; p = 0.66). HFNC vs. Non-invasive Ventilation (NIV) in Post-Extubation Care NIV has been the traditional choice for preventing reintubation, especially in high-risk patients (e.g., COPD, heart failure). However, HFNC is now being considered as an alternative.

Hernandez et al. (2016, 2019)^(14,15) found that HFNC was non-inferior to NIV in preventing reintubation in high-risk patients. **Patel et al. (2015)** showed that HFNC improved comfort and tolerance, leading to better patient compliance than NIV. HFNC may be preferred over NIV in cases where patients do not tolerate mask-based ventilation due to discomfort, claustrophobia, or skin breakdown. Despite these benefits, NIV remains superior for hypercapnic respiratory failure (e.g., COPD exacerbations) where CO₂ clearance is critical. Clinical Implementation and Challenges: While HFNC has shown clear benefits in post-extubation management, its adoption in all ICUs is still variable due to: Cost and Equipment Availability: HFNC requires specialized devices (e.g., Airvo™, Optiflow™, Vapotherm™), which may not be available in resource-limited settings. Patient Selection Criteria: HFNC is particularly beneficial for patients at moderate to high risk of reintubation, but its routine use in low-risk patients remains debated. Training and Protocols: Proper use requires staff training on flow rate titration and monitoring for hypoxemia, hypercapnia, or mask transition failure. Future Directions and Research Needs: Comparison of HFNC + NIV hybrid strategies (e.g., HFNC during the day, NIV at night). Cost-effectiveness studies in low-resource settings. More evidence on HFNC use in hypercapnic respiratory failure. Conclusion: HFNC has transformed post-extubation respiratory care, offering superior oxygenation, secretion clearance, and patient comfort compared to COT. Its role as an alternative to NIV in preventing reintubation, particularly in high-risk patients, is growing. However, further research is needed to optimize patient selection and cost-effectiveness strategies for broader ICU adoption. Mechanical ventilation is a critical intervention in intensive care units (ICUs), and the weaning process plays a crucial role in patient outcomes. Various studies have explored different approaches to classifying and optimizing the weaning process.

Boudreau et al. (2016) analysed the weaning process in 36 ICUs over a three-month period. The study included 2,729 mechanically ventilated patients, but previous classification methods failed to categorize half of them adequately. To address this, the researchers introduced a new classification system that successfully classified 99% of patients. According to this classification, 24% of patients never initiated the weaning process, while 57% experienced a weaning duration of less than 24 hours (Group 1). Another 10% faced a difficult weaning process lasting more than one day but less than a week (Group 2), and 9% had prolonged weaning of one week or longer (Group 3). The study found a significant increase in ventilation duration, ICU stay, and mortality rates across these groups, with mortality rates of 6%, 17%, and 29% respectively. Additionally, the risk of mortality increased from 19% after the first separation attempt to 37% after ten days of unsuccessful weaning. The authors concluded that this new classification provides a more comprehensive framework for categorizing all weaning scenarios.

Subirà et al. (2019)⁽¹⁷⁾ conducted a randomized controlled trial to evaluate different weaning strategies in 18 ICUs in Spain. The trial included 1,153 patients who had undergone mechanical ventilation for at least 24 hours and were deemed ready for weaning. Participants were randomly assigned to one of two weaning protocols: a two-hour T-piece trial or a 30-minute spontaneous breathing trial (SBT) using pressure support ventilation (PSV) with 8 cm H₂O pressure. The primary outcome was the success rate of extubation, while the secondary outcome focused on reintubation rates among those who were extubated following SBT. The results indicated that both methods—30 minutes of PSV and two hours of T-piece ventilation—were associated with higher successful extubation rates, suggesting that these approaches are effective strategies for weaning patients from mechanical ventilation. These studies highlight the importance of proper classification and strategy selection in the weaning process, ultimately influencing patient recovery and survival rates in ICUs. The post-extubation period is a critical phase for mechanically ventilated patients, particularly those at high risk of reintubation. Different strategies, such as high-flow oxygen therapy and non-invasive ventilation (NIV), have been evaluated to determine their effectiveness in preventing respiratory failure and reintubation.

Hernández et al. (2016) was conducted in three intensive care units in Spain to compare the efficacy of high-flow oxygen therapy and NIV in critically ill patients deemed ready for planned extubation but with at least one high-risk factor for reintubation. The study enrolled 604 patients, with a mean age of 65 years (SD 16), of whom 64% were male. Among them, 314 patients received NIV, while 290 were provided with high-flow oxygen therapy for 24 hours post-extubation. The results showed that 22.8% of patients in the high-flow oxygen group required reintubation compared to 19.1% in the NIV group, with an absolute difference of -3.7%. Additionally, post-extubation respiratory failure occurred in 26.9% of patients in the high-flow oxygen group, compared to 39.8% in the NIV group, with a risk difference of 12.9%. These findings suggest that high-flow oxygen therapy is not inferior to NIV for high-risk patients and may even provide certain advantages in post-extubation management. This study contributes to the growing body of evidence supporting the use of high-flow oxygen therapy as an alternative to NIV in preventing respiratory complications after extubation in high-risk patients.

TOPIC SPECIFIC TO STUDY

Weaning is the process of withdrawing mechanical ventilatory support and transferring the work of breathing from the ventilator to the patient.

The ability to breathe spontaneously is the criteria to measure the success or failure of weaning attempts.

Weaning success: it is defined as absence of ventilatory support 48 hours following the extubation, while the spontaneous breaths are unassisted by mechanical ventilation, supplemental oxygen, bronchodilators, pressure support ventilation or continuous positive airway pressure may be used

Weaning in progress: It is an intermediate category for patients who are extubated but continue to receive ventilatory support by non-invasive ventilation NIV. Use of NIV allows early weaning attempts and minimizes complications associated with prolonged mechanical ventilation and artificial airway.

Weaning Failure: it is defined as either the failure of SBT or the need for reintubation within 48 hours following extubation. Patients who fail SBT often show signs of Tachypnea, Tachycardia, Hypertension, Hypotension, Hypoxemia, Acidosis or Arrhythmias. They may also show agitation, distress, diminished mental status, diaphoresis and increased work of breathing.

Weaning becomes more challenging in patient who have failed an attempt, excessive secretions, hypercapnia, prolonged mechanical ventilation (>72 hours) and upper airway disorders are factors that can affect weaning outcome.

Conditions Prior to weaning

The first consideration before any weaning attempt is to assess the patient's overall clinical status.

- Has the patient recovered from the acute phase of the disease?
- Are there any other conditions that can interfere with patient spontaneous work of breathing.

