

as inappropriate for PCI (13% of all cases). Notably, this figure likely greatly underestimates the number of inappropriate PCIs because the authors were unable to determine if symptomatic patients had first tried and failed optimal medical management before undergoing PCI.

Although robust guidelines should be expected to reduce inappropriate PCI, Howard and Desai³ demonstrate how implementing such criteria depends on accurately reporting case characteristics (eg, the severity of coronary stenosis and symptoms) and highlight egregious examples for which the reporting was not only inaccurate but dishonest. Specifically, they investigated the association of the US False Claims Act, a law that allows whistleblowers to raise concerns of inappropriate care, with PCI volumes for patients without acute MI.² Between 2006 and 2016, the authors identified 8 cases of PCI-related US False Claims Act cases that became public. Compared with matched control hospitals, PCI volumes for nonacute MI decreased more from 2006 and 2016 in hospitals subject to claims of dishonest reporting (68.4% vs 81.2%; $P < .001$). Although the substantial decrease in PCI seen in all hospitals suggests an overall movement to a more evidence-based use of PCI, the differential decrease in hospitals that underwent investigations of false claims suggests that there is a role for the enforcement of accurate reporting of indications for PCI. It is unknown how commonly coronary stenosis is overestimated in centers that have not been targeted by False Claims cases. Despite the effect of these efforts, without quantitative, objective standards for stenosis, it is likely that some overestimation of coronary stenosis will remain.¹⁰

Reports of continued substantial rates of inappropriate PCI provide a compelling illustration of the considerable work that remains to protect patients and the health care system from the harms and costs of unnecessary PCI. As a conservative estimate (ie, not including cases that could be averted with optimal medical management or the costs of adverse outcomes of PCIs), if the approximately 50 000 PCI cases deemed rarely appropriate by Malik et al² were averted at a cost of \$30 000 per PCI,¹¹ this would produce a savings of \$1.5 billion annually. However, if we extrapolate from prior work showing that greater than 50% of patients undergoing PCIs with stable CAD are not receiving optimal medical therapy,¹² it is likely that at least 150 000 more PCI cases are inappropriate and cost savings are closer to \$6 billion annually. The work of these authors shows a promising method of reducing unnecessary PCI by combining robust, unambiguous consensus guidelines with enforcement of accurate reporting of indications for PCI. However, these measures are not a cure-all in a health care system propelled by enthusiasm for technology regardless of net benefits and rewarded with fee-for-service payments not associated with the appropriateness of the procedure.

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Prone Positioning in Awake, Nonintubated Patients With COVID-19 Hypoxemic Respiratory Failure

Critically ill patients with coronavirus disease 2019 (COVID-19) severely strained intensive care resources in New York City in April 2020.¹ The prone position improves oxygenation in intubated patients with acute respiratory distress syndrome.^{2,3} We investigated whether the prone position is associated with improved oxygenation and decreased risk for intubation in spontaneously breathing patients with severe COVID-19 hypoxemic respiratory failure.⁴⁻⁶

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Methods | We screened consecutive patients admitted to the Columbia University step-down unit (intermediate care unit) between April 6 and April 14, 2020 (N = 88). Inclusion criteria were laboratory-confirmed COVID-19 with severe hypoxemic respi-

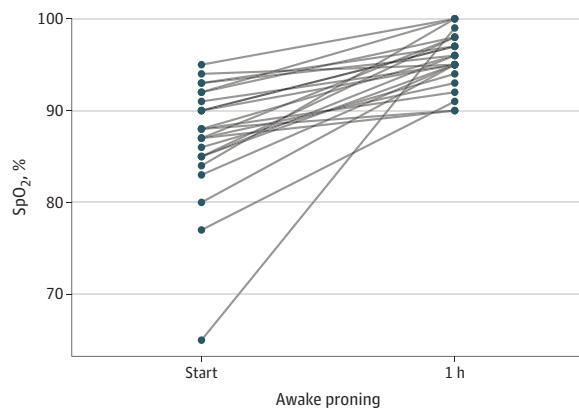
ratory failure defined as respiratory rate of 30 breaths/min or greater and oxyhemoglobin saturation (SpO₂) of 93% or less while receiving supplemental oxygen 6 L/min via nasal cannula and 15 L/min via nonrebreather face mask. A confirmed case of COVID-19 was defined by a positive result on a reverse transcriptase-polymerase chain reaction assay of a specimen collected on a nasopharyngeal swab. Exclusion criteria were altered mental status with inability to turn in bed without assistance (n = 13), extreme respiratory distress requiring immediate intubation (n = 23), or oxygen requirements less than those specified in the inclusion criteria (n = 23). We asked eligible patients (n = 29) to lie on their stomach for as long as tolerated up to 24 hours daily. They could use a pillow placed under the hips/pelvis if desired and rest in the lateral decubitus or supine position followed by repeat prone positioning. Do-not-resuscitate status did not affect the decision to initiate or continue the use of the prone position. The Columbia University institutional review board ap-

