



From medical treatment option to dogma: Low tidal volume ventilation has become an unquestioned truth in ARDS

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Abstract

Resistance to paradigm shifts is a common issue in medicine, often delaying the adoption of new therapies despite strong evidence. This perspective explores how medical treatments can transition from being evidence based practices to rigid dogma. Lung-protective ventilation for acute respiratory distress syndrome (ARDS) exemplifies this challenge.

We outline a sequence by which a single influential clinical trial can crystallize into an unquestioned standard of care. The low-tidal-volume ARDSNet strategy, established by a landmark randomized controlled trial (RCT) over twenty-five years ago, exemplifies this process.

Reanalyzing the same data used in the ARDSNet RCT demonstrated that low tidal volume ventilation is not lung-protective in all patient subgroups and may even increase mortality. Despite data clearly demonstrating that the ARDSNet strategy can be harmful and that there has been no reduction in ARDS related mortality over three decades of use, the method remains the standard of care. Indeed, the most recent Guidelines papers published in multiple leading medical journals still strongly recommend low tidal volume for ARDS patients.

This paper argues that the continued dominance of a single paradigm can hinder innovation and delay the adoption of life-saving treatments. Improvements in ARDS management and medicine overall require ongoing reassessment of established practices, openness to new evidence, and the courage to challenge accepted dogma.

Keywords: Medical dogma, Paradigm shifts, Lung protective ventilation, ARDS, VILI, Low tidal volume ventilation, ARDSNet

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In the 1840s, Ignaz Semmelweis demonstrated that handwashing with chlorinated lime significantly reduced the death rate from puerperal fever at the Vienna General Hospital.¹ Despite solid evidence, his findings met strong opposition. The medical belief at the time centered on humoral imbalance, and many doctors refused to believe they might be the ones spreading disease. Semmelweis's failure to publish in leading journals further isolated him from his colleagues, and his advice was largely ignored. Only after Louis Pasteur's germ theory was accepted and Joseph Lister's antiseptic methods were adopted was Semmelweis's work finally recognized as true, but this occurred after his death.

Unfortunately, resistance to a paradigm shift in science and medicine is common. In "The Structure of Scientific Revolutions," Thomas Kuhn described "paradigm

resistance," in which professional groups or medical societies reject scientific evidence that challenges established treatment strategies until overwhelming evidence forces a shift in the treatment paradigm. The Semmelweis example illustrates how rigid orthodoxy in medicine can lead to unnecessary morbidity and mortality.

Other examples of medicine's resistance to new ideas include William Harvey's concept of the circulatory system, Joseph Lister's antiseptic treatment for surgical infections, and Barry Marshall's evidence that peptic ulcers are caused by *H. pylori* and can be treated with antibiotics. Modern treatments that took decades to become standard of care include thrombolysis for acute myocardial infarction, β -blockers for heart failure, and endovascular therapy for strokes (Figure 1).