Conditions that may hinder successful weaning outcome:

- Patient/Pathophysiologic: fever, infection, renal failure, sepsis, sleep deprivation.
- Cardiac/Circulatory: Arrhythmias, Blood pressure, Cardiac output, Fluid imbalance, Anemia, Dysfunctional hemoglobin.
- Dietary / Acid-base/ Electrolytes: Nutritional or caloric deficit, Acid-base imbalance, Electrolytes imbalance.

Classification of weaning⁽⁶⁾

Simple weaning: Patients who proceed from initiation weaning to successful extubation on first attempt.

Difficult weaning: Patients who fail initial weaning and require up to 7days from the first SBT to achieve successful weaning.

Prolonged weaning: require more than 7 days from the first SBT to achieve successful weaning.

The simple weaning group represents 60-70% of ventilated patients, difficult group includes 20-25% of patients and remaining 15% falls into prolonged group.

Weaning criteria is used to evaluate the readiness of the patient for a weaning trial and the likelihood of a weaning success. It involves -

- Clinical criteria.
- Ventilatory criteria.
- Oxygenation criteria.
- Pulmonary reserve and measurements.

Clinical Criteria:

Resolution if acute phase of disease

Adequate cough / gag reflex

Absence of excessive secretions

Cardiovascular and hemodynamic stability

WEANING CRITERIA		
Category	Example	Note
Clinical criteria	Resolution of acute phase of disease Adequate cough Absence of excessive secretions Cardiovascular and hemodynamic stability	
Ventilatory criteria	Spontaneous breathing trial PaCO ₂ Vital capacity Spontaneous V _T Spontaneous f f/V _T Minute ventilation	Tolerates 20 to 30 min <50 mm Hg with normal pH >10 mL/kg >5 mL/kg <35/min <100 breaths/min/L* <10 L with satisfactory ABG
Oxygenation criteria	PaO ₂ without PEEP PaO ₂ with PEEP (<8 cm H ₂ O) SaO ₂ PaO ₂ /F _I O ₂ (P/F) Q _S /Q _T P(A-a)O ₂	>60 mm Hg at F _I O ₂ up to 0.4 >100 mm Hg at F _I O ₂ up to 0.4 >90% at F _I O ₂ up to 0.4 ≥150 mm Hg <20% <350 mm Hg at F _I O ₂ of 1.0
Pulmonary reserve	Vital capacity Max. insp. pressure	>10 mL/kg > -30 cm H ₂ O in 20 sec
Pulmonary measurements	Static compliance Airway resistance V _D /V _T	>30 mL/cm H ₂ O Stable or improving <60% while intubated
WEANING CRITERIA ⁽⁶⁾		

Weaning can be done using:

Spontaneous breathing trials

Pressure support ventilation

Synchronized mandatory intermittent ventilation (SIMV)

T- piece ventilation

This is a potential spontaneous breathing trial protocol.

Reduce/stop sedation to allow spontaneous breathing. If available, reduce ATC ventilation for 30 minutes. Stop the trial when weaning fails. Consider extubation or extending trial to 120

minutes if patient tolerates 30 minutes. If patient fails trial, return to mechanical ventilation and gradually decrease assistance. Trial can be given again next day.

WEANING PROTOCOL FROM MECHANICAL VENTILATOR		
Step	Criteria	Results
1	Does the patient show: <ul style="list-style-type: none"> • Evidence of some reversal of underlying cause for ventilatory failure? • Presence of inspiratory effort? • Hemodynamic stability? (absence of myocardial ischemia, hypotension, use of vasopressor) • Adequate oxygenation and acid-base status? ($\text{PaO}_2/\text{F}_1\text{O}_2 > 150$ mm Hg, $\text{PEEP} < 8$ cm H_2O and $\text{pH} \geq 7.25$) • Light sedation or better? (brief eye contact to voice command) 	If YES to <i>all five</i> questions, proceed to STEP 2. If NO to <i>any one</i> question, postpone weaning until next day.
2	Perform and measure rapid shallow breathing index (RSBI or f/V_T) with mandatory frequency turned off and pressure support ≤ 8 cm H_2O , $\text{PEEP} \leq 5$ cm H_2O , measurements taken following ≥ 3 min of spontaneous breathing. Is $\text{RSBI} (f/V_T) < 100$ breaths/min/L?	If YES, proceed to STEP 3. If NO, postpone weaning until next day.
3	Can patient tolerate: Spontaneous breathing trial for up to 30 minutes without termination? (See termination criteria* below.)	If YES, proceed to ventilator discontinuance or evaluate for extubation. If NO, repeat weaning until next day.
WEANING PROTOCOL ⁽⁶⁾		

Signs of weaning failure: Once the weaning process has been started, weaning criteria should be monitored closely to ensure the patient is tolerating the weaning attempt. The weaning process should be stopped if the patient shows signs of muscle fatigue or ventilatory failure.

Early signs of weaning failure include: Tachypnea, use of accessory muscles and paradoxical abdominal movements, dyspnea, chest pain, chest-abdomen synchrony and diaphoresis.

It is important to evaluate and apply clinical data in conjunction with patients' clinical presentation. Patient may hyperventilate due to hypoxia, pain, anxiety or inappropriate ventilator settings.

INDICATORS OF WEANING FAILURE ⁽⁶⁾	
Indicators	Examples
Blood Gases	Increasing PaCO ₂ (> 50 mm Hg) Decreasing pH (<7.30) Decreasing PaO ₂ (<60 mm Hg) Decreasing SpO ₂ (<90%) Decreasing PaO ₂ /F _I O ₂ (<150 mm Hg)
Vital Signs	Changing blood pressures (20 mm Hg systolic or 10 mm Hg diastolic) Increasing heart rate (by 20/min, or >110/min) Abnormal ECG (presence of arrhythmias)
Respiratory Parameters	Decreasing V _T (<250 mL) Increasing f (>30/min) Increasing f/V _T (>100 breaths/min/L) Decreasing MIP (<- 20 cm H ₂ O) Decreasing static compliance (<30 mL/cm H ₂ O) Increasing V _D /V _T (>60%)

Terminal weaning: Terminal weaning is defined as withdrawal of mechanical ventilation that results in death of a patient. When terminal weaning is considered four concerns must be evaluated: patients informed request, medical futility, reduction of pain and suffering and fear/distress.

MATERIALS AND METHODS

SOURCE OF DATA:

This study was carried out in the critical care unit of B.L.D.E(DU) Shri. B M Patil medical college hospital and research centre Vijayapura, Karnataka. Study has included age group more than 18 years. Study has carried out Under high risk with written informed consent from patient and after obtaining approval from institutional and ethical committee.

