

others, particularly as policy changes affect the number and composition of hospitals and markets required to participate.

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- Centers for Medicare & Medicaid Services. Comprehensive care for joint replacement model. <https://innovation.cms.gov/initiatives/cjr>. Accessed December 17, 2017.
- Centers for Medicare & Medicaid Services. Medicare program; cancellation of advancing care coordination through episode payment and cardiac rehabilitation incentive payment models; changes to comprehensive care for joint replacement payment model (CMS-5524-P). *Fed Regist*. 2017;82(230):57066-57104.
- Centers for Medicare & Medicaid Services. Overview of CJR quality measures, composite quality score, and pay-for-performance methodology. <https://innovation.cms.gov/Files/x/cjr-qualsup.pdf>. Accessed January 5, 2018.

4. Werner RM, Goldman LE, Dudley RA. Comparison of change in quality of care between safety-net and non-safety-net hospitals. *JAMA*. 2008;299(18):2180-2187.

5. Annual Hospital Association. AHA annual survey database. <https://www.ahadataviewer.com/additional-data-products/aha-survey/>. Accessed January 5, 2018.

6. Navathe AS, Troxel AB, Liao JM, et al. Cost of joint replacement using bundled payment models. *JAMA Intern Med*. 2017;177(2):214-222.

## COMMENT & RESPONSE

### Lung Recruitment and Positive End-Expiratory Pressure Titration in Patients With Acute Respiratory Distress Syndrome

**To the Editor** The trial by the Alveolar Recruitment for Acute Respiratory Distress Syndrome Trial (ART) Investigators<sup>1</sup> compared a low positive end-expiratory pressure (PEEP) strategy<sup>2</sup> with one combining a recruitment maneuver and PEEP titration personalized to respiratory system compliance among adults with moderate to severe acute respiratory distress syndrome (ARDS). The recruitment maneuver and personalized PEEP approach lowered driving pressure but increased mortality. Although one potential explanation for increased mortality is the negative effects of the recruitment maneuver, another is ventilator-induced lung injury from overdistension of alveoli at end-inspiration (tidal hyperinflation) resulting from the method of personalizing PEEP.

The ART intervention protocol used a tidal volume of 5 mL/kg predicted body weight to determine the PEEP of maximal compliance. If multiple PEEP levels had similar compliance (within 1 mL/cm H<sub>2</sub>O), PEEP was set at 2 cm above the highest of these levels. This approach inherently leads to ventilation near the upper inflection point of the pressure-volume curve at a tidal volume of 5 mL/kg predicted body weight. The mean tidal volume on day 1 in the intervention group was 5.6 mL/kg predicted body weight, suggesting that many patients were ventilated at tidal volumes above those used to identify maximal compliance in the decremental PEEP trial.

Much has been made of personalizing therapy in critical illness. Is it possible that the personalization of PEEP in the intervention group of the ART trial inadvertently introduced injurious tidal hyperinflation, which was avoided in the control group by applying a simple one-size-fits-all approach to lower PEEP?

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1. Cavalcanti AB, Suzumura ÉA, Laranjeira LN, et al; Writing Group for the Alveolar Recruitment for Acute Respiratory Distress Syndrome Trial (ART) Investigators. Effect of lung recruitment and titrated positive end-expiratory pressure (PEEP) vs low PEEP on mortality in patients with acute respiratory distress syndrome: a randomized clinical trial. *JAMA*. 2017;318(14):1335-1345.
2. Brower RG, Matthay MA, Morris A, Schoenfeld D, Thompson BT, Wheeler A; Acute Respiratory Distress Syndrome Network. Ventilation with lower tidal volumes as compared with traditional tidal volumes for acute lung injury and the acute respiratory distress syndrome. *N Engl J Med*. 2000;342(18):1301-1308.

**To the Editor** In a systematic review and meta-analysis of 2299 patients with moderate or severe ARDS, lower mortality was found in the high-PEEP group compared with the low-PEEP group (34.1% vs 39.1%, respectively;  $P = .049$ ).<sup>1</sup> In a second systematic review and meta-analysis of 1594 patients with ARDS, alveolar recruitment maneuvers were associated with reduced in-hospital mortality without increasing the risk of adverse events.<sup>2</sup> In addition, a multicenter, randomized clinical trial of 200 patients with moderate to severe ARDS showed that an open-lung approach improved oxygenation and driving pressure, without detrimental effects on mortality, ventilator-free days, or barotrauma.<sup>3</sup>

In contrast, the ART investigators reported the results of a multicenter, randomized clinical trial of 1010 patients who either received an alveolar recruitment maneuver followed by best-compliance PEEP titration or a low-PEEP strategy.<sup>4</sup> The study found high 6-month mortality in both groups, which was higher in the intervention group (65.3% vs 59.9%, respectively;  $P = .04$ ). How can these unexpected results be explained?