History Remembers the Innovators, but the Establishment Resisted Them

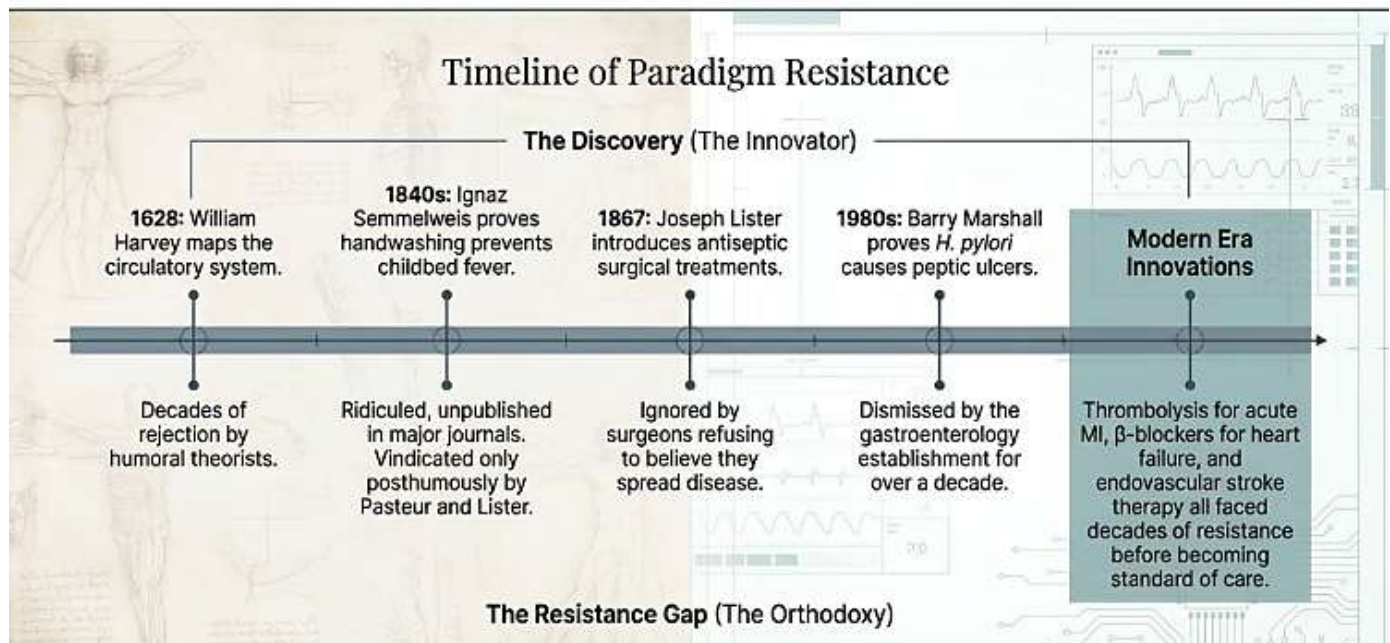


Figure 1: Suppressing scientific evidence throughout history.

The ancient Greek philosopher Heraclitus stated that "*The only thing constant in science is change*" yet this has not held true in lung-protective ventilation, where the same Low Tidal Volume (LTV) strategy has been used for 25 years. The

question arises: how does this happen? What causes this shift from one of several treatment options to dogma? Figure 2 illustrates the sequence of events that can turn a therapy into an unshakable truth.

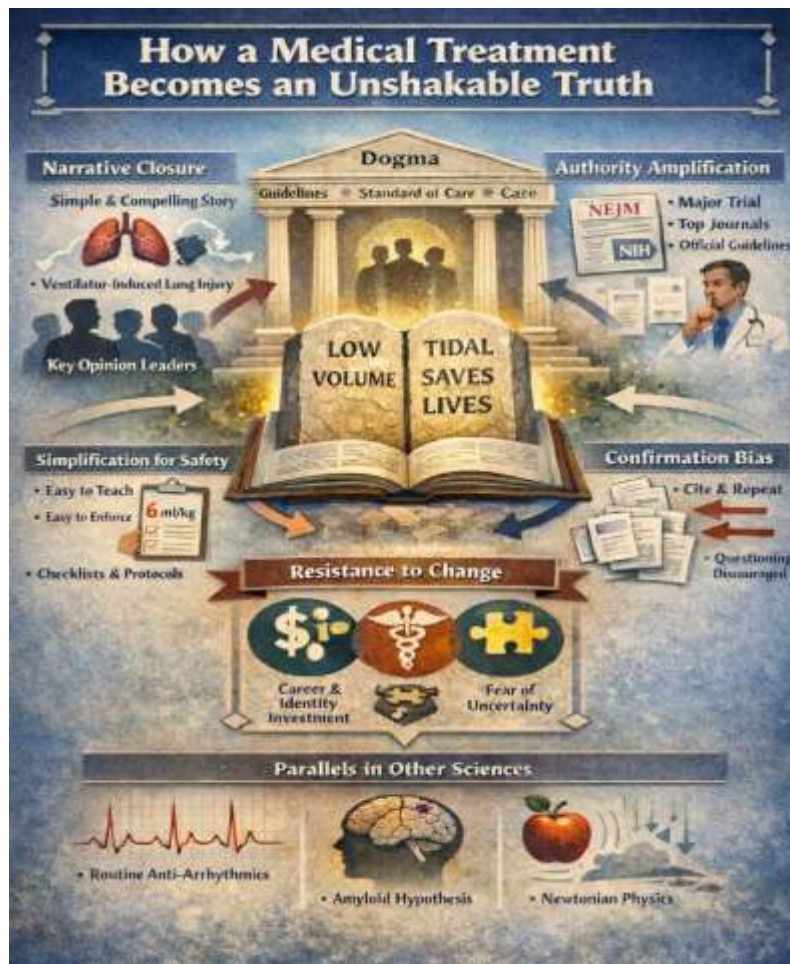


Figure 2: The perfect storm of elevating a medical treatment to an unshakable truth. It can begin with a single piece of evidence generated in a clinical trial and published in high-powered journals. The treatment story is simple and compelling, easy to teach and enforce, and supported by key opinion leaders in the field. This leads to an explosion of publications that confirm the bias. There is strong resistance to change because the careers of the key opinion leaders depend on the success of this treatment regimen. This sequence of events has been repeated many times in science and medicine (Figure 1).