METHODS AND COLLECTION OF DATA:

Study type: Prospective Randomized Controlled trial.

Study period: From June 2023 to December 2024

Sample size: Using G*Power ver 3.1.9.4 software for sample size calculation, The Lactate mmol/L T- Piece SBT Group (Mean=1.9, SD=0.8148) and High-flow Oxygen SBT (Mean=1.4, SD=0.8148) This study requires a total sample size of 110(for each group 55, assuming equal group sizes), so To achieve a power of 89% for detecting a difference in Means: Inequality, two independent Means (two groups) (t-test) with a 5% level of significance.

STATISTICAL ANALYSIS

The data obtained are entered into a Microsoft Excel sheet, and statistical analyses are Performed using a statistical package for the social sciences (SPSS) (Version 20). Results are Presented as Mean, SD, counts and percentages, and diagrams. For normally distributed Continuous variables between the two groups will be compared using an independent sample t- Test. For not normally distributed variables, the Mann-Whitney U test is used. For Categorical Variables between the two groups are compared using the Chi-square test/Fisher's exact test. If $p < 0.05$ will be considered statistically significant. All statistics are performed in two tailed.

METHODOLOGY

- In patients assign to receive the T-piece ventilation strategy during SBT (T-piece group), the ventilator will disconnect from the endotracheal tube and the T piece is connected to the endotracheal tube. T-piece ventilation is powered by air entrainment nebulizer, which can deliver FiO_2 of 0.21–1.00. The air entrainment nebulizer set at a flow of 8 L/min to provide FiO_2 of 0.4.
- In patients assigned to receive the high-flow oxygen ventilation strategy during SBT (high-flow group), the ventilator setting will change to inbuilt high flow oxygen mode.
- FiO_2 set as 0.4, and flow is set at 60 L/min to gain the maximum benefit from high-flow oxygen. To minimize the effects of oxygenation on the weaning failure, FiO_2 level is set at 0.4 in both groups. In both groups, SBT will perform for 30–60 min (or less in case of clinical intolerance).

All patients who successfully completed SBT will protocolize to be reconnected to mechanical ventilation using the previous ventilator parameters for at least 1 h rest and then directly extubated in both groups. Patients who are not tolerating the SBT will again be reconnected to mechanical ventilation and received once-daily SBT using the same method according to the assigned group within 72 h after starting the first SBT. Patients who are not completing the SBT successfully within 72 h after the first SBT will classify as weaning failure.

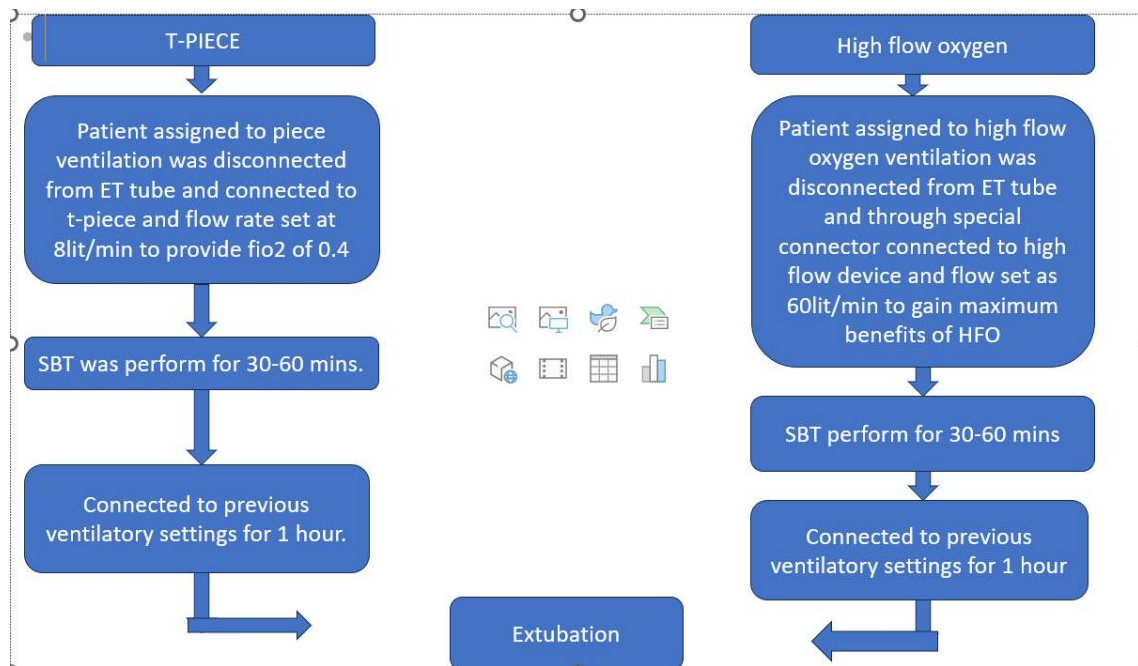
- According to previous studies, prophylactic use of HFNC/PS and/or NIV after extubation was considered for all patients for at least 48 h, but was not protocolled and remained at the discretion of ICU attending physician.

Comparing parameters before and after extubation

- Age
- Length of mechanical ventilation before SBT.
- APACHE II score at ICU admission.
- Reason for intubation(respiratory, non-respiratory, cardiogenic, respiratory, sepsis, others)
- Comorbidities(CVS, DM, malignancies, neurological disease)
- Arterial blood gas analysis (PH, PaO₂/fio₂, PaCo₂, lactate)

RANDOMISATION:

They are randomized to 2 groups. Group A receives HFNC and group B receives T-piece. Randomization done by selecting admitted patient in 1:1 ratio by physician. Random envelope containing a number card selected for patient by allotted nurse.



INCLUSION CRITERIA

- Patient on mechanical ventilation of age group > 18 years of age.
- Receiving mechanical ventilation for at least 12 hours.