First, the recruitment maneuver was abrupt and short and not monitored with lung imaging. Second, no check for the efficiency of the recruitment maneuver was conducted, and, because the study was multicenter, trained but inexperienced physicians might not have noticed and fixed the possible but reversible complications that could occur during the maneuver.

Third, 21.6% of the ARDS patients did not perform the second alveolar recruitment maneuver after PEEP titration as established by protocol, compromising the efficacy of the recruitment and PEEP titration strategy. Fourth, recruitment was not repeated from day 1 to day 7 in 62.7% of patients in the intervention group, whereas 28 patients in the control group received recruitment maneuvers. Fifth, the authors introduced the use of the prone position prior to the recruitment maneuver after publication of the Prone Severe ARDS Patients (PROSEVA) study in 2013, possibly introducing a new confounder to the study results.<sup>5</sup>

The most effective recruitment maneuver and PEEP remain to be determined.

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1. Briel M, Meade M, Mercat A, et al. Higher vs lower positive end-expiratory pressure in patients with acute lung injury and acute respiratory distress syndrome: systematic review and meta-analysis. *JAMA*. 2010;303(9):865-873.
2. Suzumura EA, Figueiró M, Normilio-Silva K, et al. Effects of alveolar recruitment maneuvers on clinical outcomes in patients with acute respiratory distress syndrome: a systematic review and meta-analysis. *Intensive Care Med*. 2014;40(9):1227-1240.
3. Kacmarek RM, Villar J, Sulemanji D, et al; Open Lung Approach Network. Open lung approach for the acute respiratory distress syndrome: a pilot, randomized controlled trial. *Crit Care Med*. 2016;44(1):32-42.
4. Cavalcanti AB, Suzumura ÉA, Laranjeira LN, et al; Writing Group for the Alveolar Recruitment for Acute Respiratory Distress Syndrome Trial (ART) Investigators. Effect of lung recruitment and titrated positive end-expiratory pressure (PEEP) vs low PEEP on mortality in patients with acute respiratory distress syndrome: a randomized clinical trial. *JAMA*. 2017;318(14):1335-1345.
5. Guérin C, Reignier J, Richard JC, et al; PROSEVA Study Group. Prone positioning in severe acute respiratory distress syndrome. *N Engl J Med*. 2013;368(23):2159-2168.

**To the Editor** The ART investigators performed a multicenter randomized clinical trial comparing a high-PEEP strategy using lung recruitment with titrated PEEP vs a low-PEEP strategy in patients with ARDS.<sup>1</sup> The trial, however, still leaves unanswered questions.

Hyperoxia-induced lung injury causes an ARDS-type picture with edema, fibrosis, and vascular remodeling,<sup>2</sup> although the mechanisms by which reactive oxygen species promote cellular apoptosis and necrosis are not yet fully understood. All patients with ARDS are exposed to prolonged high fractional inspired concentrations of oxygen ( $F_{IO_2}$ ) to manage hypoxemia. In the ART trial, participants were subjected to an additional  $F_{IO_2}$  of 1.0 for 30 minutes prior to alveolar stretch, the necessity of which is unclear, because this is neither a required step for establishing the presence of ARDS nor grading its severity.<sup>3</sup>

Hyperoxia when combined with alveolar stretch may cause more harm to alveolar epithelial cells than either of these processes in isolation.<sup>2,4,5</sup> The combination of population selection and these events as part of the trial protocol may have led to the poorer outcomes demonstrated in the high-PEEP strategy group.

Therefore, this study may not mean the end of the open-lung principle but may highlight the need for a more proactive approach to ARDS management by performing recruitment maneuvers and targeted PEEP strategies earlier as part of ARDS prevention rather than treatment. Rationally, the timing for this would be a clinical compromise between ensuring optimal fluid resuscitation and cardiac stability vs avoidance of prolonged exposure to a high  $F_{IO_2}$  prior to a recruitment maneuver. From a practical perspective, this could be achieved as soon as optimal fluid responsiveness is reached after intubation. This approach is similar to the use of greater fluid resuscitation in the first 6 to 12 hours followed by a more conservative approach.

The deleterious synergistic effects of hyperoxia and volutrauma should be considered in the context of this trial, and further studies are required before the era of open-lung ventilation is truly considered to be over.