proved the study and waived the need for informed consent from the participants, as we analyzed deidentified data collected from electronic medical records. The primary outcome was change in SpO₂ before and 1 hour after initiation of the prone position. We report the median change in SpO₂ with 95% CIs. We used the Wilcoxon test for analysis of change in SpO₂. We assessed the mean risk difference in intubation rates for patients with SpO₂ of 95% or greater vs SpO₂ less than 95% 1 hour after initiation of the prone position. We assessed intubation rates across demographic and other clinical factors with RStudio, version 1.2.5019 (RStudio).

Results | Among 29 eligible patients, 25 had at least 1 awake session of the prone position lasting longer than 1 hour; 4 refused the prone position and were intubated immediately. One hour after initiation of the prone position, SpO₂ increased compared with baseline (**Figure**). The range of improvement in SpO₂ was 1% to 34% (median [SE], 7% [1.2%]; 95% CI, 4.6%-9.4%). In all patients, the levels of supplemental oxygen were unchanged during the first hour of the prone position. One hour after initiation of the prone position, 19 patients had SpO₂ of 95% or greater; subsequently, 7 (37%) required intubation. Among 6 patients whose SpO₂ remained less than 95% 1 hour after initiation of the prone position, 5 (83%) were intubated. The mean difference in the intubation rate among patients with SpO₂ of 95% or greater vs SpO₂ less than 95% 1 hour after initiation of the prone position was 46% (95% CI, 10%-88%). The **Table** shows other patient characteristics, none of which were associated with the need for intubation. Among 12 patients who required intubation, 3 died subsequently in the intensive care unit. Among 13 patients who did not require intubation, 9 recovered and were discharged from the hospital, 2 were transferred to the medical ward, and 2 remained in the step-down unit at the time data were censored on May 25, 2020.

Discussion | In this small single-center cohort study, we found that the use of the prone position for awake, spontaneously breathing patients with COVID-19 severe hypoxemic respira-

Figure. Oxyhemoglobin Saturation (SpO₂) 1 Hour After Initiation of the Prone Position in Awake, Nonintubated Patients With COVID-19



SpO₂ before and 1 h after initiation of the prone position in awake, nonintubated patients with COVID-19 severe hypoxemic respiratory failure (n = 25).

Table. Bivariate Analysis of Patient Characteristics and Their Association With Intubation After Use of the Prone Position in the 25 Awake, Nonintubated Patients With COVID-19

Characteristic	No. (%)		Intubation rate difference, % (95% CI) ^a
	Not intubated (n = 13)	Intubated (n = 12)	
Age, median (range), y	67.0 (45.0 to 71.0)	66.0 (53.0 to 87.0)	4 (-35 to 43)
Sex (female)	3 (23)	4 (33)	7 (-36 to 50)
Body mass index, median (range) ^b	29.0 (21.0 to 47.0)	27.5 (22.0 to 33.0)	-4 (-43 to 35)
Hypertension	7 (54)	5 (42)	12 (-26 to 51)
Diabetes	5 (39)	5 (42)	-3 (-43 to 36)
Hyperlipidemia	1 (8)	2 (17)	-21 (-78 to 36)
Coronary artery disease	1 (8)	1 (8)	-2 (-74 to 70)
Chronic lung disease ^c	2 (15)	2 (17)	-2 (-74 to 70)
Chronic kidney disease	1 (8)	0	NA
Symptom onset to prone position, median (range), d	12.0 (6.0 to 24.0)	12.0 (4.0 to 19.0)	-20 (-59 to 19)
Days from admission to prone position, median (range)	3.0 (1.0 to 12.0)	3.5 (1.0 to 7.0)	-20 (-59 to 19)
Duration of prone position on day 1, median (range), h	4.0 (1.0 to 24.0)	6.0 (1.0 to 24.0)	-35 (-72 to 0)
Days for use of the prone position, median (range)	2.0 (1.0 to 5.0)	2.0 (1.0 to 3.0)	26 (-13 to 67)

Abbreviation: NA, not applicable.