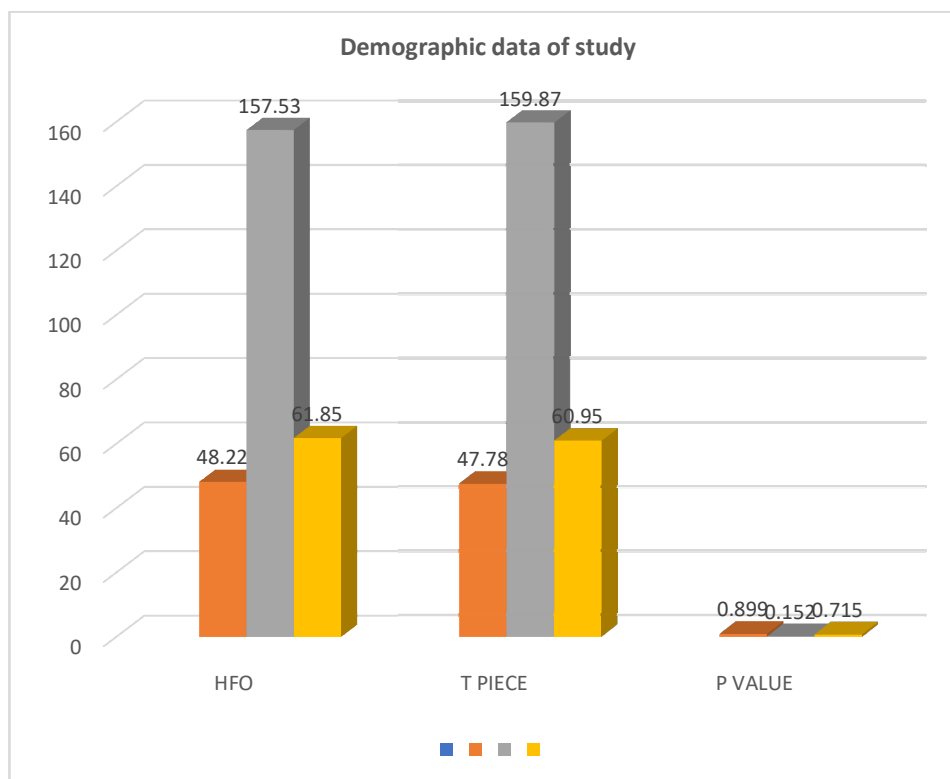
EXCLUSION CRITERIA.

- A patient who is undergone tracheostomy.
- Those who are not willing to continue on a life support system.
- Intubated for more than one month.

RESULTS

DEMOGRAPHIC DETAILS

DEMOGRAPHIC DETAILS	HFO	T PIECE	P VALUE
AGE	48.22	47.78	0.899
HEIGHT	157.53	159.87	0.152
WEIGHT	61.85	60.95	0.715



LOS and MV	HFO	T PIECE	P VALUE
LEGHTH OF MV BEFOREBSBT	1.91	2.24	0.301
LENGTH OF ICU STAY	5.47	7.29	0.019



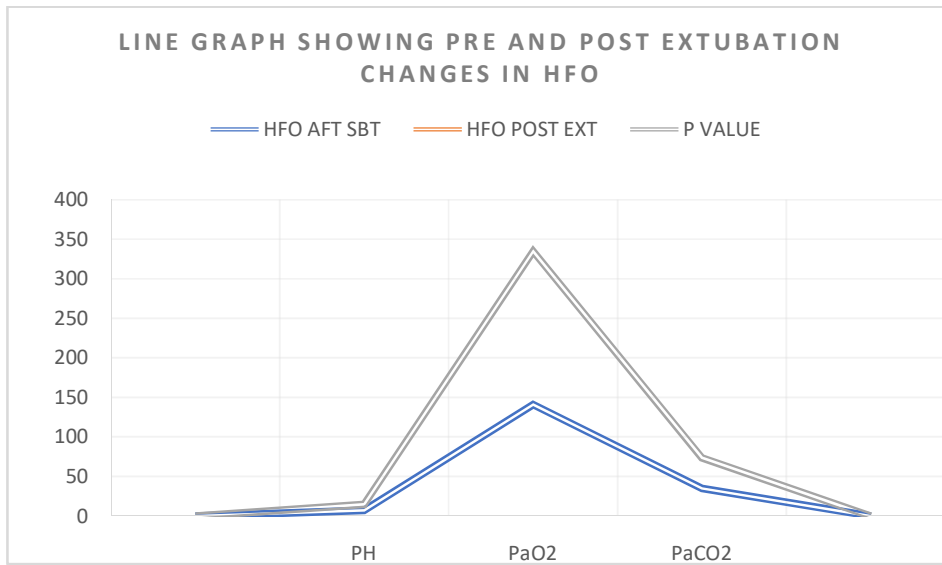
Shorter ICU Stays with High Flow Therapy:

- Group 1 (High Flow): Patients had an average ICU stay of 5.49 days.
- Group 2 (T-Piece): Patients stayed longer, averaging 7.29 days.
- P-value: 0.019 (statistically significant).

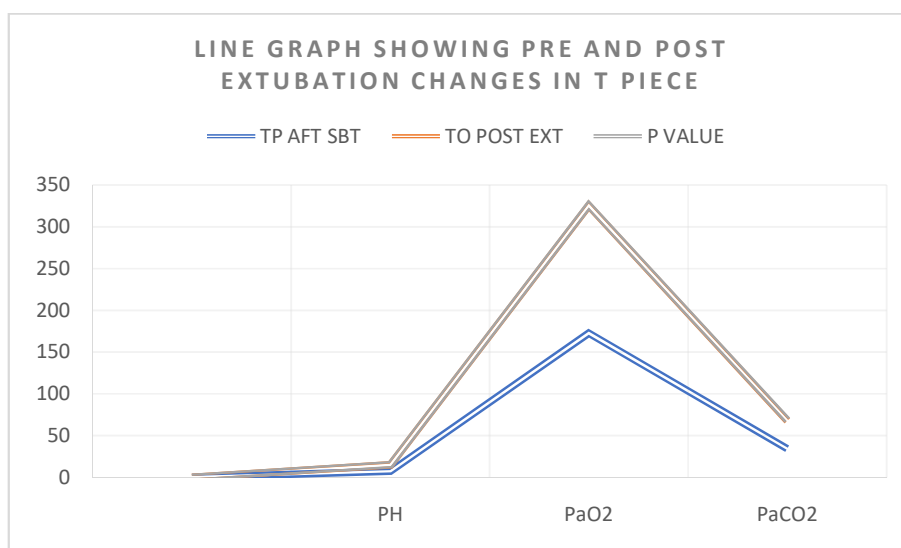
This suggests that patients weaned using High Flow therapy were able to leave the ICU sooner than those using the T-Piece method. That's not just a statistic—that's precious time reclaimed for patients and resources freed up for critical care units.

This visualization would clearly show that patients in the High Flow group have a shorter ICU stay (5.49 days) compared to the T-Piece group (7.29 days), highlighting the statistically significant difference ($p = 0.019$).