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1. Cavalcanti AB, Suzumura EA, Laranjeira LN, et al; Writing Group for the Alveolar Recruitment for Acute Respiratory Distress Syndrome Trial (ART) Investigators. Effect of lung recruitment and titrated positive end-expiratory pressure (PEEP) vs low PEEP on mortality in patients with acute respiratory distress syndrome: a randomized clinical trial. *JAMA*. 2017;318(14):1335-1345.
2. Roan E, Wilhelm K, Bada A, et al. Hyperoxia alters the mechanical properties of alveolar epithelial cells. *Am J Physiol Lung Cell Mol Physiol*. 2012;302(12):L1235-L1241.
3. Ranieri VM, Rubenfeld GD, Thompson BT, et al; ARDS Definition Task Force. Acute respiratory distress syndrome: the Berlin definition. *JAMA*. 2012;307(23):2526-2533.
4. Wilhelm KR, Roan E, Ghosh MC, Parthasarathi K, Waters CM. Hyperoxia increases the elastic modulus of alveolar epithelial cells through Rho kinase. *FEBS J*. 2014;281(3):957-969.
5. Quinn DA, Moufarrej RK, Volokhov A, Hales CA. Interactions of lung stretch, hyperoxia, and MIP-2 production in ventilator-induced lung injury. *J Appl Physiol* (1985). 2002;93(2):517-525.

**In Reply** Dr McKown and colleagues suggest that the method used to personalize PEEP might be one explanation for the higher mortality in the recruitment maneuver and PEEP titration group. When multiple PEEP levels had similar compliance, we set the PEEP at 2 cm above the highest of these levels based on observations from a previous case series.<sup>1</sup> Mean PEEP levels used in the experimental group were similar to other high-PEEP trials. We also used a tidal volume of 5 mL/kg predicted body weight during PEEP titration, although tidal volume was set at 6 mL/kg during maintenance ventilation (or lower if plateau pressure >30 cm H<sub>2</sub>O). We acknowledge that using the same tidal volume both during PEEP titration and maintenance ventilation would have been a better choice, although the small differences between tidal volume during PEEP titration and maintenance ventilation were unlikely to substantially change the level of optimal PEEP.

Dr Barbas and colleagues offer 5 potential explanations for the results. First, the recruitment maneuver was abrupt and short. The recruitment maneuver adopted in the trial was based on 2 noncontrolled studies that showed excellent lung recruitability and safety.<sup>1,2</sup> We started the recruitment maneuver with the same PEEP level as the study by Borges et al<sup>1</sup> and increased PEEP in steps of 10 cm H<sub>2</sub>O, similarly to Matos et al,<sup>2</sup> or in steps of 5 cm H<sub>2</sub>O in the second half of the trial. Our recruitment maneuver was shorter (1 minute) based on evidence showing that most lung recruitment occurs in 10 seconds of a sustained inflation, while the risk of hypotension increases after this time.<sup>3</sup> Second, Barbas and colleagues suggest that intensivists had little experience with recruitment maneuvers, sometimes not noticing a reversible complication. Adequate implementation of the protocol was pursued zealously in ART using multiple strategies. All sites were visited and received training (except 1 site trained with web con-

ference), used bedside manuals to guide procedures, and were contacted immediately after each patient was enrolled to promote adherence to study procedures. We also conducted periodic teleconferences and sent monthly newsletters. The proposition that inexperience might explain the results is not supported by data: there was no evidence of heterogeneity of treatment effect on mortality across sites, including sites with experienced investigators. Third, Barbas and colleagues state that about 22% of the patients did not receive the second recruitment maneuver after PEEP titration. In fact, the protocol established that whenever complications occurred during the first recruitment maneuver, the second should be omitted. Fourth, it was argued that most patients in the experimental group did not receive a new recruitment maneuver from day 1 to 7, whereas some patients in the control group received a recruitment maneuver. Similar to previous studies,<sup>1,2</sup> recruitment was only repeated after day 1 when oxygenation worsened or circuits were disconnected. Most patients continuously improved oxygenation, thus repeating the recruitment maneuver was inappropriate. The control group followed the ARDS Network protocol, which allowed recruitment maneuvers in cases of refractory hypoxemia. Fifth, allowing prone position after evidence of benefit provided by the PROSEVA trial was an ethical imperative but not a confounder because prone positioning was well-balanced between groups.<sup>4</sup>

All patients were submitted to FIO<sub>2</sub> of 100% for 30 minutes before defining eligibility with the aim of enrolling those with a higher amount of lung collapse.<sup>5</sup> Dr Morris and colleagues suggest that the association of hyperoxia after FIO<sub>2</sub> of 100% and alveolar stretch in the intervention group might help explain the results. Although interaction between hyperoxia and alveolar stretch has been suggested in physiological studies,<sup>6</sup> its clinical significance is unknown. Nevertheless, we agree this association might have had a detrimental role.