^a For a binary risk factor *x*, the intubation risk difference is defined by $\Delta = [\text{intubation rate} | x=\text{yes}] - [\text{intubation rate} | x=\text{no}]$. When *x* is a continuous risk factor, the intubation risk difference is defined by $\Delta = [\text{intubation rate} | x \geq \text{median}] - [\text{intubation rate} | x < \text{median}]$. The 95% CI of Δ is constructed by $\Delta \pm SE_{\Delta}$ where SE_{Δ} is the standard error of Δ . None of the differences were significant.

^b Calculated as weight in kilograms divided by height in meters squared.

^c Chronic lung disease includes asthma, chronic obstructive pulmonary disease, and interstitial lung disease.

tory failure was associated with improved oxygenation. In addition, patients with an SpO₂ of 95% or greater after 1 hour of the prone position was associated with a lower rate of intubation. Limitations of our study are the lack of control group and a small sample size. Randomized clinical trials are needed to establish whether improved oxygenation after use of the prone position in awake, nonintubated patients improves survival.

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Acquisition, analysis, or interpretation of data: All authors.

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Additional Information: The study was registered on ClinicalTrials.gov on May 25, 2020, owing to the emergency nature of the treatment being administered based on clinical decision to critically ill patients with severe COVID-19 hypoxemic respiratory failure.

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Invited Commentary

Prone Positioning in Awake, Nonintubated Patients With COVID-19: Necessity Is the Mother of Invention

In this issue of *JAMA Internal Medicine*, Thompson and colleagues report the association of prone positioning with pulse oximetry in 25 awake, nonintubated patients with hypoxemic respiratory failure due to coronavirus disease 2019 (COVID-19).¹ This study included patients who were hypoxemic (oxyhemoglobin saturation [SpO₂] ≤ 93%) despite receiving 15 L/min oxygen by face mask and 6 L/min oxygen by nasal cannula and excluded patients who were unable to turn in bed without assistance and those determined to be in respiratory distress and requiring immediate intubation. The median (SE) improvement in oxygen saturation was 7% (1.2%) (95% CI, 4.6%-9.4%) after 1 hour of prone positioning. This study adds to a growing body of literature suggesting that prone positioning may improve oxygenation in patients with early acute respiratory distress syndrome (ARDS) prior to intubation.

Prone positioning has several beneficial effects on pulmonary physiology in patients with ARDS.² In the supine position, pulmonary edema accumulates in basilar regions, and the heart and abdominal contents further compress these dependent lung regions. This leads to heterogeneous ventilation, with increased volume delivered to apical and anterior lung units, which are also the regions that receive less of the pulmonary circulation. Together, these factors lead to perfusion of poorly ventilated lung units and hypoxemia. Prone positioning of the patient leads to a more homogeneous distribution of ventilation, thus decreasing the shunt fraction and improving matching of ventilation and perfusion. Moreover, homogeneous ventilation may decrease lung injury by more evenly distributing mechanical force from the ventilator across the lung during inhalation.²

Despite compelling experimental evidence of these physiologic changes, most of the early randomized clinical trials of the prone position in mechanically ventilated patients with ARDS did not demonstrate a benefit compared with standard care. These trials, however, may have been limited by the late initiation and short duration of the use of the prone position. To address these limitations, the Prone Severe ARDS Patients (PROSEVA) trial,³ published in 2013, randomized patients with a ratio of arterial oxygen tension (PaO₂) to fraction of inspired oxygen (FIO₂) less than 150 mm Hg within 36 hours of intubation to be placed in the prone position for long durations—on average, 17 hours a day. The comparison group was patients ventilated in the supine position. The trial found a hazard ratio for death of 0.39 (95% CI, 0.25-0.63) in the study arm with prone positioning compared with standard care (mortality at 28 days, 16.0% vs 32.8%). The findings have led to increased adoption of prone positioning for mechanically ventilated patients with moderate to severe ARDS.