ABG	HFO AFT SBT	HFO POST EXT	P VALUE
PH	7.36944	7.38815	0.042
PaO2	141.109	193.596	0.001
PaCO2	35.118	38.5413	0.035



ABG	TP AFT SBT	TP POST EXT	P VALUE
PH	7.37805	7.39022	0.296
PaO2	172.751	152.7335	0.195
PaCO2	34.164	33.6013	0.593



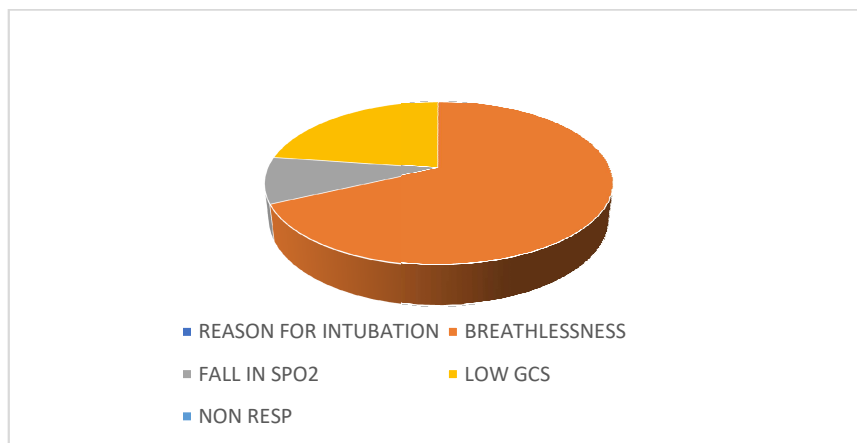
Breathing Easier Post-Extubation in Group 1:

- pH Levels: Slight increase post-extubation ($p = 0.042$), indicating a minor shift towards alkalinity.
- PAO₂ (Arterial Oxygen): Significant jump from 141.11 to 193.60 mmHg ($p = 0.001$). That's a substantial boost in oxygenation after removing the ventilator.
- PACO₂ (Arterial Carbon Dioxide): Increase from 35.12 to 38.54 mmHg ($p = 0.035$), possibly reflecting changes in ventilation post-extubation.

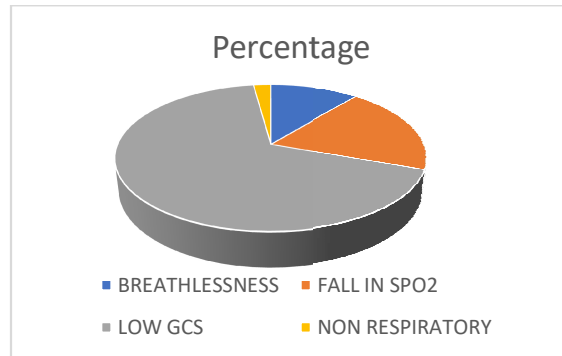
Stable Parameters in Group 2:

For the T-Piece group, none of the measured parameters showed significant changes after extubation. Their bodies didn't exhibit the same shifts in gas exchange as seen in the High Flow group.

REASON FOR INTUBATION	BREATHLESSNESS	FALL IN SPO2	LOW GCS	NON-RESP
HFO	54.50%	7.30%	18.20%	0.00%

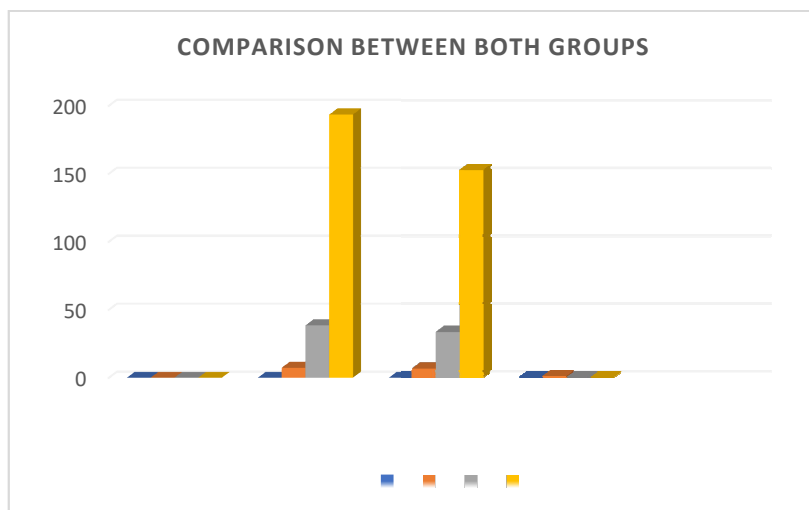


REASON FOR INTUBATION	BREATHLESSNESS	FALL IN SPO2	LOW GCS	NON-RESPIRATORY
T PIECE	9.19%	16.40%	56.40%	1.80%



- High Flow Group: Primarily intubated for breathlessness, indicating its use in patients with respiratory distress but stable consciousness.
- T-Piece Group: Predominantly intubated for low GCS, suggesting its application in more severe cases with neurological impairment.
- The significant association ($p = 0.000$) between the intubation reason and weaning method underscores the importance of initial patient assessment in optimizing weaning strategies.

post extubation	PH	PaCO2	PaO2
HFO	7.38815	38.5413	193.5964
T PIECE	7.39022	33.6013	152.7335
P VALUE	0.886	0.013	0.014



here's a significant association between the weaning method and the reason for intubation ($p = 0.000$). High Flow therapy was more commonly used in patients intubated due to breathlessness, whereas the T-Piece was prevalent among patients with low GCS.

DISCUSSION

The comparison of High Flow therapy and the T-Piece method in ICU settings shows several important findings that can help during clinical practice and patient care strategies. ICU Stays is the most important factor for patient in point of high cost of ventilator and the mortality and morbidity associated with mechanical ventilation. This study strongly shows High Flow therapy significantly reduces ICU stays compared to the T-Piece method. Ultimately it reduces burden on critical care system in terms of **Resource Allocation**. Shorter ICU stays mean that beds and critical care resources can be freed up more quickly for other patients in need. This can improve overall hospital efficiency and patient turnover rates.

Patient point of view Spending less time in the ICU can reduce the risk of hospital-acquired infections and other complications, potentially improving patient outcomes and recovery times. This study shows significant improvement in arterial Oxygenation (PAO₂) post extubation, and this can lead to better respiratory function and can contribute to lung recovery. Weaning plan is highly patient dependent and personalise as per patients' pathological recovery. There is a significant association between the reason for intubation and the choice of weaning method. Although, the findings emphasize the importance of initial patient assessment in guiding weaning strategies. Clinicians should consider Patient Characteristics like reason for intubation and overall condition. the weaning method based on the patient's reason for intubation and overall condition can lead to better outcomes. Continuous monitoring of gas exchange parameters post-extubation can help in assessing the effectiveness of the weaning method and making necessary adjustments.