Step 1: Narrative closure

A successful clinical trial demonstrating reduced mortality in a medical condition that has stubbornly resisted all treatment efforts brings excitement to the field and is supported by key opinion leaders.

Step 2: Authority amplification

The ARDSNet study was not merely another randomized controlled trial (RCT); it was NIH-funded and published in a high impact journal (New England Journal of Medicine) by leading experts in the field at the time. This was followed by years of review articles, board exam questions, and keynote lectures at major medical conferences and symposia, all of which endorsed the ARDSNet method. This shift from evidence to doctrine means that dissent is no longer scientific disagreement; it becomes malpractice. The influence of prominent scientists receiving disproportionately more

recognition for their contributions, while lesser-known scientists often receive little credit for equally important discoveries, is known as The Matthew Effect.²

Step 3: Simplification for safety

Will boost the dogma. LVT is easy to teach and monitor, and when a treatment is simple and “known” to be lifesaving, it becomes risk averse.

Step 4: Confirmation bias and citation cascade

Once it is accepted that LVT saves lives, evidence is no longer tested; it is assumed. The ARDSNet NEJM paper is cited thousands of times, yet the treatment strategy has never been retested. The current question is not whether LVT saves lives but how to use it more effectively (e.g., ultra-low VT or personalized LVT based on lung compliance).

Step 5: Resistance to change

Key opinion leaders built their reputations and careers around the ARDSNet RCT, often cited as the foundational study on protective mechanical ventilation. Questioning whether the LVT strategy is essential for lung protection and whether new RCTs should be conducted to replicate the positive findings or test alternative approaches could threaten their authority and career status.

Other scientific dogmas include

- 1) An observational study suggested that suppressing ventricular ectopy after a myocardial infarction reduces mortality, and this treatment was widely accepted and used without question for years.³ A later study reported increased mortality with pharmaceutical suppression of ventricular ectopy.⁴
- 2) The amyloid hypothesis of Alzheimer's disease was the unquestioned mechanism of injury, with the belief that removal would stop cognitive decline,⁵ despite failures in clinical trials to prove this. Later studies suggest that amyloid may be a downstream marker rather than a primary cause.⁶
- 3) Newtonian mechanics was long thought to be complete regardless of scale. However, it has been shown that Newton's calculations fail at high velocities, in strong gravitational fields, and on atomic scales. Newton wasn't wrong, just incomplete (Figure 1).

Successful RCTs may not translate into effective treatments

Sound clinical practice requires that an effective treatment identified in an RCT and implemented in clinical practice be replicated in future studies to confirm the treatment effect. However, there is currently a Replication Crisis in the ICU, where clinical studies that were effective in the first trial are shown to be ineffective in subsequent studies. A primary example is Early Goal Directed Therapy (EGDT) and the Fluids and Catheters Treatment Trial (FACTT):

The EGDT study, published in 2001, was a single-center study of 263 patients that became the gold standard for treating severe sepsis and septic shock, but it was not replicated for 13 years.⁷ Then, in 2014–2015, three studies with a combined enrollment of over 4,000 patients attempted to replicate the EGDT study results.^{8–10} The results showed no mortality benefit in any of the three studies.

The FACTT study, published in 2006 and conducted by the ARDS Network, showed that conservative versus liberal fluid management reduced ventilator days and ICU length of stay but did not decrease mortality.¹¹ The

CLOVERS trial, published in 2023, did not replicate the FACTT study, showing no difference in mortality or secondary outcomes between resuscitation strategies.¹²

When conditions are favorable, medicine can transform a successful clinical trial into a universal treatment law, analogous to the laws of thermodynamics (Figure 2). Once a treatment becomes an undeniable truth, it can suppress ongoing research and potentially delay progress in patient care for decades. Heraclitus's theorem reemerges only when intellectual courage dares to ask the forbidden questions. The low tidal volume strategy developed by the ARDS Network (ARDSNet) has been the standard of care and remains the accepted approach.¹³ Strict adherence to using only low tidal volumes to prevent ventilator induced lung injury (VILI) and resistance to considering or adopting alternative methods have hindered the widespread implementation of innovative strategies, and ARDS related mortality has not decreased.¹⁴