Before COVID-19, there was limited published research on prone positioning in nonintubated patients.⁴ The COVID-19 pandemic, however, has led to a sudden and dramatic increase in the number of patients requiring respiratory support for ARDS, straining critical care resources at many hos-



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pitals and forcing clinicians to use innovative approaches to limit the need for mechanical ventilation, including so-called awake proning. In a report on 50 nonintubated hypoxemic patients with suspected COVID-19 who presented to an emergency department in New York City, Caputo and colleagues⁵ found a significant increase in SpO₂ 5 minutes after proning (preproning: 84%; interquartile range [IQR], 75%-85%; post-proning: 94%; IQR, 90%-95%; *P* = .001). Elharrar et al⁶ conducted an observational study of prone positioning in patients with confirmed COVID-19 and posterior lung opacities on chest computed tomography who were admitted to a single center in France, most of whom were on 4 L or less of oxygen delivered via nasal cannula. Among 24 eligible patients, the majority (15 [63%]) were able to tolerate being prone for at least 3 hours, but oxygenation increased with the prone position in only 6 patients (25%). Finally, Sartini et al⁷ tested prone positioning in 15 patients admitted to a single center in Milan, Italy, who were hypoxemic despite 10 cm H₂O continuous positive airway pressure and 0.6 FIO₂, and SpO₂ increased in all 15 patients. The report by Thompson et al adds to this body of observational evidence by demonstrating that many patients with severe acute hypoxemic respiratory failure yet not on positive pressure ventilation had improved oxygenation in the prone position.¹

Although promising, these case series should be interpreted with caution because of the lack of randomization. Even in this selected group of patients, not all patients tolerated the prone position, and nearly half the patients in the case series from Thompson et al eventually required intubation. Although improved oxygen saturation with the prone position is important, hypoxemia has not been a reliable surrogate biomarker for mortality in clinical trials of ARDS. Notably, in the National Heart, Lung, and Blood Institute ARDS Network trial of low tidal volumes,⁸ the PaO₂/FIO₂ ratio was higher in the high-tidal-volume arm than the low-tidal-volume arm on study days 1 and 3. Nonetheless, mortality was lower in the low-tidal-volume arm (31.0% vs 39.8%).⁸

One potential concern with the use of the prone position in spontaneously breathing patients is that it could delay intubation and mechanical ventilation. The optimal timing of intubation and mechanical ventilation for patients with ARDS is not known, but delayed intubation has been associated with increased mortality in patients with ARDS.⁹ Spontaneously breathing patients with ARDS generate relatively large tidal volumes; the result could be inadvertent self-inflicted lung injury. Controlled modes of mechanical ventilation minimize progression of lung injury owing to barotrauma. These benefits should be balanced with the risks of mechanical ventilation, including the need for prolonged sedation and the risk of ventilator-associated pneumonia. Ongoing clinical trials of prone positioning in non-mechanically ventilated patients (eg, [NCT04383613](#), [NCT04359797](#)) should help clarify the role of this simple, low-cost approach for patients with acute hypoxemic respiratory failure.

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LESS IS MORE

Potential Association of the ISCHEMIA Trial With the Appropriate Use Criteria Ratings for Percutaneous Coronary Intervention in Stable Ischemic Heart Disease

Decreasing the risk for major adverse cardiovascular events (eg, myocardial infarction and death) and alleviating symptoms are primary therapeutic goals of percutaneous coronary intervention (PCI)



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in patients with stable ischemic heart disease (SIHD). Current appropriate use criteria (AUC) developed by national cardiovascular societies classify PCIs as appropriate, maybe appropriate, or rarely appropriate.¹ Recently, the International Study of Comparative Health Effectiveness With Medical and Inva-

eties classify PCIs as appropriate, maybe appropriate, or rarely appropriate.¹ Recently, the International Study of Comparative Health Effectiveness With Medical and Inva-