Lee et al.(2022)⁽¹⁶⁾ conducted a randomised control trial in intensive care unit. In this study patients randomised into 2 groups i.e. high flow oxygen therapy and t-piece oxygenation during weaning period from mechanical ventilation 108 patients (mean age, 67.0 ± 11.1 years; 64.8% men) were included, with 54 patients in each group. Primary outcome of study was Weaning failure on day 2 occurred in 5 patients (9.3%) in the T-piece group and 3 patients (5.6%) in the high-flow group. The difference was not statistically significant ($p = 0.713$). Weaning failure on day 7 occurred in 13 patients (24.1%) in the T-piece group and 7 patients (13.0%) in the high-flow group. This difference was also not statistically significant ($p = 0.215$). Also, HFO SBT was associated with lower rate of weaning failure especially patient those who were intubated for respiratory failure (OR, 0.17 [95% CI, 0.04–0.78]; p for interaction = 0.020). this study didn't show difference in length of stay in ICU between both groups. This study may be underpowered to detect a clinically important treatment effect for individual patient.

Subira et al. (2019)⁽¹⁷⁾ conducted a randomized controlled trial to evaluate different weaning strategies in 18 ICUs in Spain. The trial included 1,153 patients who had undergone mechanical ventilation for at least 24 hours and were ready for weaning. Patients were

randomised into 2 groups either two-hour T-piece SBT or 30 mins SBT with 8cmH₂O PSV. primary outcome was successful extubation and free from mechanical ventilation for 72 hours after SBT while secondary outcome was reintubation rates, ICU stays and 90-day mortality. Result of PSV group showed 82.3% (473 patients) achieved successful extubation and T-piece group showed: 74.0% (428 patients) achieved successful extubation. The difference of 8.2% between the groups was statistically significant (95% CI, 3.4%-13%; $P = .001$). re-intubation rate was PSV Group: 11.1% (59 patients) in PSV group and 11.9% (58 patients) in T-piece group. The difference was not statistically significant ($P = .63$). ICU stay was less with PSV group than T-piece group. Hospital Mortality rate was 10.4% in PSV while 14.9% in T-piece group. The difference was statistically significant ($P = .02$). The study concluded that a spontaneous breathing trial consisting of 30 minutes of pressure support ventilation, compared with 2 hours of T-piece ventilation, led to significantly higher rates of successful extubation.

CONCLUSION

The study indicates that although there was no weaning failure was observed in both the groups at 48 hour and 72 hours and P value has come insignificant but the study shows that **High Flow therapy** is more effective in reducing ICU stay as compared to the **T-Piece method**. Patients weaned using High Flow therapy shifted out of ICU earlier (average 5.49 days) than those using the T-Piece method (average 7.29 days), with this difference being statistically significant ($p = 0.019$). High Flow therapy also shows significant improvements in oxygenation post-extubation, as shown by increased PAO_2 levels ($p = 0.001$).

Patients in the High Flow group were primarily intubated for breathlessness, whereas those in the T-Piece group were mostly intubated for low Glasgow Coma Scale (GCS) scores, indicating more severe cases with neurological injuries. This significant association ($p = 0.000$) between the intubation reason and the weaning method underscores the importance of initial patient assessment in optimizing weaning strategies.

In brief, High Flow therapy offers significant advantages in reducing ICU stay duration and improving post-extubation oxygenation, particularly for patients intubated due to respiratory distress.

BIBLIOGRAPHY

1. Slutsky, A. S. (2015). History of mechanical ventilation. From Vesalius to ventilator-induced lung injury. *American Journal of Respiratory and Critical Care Medicine*, 191(10), 1106–1115. <https://doi.org/10.1164/rccm.201503-0421pp>
2. Kacmarek, R. M. (2011). The Mechanical Ventilator: past, present, and future. *Respiratory Care*, 56(8), 1170–1180. <https://doi.org/10.4187/respcare.01420>
3. McLachlan G. Sir Ivan Magill KCVO, DSc, MB, BCh, BAO, FRCS, FFARCS (Hon), FFARCSI (Hon), DA, (1888-1986). *Ulster Med J.* 2008 Sep;77(3):146-52. PMID: 18956794; PMCID: PMC2604469.
4. Kacmarek, R. M. (2011c). The Mechanical Ventilator: past, present, and future. *Respiratory Care*, 56(8), 1170–1180. <https://doi.org/10.4187/respcare.01420>
5. Bersten, A. D., Skowronski, G. A., & Oh, T. E. (1986). New generation ventilators. *Anaesthesia and Intensive Care*, 14(3), 293–305. <https://doi.org/10.1177/0310057x8601400309>
6. Kacmarek, R. M., & Hess, D. R. (2014). *Essentials of Mechanical Ventilation, third edition*. McGraw-Hill Education / Medical
7. Kreit, J. W., & Kellum, J. A. (2017). Mechanical ventilation. In *Oxford University Press eBooks*. <https://doi.org/10.1093/med/9780190670085.001.0001>
8. Esteban, A., Anzueto, A., Frutos, F., Alía, I., Brochard, L., Stewart, T. E., Benito, S., Epstein, S. K., Apezteguía, C., Nightingale, P., Arroliga, A. C., & Tobin, M. J. (2002b). Characteristics and Outcomes in Adult Patients Receiving Mechanical Ventilation<SUBTITLE>A 28-Day International Study</SUBTITLE>*JAMA*, 287(3), 345. <https://doi.org/10.1001/jama.287.3.345>
9. Parthasarathy, S., Jubran, A., & Tobin, M. J. (2000b). Assessment of neural inspiratory time in ventilator-supported patients. *American Journal of Respiratory and Critical Care Medicine*, 162(2), 546–552. <https://doi.org/10.1164/ajrccm.162.2.9901024>

10. Thille, A. W., Muller, G., Gacouin, A., Coudroy, R., Decavèle, M., Sonnevile, R., Beloncle, F., Girault, C., Dangers, L., Lautrette, A., Cabasson, S., Rouzé, A., Vivier, E., Meur, A. L., Ricard, J., Razazi, K., Barberet, G., Lebert, C., Ehrmann, S., . . . Frat, J. (2019). Effect of Postextubation High-Flow Nasal Oxygen with Non-invasive Ventilation vs High-Flow Nasal Oxygen Alone on Reintubation Among Patients at High Risk of Extubation Failure. *JAMA*, 322(15), 1465. <https://doi.org/10.1001/jama.2019.14901>