In 2005, Katherine Deans demonstrated that LVT was not lung protective for all patients. She reanalyzed the ARDSNet data, dividing ARDS patients into two groups based on lung compliance.¹⁵ She found, as expected, that LVT reduced mortality in patients with lower compliance; however, it unexpectedly increased mortality in patients with higher compliance. Additionally, a third group of patients (2,587), excluded from the study for technical reasons but with similar recorded data, received standard of care ventilation at the time, which was 10 cc/kg, and had nearly the same mortality as the group with 6 cc/kg (Figure 3). Therefore, over 20 years ago, analyzing the same data used by the ARDSNet group, we understood that 6 cc/kg VT was not suitable for everyone, could harm specific patient groups, was no better than 10 cc/kg VT, and yet it remains the unquestioned standard of care. A quote from Thomas Henry Huxley seems appropriate: *"The great tragedy of Science – the slaying of a beautiful hypothesis by an ugly fact"*.

For example, the European and USA consensus conference guidelines "strongly recommended" LVT for ARDS patients; however, the evidence supporting this recommendation is highly questionable. The guidelines' recommendation was based on a meta-analysis showing that LVT did not significantly reduce mortality or barotrauma, nor did it increase ventilator free days. How can LVT be highly recommended based on these results? Doesn't this data suggest that LVT did not improve outcomes and that other ventilation strategies should be explored?^{16,17} This demonstrates the old axiom: *"The truth is what those in power wish it to be"*.

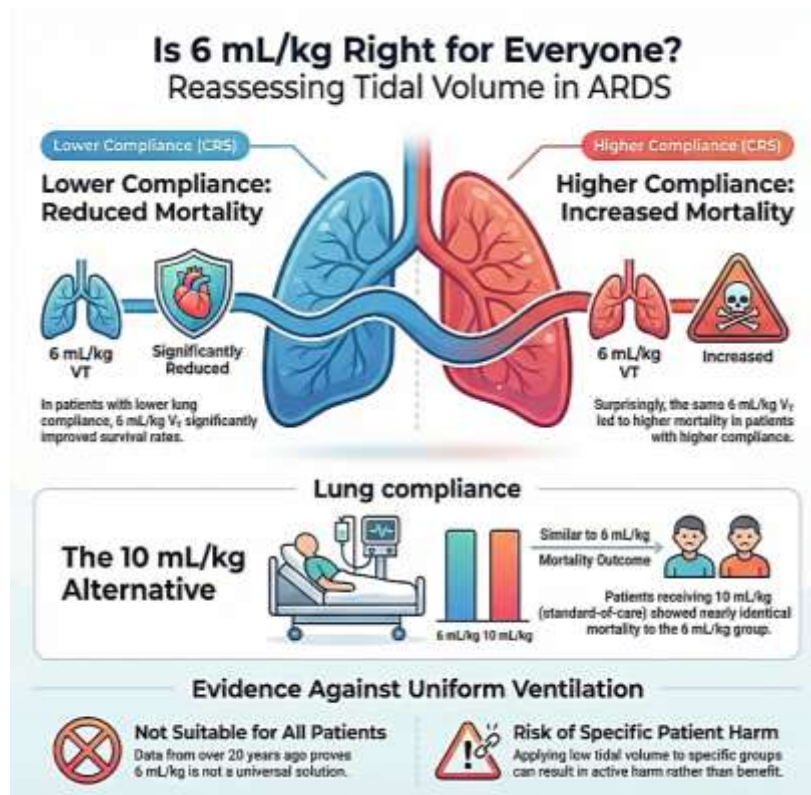


Figure 3: A retrospective analysis was conducted to examine the impact of tidal volume (VT) size on mortality in patients with low and high respiratory system compliance (CRS) using data from the ARDS Network. A third group of patients (2,587), excluded from the study but with similar recorded data, received standard-of-care ventilation at the time, which was 10mL/kg. A) All patients, regardless of CRS, who were ventilated with a VT of 10cc/kg, showed similar mortality rates as those with 6cc/kg. B) In patients with lower CRS, a VT of 6cc/kg significantly reduced mortality compared to those with higher CRS. C) However, in patients with higher CRS, the low VT of 6cc/kg increased mortality.¹⁵