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1. Borges JB, Okamoto VN, Matos GF, et al. Reversibility of lung collapse and hypoxemia in early acute respiratory distress syndrome. *Am J Respir Crit Care Med*. 2006;174(3):268-278.
2. de Matos GF, Stanzani F, Passos RH, et al. How large is the lung recruitability in early acute respiratory distress syndrome: a prospective case series of patients monitored by computed tomography. *Crit Care*. 2012;16(1):R4.
3. Arnal JM, Paquet J, Wysocki M, et al. Optimal duration of a sustained inflation recruitment maneuver in ARDS patients. *Intensive Care Med*. 2011;37(10):1588-1594.

4. Guérin C, Reignier J, Richard JC, et al; PROSEVA Study Group. Prone positioning in severe acute respiratory distress syndrome. *N Engl J Med*. 2013; 368(23):2159-2168.
5. Reske AW, Costa EL, Reske AP, et al. Bedside estimation of nonaerated lung tissue using blood gas analysis. *Crit Care Med*. 2013;41(3):732-743.
6. Roan E, Wilhelm K, Bada A, et al. Hyperoxia alters the mechanical properties of alveolar epithelial cells. *Am J Physiol Lung Cell Mol Physiol*. 2012;302(12):L1235-L1241.

## Patient Data Ownership

**To the Editor** The Viewpoint by Ms Mikk and colleagues<sup>1</sup> aimed to improve patient engagement and health care informatics and to recommend technical improvements to electronic health care records. The authors proposed a data use agreement (DUA) that relates to data quality, integrity, privacy, and security. Our principal concern is with the use of such a DUA to grant patients control over all uses of health data, including in secondary research. This measure of control is apparently what the authors referred to as “patient data ownership” in their title, although the term was not used in the body of the article.

Individual ownership of data, whether health related or otherwise, is contrary to well-established legal precedent in the United States, United Kingdom, and many other jurisdictions, which for good reasons do not recognize property interests in mere facts or information.<sup>2,3</sup> Instead, the authors would establish property-like rights through contract. Granting individuals a high degree of control over health data may hinder valuable biomedical research, whether this is conferred under a property or contract-based legal regime. For example, giving patients the right to specify that they approve of research relating to cancer but not to HIV, or to change their minds regarding permissions previously granted, could have disruptive and far-reaching consequences for legitimate and potentially lifesaving research.

Thus, although telling patients that they own their data may elicit a short-term, positive response in patients, physicians, and policymakers, it may result in less-effective research and flawed health policy. Accordingly, we caution health care systems and informatics providers against expanding the use of DUAs in a manner that gives individuals property-like control over data.

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1. Mikk KA, Sleeper HA, Topol EJ. The pathway to patient data ownership and better health. *JAMA*. 2017;318(15):1433-1434.
2. Contreras JL. Genetic property. *Georgetown Law J*. 2016;105(1):1-54.
3. Evans BJ. Much ado about data ownership. *Harvard J Law Tech*. 2011;25(1):69-130.

**In Reply** Mr Contreras and colleagues express concern that providing individuals with control over their complete, longitudinal health data could result in less-effective scientific research because individuals may not choose to share their data. However, multiple studies have shown that individuals are far more willing to share their medical data for research purposes than are their physicians.<sup>1,2</sup>

Our proposal would create a longitudinal health data set for individuals that aggregates health data from various care settings using common data elements. Data would be updated with automatic patient encounter data receipts in near real time and curated by a health data manager under a data use agreement with the patient. The aggregated data are meant to elevate patient self-care and enhance clinical care. Not only would patients benefit from access to all of their data, but clinicians could benefit too by seeing a more complete and accurate picture of the patients in front of them.

Data could also be shared by the patient for secondary uses such as research. Our proposal would supplement, not replace, records that clinicians must maintain today. By providing patients with options to share all, some, or none of their data, patients may actually be more comfortable providing health data for research.<sup>3</sup>

Researchers will still have the opportunity to invite patients to participate in clinical trials. Other than regular automated data receipts sent to patients' aggregated data sets, there would be no other effect on clinical studies (except that patients may agree to share additional, patient-recorded health data with researchers). Of note, informed consents today must indicate that patients can stop participating at any time and, in some cases, this choice can include revocation of prior consent to share data.

The writers also express concern that our proposal will result in flawed health policy and is contrary to legal precedent. Our proposal creates a data set controlled by patients through contract law and other mechanisms that do not contravene existing law. Other scholars have reviewed the interplay of property law and privacy law on health records and health data, with the bottom line being that neither property nor privacy law is completely applicable to health data or a patient's ability to control their health data.<sup>4</sup>

Third-party, patient-controlled compilations of health data, such as mobile health records kept in secure apps, already exist.<sup>5,6</sup> Our proposal advances and adds to elements of existing ideas. We believe the result will be better, computable health data about patients that are timely, reliable, and can be used by patients and their care teams to maintain an improved, complete picture of patients' health.

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