11. Thille, A. W., Gacouin, A., Coudroy, R., Ehrmann, S., Quenot, J., Nay, M., Guitton, C., Contou, D., Labro, G., Reignier, J., Pradel, G., Beduneau, G., Dangers, L., Saccheri, C., Prat, G., Lacave, G., Sedillot, N., Terzi, N., La Combe, B., . . . Frat, J. (2022). Spontaneous-Breathing Trials with Pressure-Support Ventilation or a T-Piece. *New England Journal of Medicine*, 387(20), 1843–1854. <https://doi.org/10.1056/nejmoa2209041>

12. Xu, Z., Li, Y., Zhou, J., Li, X., Huang, Y., Liu, X., Burns, K. E. A., Zhong, N., & Zhang, H. (2018). High-flow nasal cannula in adults with acute respiratory failure and after extubation: a systematic review and meta-analysis. *Respiratory Research*, 19(1). <https://doi.org/10.1186/s12931-018-0908-7>

13. Frat, J., Thille, A. W., Mercat, A., Girault, C., Ragot, S., Perbet, S., Prat, G., Boulain, T., Morawiec, E., Cottreau, A., Devaquet, J., Nseir, S., Razazi, K., Mira, J., Argaud, L., Chakarian, J., Ricard, J., Wittebole, X., Chevalier, S., . . . Robert, R. (2015). High-Flow Oxygen through Nasal Cannula in Acute Hypoxemic Respiratory Failure. *New England Journal of Medicine*, 372(23), 2185–2196. <https://doi.org/10.1056/nejmoa1503326>

14. Fernandez, R., Subira, C., Frutos-Vivar, F., Rialp, G., Laborda, C., Masclans, J. R., Lesmes, A., Panadero, L., & Hernandez, G. (2017). High-flow nasal cannula to prevent Postextubation respiratory failure in high-risk non-hypercapnic patients: a randomized multicentre trial. *Annals of Intensive Care*, 7(1). <https://doi.org/10.1186/s13613-017-0270-9>

15. Hernández, G., Vaquero, C., Colinas, L., Cuenca, R., González, P., Canabal, A., Sanchez, S., Rodriguez, M. L., Villasclaras, A., & Fernández, R. (2016). Effect of Postextubation High-Flow Nasal Cannula vs Non-invasive Ventilation on Reintubation and Postextubation Respiratory Failure in High-Risk Patients. *JAMA*, 316(15), 1565. <https://doi.org/10.1001/jama.2016.14194>

16. Lee, H. Y., Lee, J., & Lee, S. (2022). Effect of high-flow oxygen versus T-piece ventilation strategies during spontaneous breathing trials on weaning failure among patients receiving mechanical ventilation: a randomized controlled trial. *Critical Care*, 26(1). <https://doi.org/10.1186/s13054-022-04281-w>

17. Subirà, C., Hernández, G., Vázquez, A., Rodríguez-García, R., González-Castro, A., García, C., Rubio, O., Ventura, L., López, A., De La Torre, M., Keough, E., Arauzo, V., Hermosa, C., Sánchez, C., Tizón, A., Tenza, E., Laborda, C., Cabañes, S., Lacueva, V., . . . Fernández, R. (2019). Effect of Pressure Support vs T-Piece Ventilation Strategies During Spontaneous Breathing Trials on Successful Extubation Among Patients Receiving Mechanical Ventilation. *JAMA*, 321(22), 2175. <https://doi.org/10.1001/jama.2019.7234>

ANNEXURE

Ethical committee approval certificate



BLDE

(DEEMED TO BE UNIVERSITY)

Declared as Deemed to be University u/s 3 of UGC Act, 1956

Accredited with 'A' Grade by NAAC (Cycle-2)

The Constituent College

SHRI B. M. PATIL MEDICAL COLLEGE, HOSPITAL & RESEARCH CENTRE, VIJAYAPURA

BLDE (DU)/IEC/ 948/2023-24

10/4/2023

INSTITUTIONAL ETHICAL CLEARANCE CERTIFICATE

The Ethical Committee of this University met on **Saturday, 18th March, 2023 at 11.30 a.m. in the CAL Laboratory, Dept. of Pharmacology**, scrutinized the Synopsis/ Research Projects of Post Graduate Student / Under Graduate Student /Faculty members of this University /Ph.D. Student College from ethical clearance point of view. After scrutiny, the following original/ corrected and revised version synopsis of the thesis/ research projects has been accorded ethical clearance.

TITLE: "ASSESSMENT OF OUTCOME OF USING HIGH FLOW OXYGEN AND T PIECE VENTILATION AMONG PATIENT RECEIVING MECHANICAL VENTILATION DURING WEAN OFF PHASE".

NAME OF THE STUDENT/PRINCIPAL INVESTIGATOR: DR.RADHIKA MILIND PATIL

NAME OF THE GUIDE: DR.VIJAYKUMAR T.K., PROFESSOR,DEPT. OF ANAESTHESIOLOGY

Dr. Santoshkumar Jeevangi
Chairperson
IEC, BLDE (DU),
VIJAYAPURA

Chairman,
Institutional Ethical Committee,
BLDE (Deemed to be University)
Vijayapura

Following documents were placed before Ethical Committee for Scrutinization.

- Copy of Synopsis/Research Projects
- Copy of inform consent form
- Any other relevant document

Dr. Akram A. Naikwad
Member Secretary
IEC, BLDE (DU),
VIJAYAPURA
MEMBER SECRETARY
Institutional Ethics Committee
BLDE (Deemed to be University)
Vijayapura-586103, Karnataka

Smt. Bangaramma Sajjan Campus, B. M. Patil Road (Sholapur Road), Vijayapura - 586103, Karnataka, India.

BLDE (DU): Phone: +918352-262770, Fax: +918352-263303, Website: www.bldeu.ac.in, E-mail: office@bldeu.ac.in

College: Phone: +918352-262770, Fax: +918352-263019, E-mail: principal@bldeu.ac.in

Plagiarism certificate screen shot



Page 2 of 52 - Integrity Overview

9% Overall Similarity

The combined total of all matches, including overlapping sources, for each data

Filtered from the Report

- Bibliography
 - Quoted Text
 - Small Matches (less than 10 words)
-

Match Groups



62 Not Cited or Quoted 20%

Matches with neither in-text citation nor quotation marks



5 Missing Quotations 1%

Matches that are still very similar to source material



0 Missing Citation 0%

Matches that have quotation marks, but no in-text citation



0 Cited and Quoted 0%

Matches with in-text citation present, but no quotation marks

Patient consent form

TITLE

ASSESSMENT AND OUTCOME OF USING HIGH FLOW OXYGEN AND T
PIECE VENTILATION AMONG PATIENT RECEIVING MECHANICAL
VENTILATION DURING WEAN OFF PHASE

PRINCIPAL INVESTIGATOR: Dr. RADHIKA MILIND PATIL Department of
Anaesthesiology BLDE DU's Shri B M Patil Medical College & Research
Centre, Sholapur Road Vijayapura-03

Email: radhika2patil@gmail.com

PG GUIDE: Dr. VIJAYKUMAR. T.K M. D, DA

Professor Dept. of Anaesthesiology BLDE DU's Shri B M Patil Medical College
& Research Centre, Sholapur Road Vijayapura-03

PURPOSE OF THE STUDY:

I have been notified that this study is a Prospective randomized study of comparison of T Piece and high flow oxygen for patient on mechanical ventilation. I have been given an explanation about the reason for doing this study and selecting me/my ward as a subject for this study. I have also been given free choice of either being included or not in the study.