Current research indicates that metrics reflecting lung pathophysiology such as lung compliance or elastance, driving pressure (ΔP), and mechanical power (MP) better predict outcomes in ARDS patients than low VT alone¹⁸⁻²⁰. Therefore, personalizing ventilation strategies based on lung injury is increasingly recognized as more effective than a one-size fits all low VT approach.²¹ Goligher et al. demonstrated that the mortality benefit of lower VT varies with lung elastance.¹⁹ Thus, it is not just the size of VT but also the size and pathophysiology of the lung being ventilated. The study, a secondary analysis of 1,096 ARDS patients, reported a 60-day mortality of 38%, well above the 31% in the ARDSNet ARMA study 21 years earlier,¹³ supporting other studies demonstrating persistently high ARDS-related mortality.¹⁴

It is possible that the current ARDS related mortality is almost 10% higher than it was almost three decades ago because of worsening patient complexity, poorer guideline adherence, or expanded definitions of ARDS, resulting in different cohorts being studied. However, the increase in mortality rather than a decrease over 26 years, and the lack of subsequent RCTs

attempting to replicate the ARMA study's results, suggest that paradigm entrenchment may also be an under-recognized contributing factor.

Identifying lung pathophysiology, as measured by lung compliance or elastance, is an important advance in the treatment of VILI. Elevated ΔP is associated with poorer outcomes.¹⁸ Driving Pressure is the difference between the plateau (Pplat) and end-expiratory (PEEP) airway pressure and can also be calculated using the equation: $\Delta P = V_T / C_{RS}$.¹⁸ A ΔP above 14-15 cmH₂O is strongly associated with increased VILI risk.

But with this knowledge, what can the clinician do with current ventilator strategies to reduce ΔP ? You could reduce Pplat by lowering airway pressure or VT. Both approaches would lead to greater lung collapse and a lower C_{RS} . PEEP could be increased, but if the lung does not recruit, it could further decrease C_{RS} and increase pulmonary vascular resistance (PVR), resulting in right heart failure.²² Thus,

reducing a high $\dot{V}_P$, without causing further lung collapse and hemodynamic compromise, is easier said than done.

Another strategy to reduce ΔP that is not often considered is to increase C_{RS} by opening the lung and keeping it open. However, the most recent RCT attempting this goal increased mortality.²³ The lung was recruited rapidly, within 60 minutes, and PEEP was set to the best C_{RS} to prevent re-collapse. Analysis of the data showed that, for most of the study period, the PaO_2/FiO_2 ratio and C_{RS} did not differ significantly between the open lung and control groups, suggesting that the lung was not actually open. Thus, the open lung strategy didn't fail; rather, the ventilator tools used to open the lung were ineffective. Since the conventional method for opening and stabilizing the lung (rapidly opening the entire lung with high airway pressure and increasing PEEP to prevent re-collapse) did not reduce mortality,²³ novel methods should be explored. It has been shown that an innovative inflate and brake method that gradually 'ratchets' the lung open over hours or days, depending on the severity of lung pathophysiology, can achieve durable lung recruitment.²⁴

Conclusions

Clinicians must keep an open mind and avoid blindly adopting treatments that proved successful in an RCT only to be shown ineffective years later. Consensus conference treatment recommendations should also be evaluated to determine whether the suggested treatments actually improve patient outcomes, as assessed in studies such as meta-analyses. There are many instances that demonstrate the high resistance to a paradigm shift in science and medicine. A specific sequence of events can transform a medical therapy into an unshakable truth that cannot be openly questioned. This occurs even though it is well known that successful RCTs used to guide clinical care are found to be ineffective or even dangerous years later. The LVT lung protective ventilation method is a recent example of an unshakable truth, even though a confirming replication study has never been performed. There is significant evidence that the one size fits all LVT strategy does not benefit all patients. A study using the same database as the ARDSNet group used to establish LVT as the standard of care found that mortality with 6 cc/kg is identical to that with 10 cc/kg; 6 cc/kg increased mortality in patients with higher C_{RS} , whereas 12 cc/kg reduced mortality in patients with higher C_{RS} (Figure 3).¹⁵ However, the dogma is so entrenched that current consensus guidelines continue to strongly recommend LVT for ARDS patients, even though their own meta-analysis shows no mortality, barotrauma, or ventilator free days benefit. It is time to

consider alternative methods to protect the lungs beyond simply lowering tidal volume.

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