PROCEDURE: I understand that I will be taking part in the study: Prospective randomized study of comparison of t piece and high flow oxygen for patient on mechanical ventilation and full filling criteria to wean off.

RISKS AND DISCOMFORTS: I understand that my ward may experience some discomfort during the procedure, and I know that necessary measures will be taken to reduce them.

BENEFITS: I understand that my ward participating in this study will help in finding out a Prospective randomized study of comparison of t piece and high flow oxygen for early extubation.

CONFIDENTIALITY: I understand that this study's medical information will become a part of this hospital record and will be subjected to the confidentiality and privacy regulation of this hospital. Suppose the data are used for publication in the medical literature or teaching purposes. In that case, no names will be used, and other identities such as photographs and audio and videotapes will be used only with my special written permission. I understand that I may see the picture and videotapes and hear audiotapes before giving consent.

REQUEST FOR MORE INFORMATION: I understand that I may ask as many questions about the study at any point in time. Dr.RADHIKA MILIND PATIL is available to answer my questions or concerns. I know that I will be notified of any significantly novel findings revealed during the period of this study, which may influence my continued participation. If during this study, or at a later period, I wish to discuss my involvement in or concerns regarding this study with a third party not directly involved, I am aware that the social worker of the hospital has been made available for me to talk to. And that a copy of this consent form will be given to me to keep for careful reading.

REFUSAL OR WITHDRAWAL OF PARTICIPATION: I understand that my engagement in this clinical study is on a voluntary basis, and I may refuse participation or may withdraw consent and discontinue participation in the study at any time without prejudice to my present or forthcoming care at this hospital. I also understand Dr. RADHIKA MILIND PATIL will

terminate my participation in this study at any time after she has explained the reason for doing so and has helped arrange for my continued care by my own physician or therapist if this is appropriate.

INJURY STATEMENT:

I understand that in the unlikely events of injury to me/my ward, resulting directly due to my participation in this study; such harm will be reported promptly. Medical treatment would be made available to me, but no further compensation will be made available. I understand that by me agreeing to participate in this study, I am not waiving my legal rights. I have explained in detail to _____ the purpose of this research, the procedures which are required and the possible risk and benefits, to the best of my ability in patients own language.

DATE:

INVESTIGATOR NAME: Dr. Radhika Milind Patil

SIGNATURE: -----

ATTENDER/RELATIVE NAME:

SIGNATURE: -----

WITNESS NAME:

SIGNATURE: -----

PLACE:

STUDY SUBJECT CONSENT STATEMENT:

I confirm that Dr. RADHIKA MILIND PATIL has explained the purpose of this research, the study procedure that I will undergo, and the possible discomforts and benefits that I may experience in my own language.

I have been explained all the above in detail in my own language, and I understand the same. Therefore, I agree to by giving my consent to participate as a subject in this research project.

PARTICIPENT NAME:

SIGNATURE: -----

WITNESS TO ABOVE SIGN:

NAME:

SIGNATURE: -----

DATE:

PLACE:

PROFORMA

SCHEME OF CASE TAKING STUDY

ASSESSMENT OF OUTCOME OF USING HIGH FLOW OXYGEN AND T
PIECE VENTILATION AMONG PATIENT S RECEIVING MECHANICAL
VENTILATION DURING WEAN OFF PHASE.

Patient Details

Patient name	
Age / Gender	
Weight	
Height	
Diagnosis	
Past history	

Systemic and general examination

CVS	
CNS	
RS	
PA	

Pallor	
Icterus	
Cyanosis	
Clubbing	
Lymphadenopathy	
Other findings	

Vitals:

Blood pressure	
Pulse rate	
Respiratory rate	
Temperature	

Investigation:

Haemoglobin	
Total WBC count	
Platelet count	
HIV status	
HBSAG status	
HCV status	
ASA grading	

Length of MV before SBT in days	
Length of ICU stay in days	
APACHE II score	
Comorbidities	
Reason for intubation	
GCS	

HFNC:

Parameter	Before SBT	After SBT	Post extubation
Heart rate			
Respiratory rate			
MAP			
SPO2			
Arterial pH			
PaO2			
PaCO2			
HCO3			
Serum sodium			
Serum potassium			
Serum creatinine			
Lactate			

t-piece

Parameter	Before SBT	After SBT	Post extubation
Heart rate			
Respiratory rate			
MAP			
SPO2			
Arterial pH			
PaO2			
PaCO2			
HCO3			
Serum sodium			
Serum potassium			
Serum creatinine			
Lactate			

Primary outcome	HFNC	T-Piece
Weaning failure on Day 2		
Weaning failure on Day 7		
Successful SBT within 72 hrs		
Extubation after 1st SBT		
Re-intubation within 48hrs of SBT		
Re-intubation within 7 days		
Apply NIV within 48 hrs after extubation		
ICU mortality		

BIO-DATA

Guide Name: Dr. Vijaykumar T Kalyanappagol

Date of Birth: 08/09/1964

Education: MBBS from M R Medical College Kalaburagi

M D from Shri B M PATIL Medical college Vijayapura

D A from J N Medical College Belgaum

Designation: Professor in Anaesthesiology

Teaching: Total work experience 29 years

PG teaching: 20 years PG guide 10 years

Address: Plot No.43, Basaveshwar Nagar, Opposite BLDE Hospital, Ashram
Road, Vijayapura.

INVESTIGATOR

Name: Dr. Radhika Milind Patil

Qualification: MBBS from Dr. D Y Patil Medical college and Hospital kadam
Wadi, Kolhapur, Maharashtra.

Registration No 180926

Address: 71/72 TISA Balaji Nagar, khandsari, kannad dist. Chhatrapati
Sambhajinagar, Maharashtra.

