# Outcomes and Their State-level Variation in Patients Undergoing Surgery With Perioperative SARS-CoV-2 Infection in the USA

## *A Prospective Multicenter Study*

*COVIDSurg Collaborative*

**Objective:** To report the 30-day outcomes of patients with perioperative SARS-CoV-2 infection undergoing surgery in the USA.

**Background:** Uncertainty regarding the postoperative risks of patients with SARS-CoV-2 exists.

**Methods:** As part of the COVIDSurg multicenter study, all patients aged ≥17 years undergoing surgery between January 1 and June 30, 2020 with perioperative SARS-CoV-2 infection in 70 hospitals across 27 states were included. The primary outcomes were 30-day mortality and pulmonary complications. Multivariable analyses (adjusting for demographics, comorbidities, and procedure characteristics) were performed to identify predictors of mortality.

**Results:** A total of 1581 patients were included; more than half of them were males (n = 822, 52.0%) and older than 50 years (n = 835, 52.8%). Most procedures (n = 1261, 79.8%) were emergent, and laparotomies (n = 538, 34.1%). The mortality and pulmonary complication rates were 11.0 and 39.5%, respectively. Independent predictors of mortality included age ≥70 years (odds ratio 2.46, 95% confidence interval [1.65–3.69]), male sex (2.26 [1.53–3.35]), ASA grades 3–5 (3.08 [1.60–5.95]), emergent surgery (2.44 [1.31–4.54]), malignancy (2.97 [1.58–5.57]), respiratory comorbidities (2.08 [1.30–3.32]), and higher Revised Cardiac Risk Index (1.20 [1.02–1.41]). While statewide elective cancelation orders were not associated with a lower mortality, a sub-analysis showed it to be associated with lower mortality in those who underwent elective surgery (0.14 [0.03–0.61]).

**Conclusions:** Patients with perioperative SARS-CoV-2 infection have a significantly high risk for postoperative complications, especially elderly males. Postponing elective surgery and adopting non-operative management, when reasonable, should be considered in the USA during the pandemic peaks.

**Keywords:** COVID-19, COVIDSurg, elective surgery, emergency surgery, mortality, pulmonary complications

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The ongoing coronavirus disease 2019 (COVID-19) pandemic has resulted in significant disruption of surgical care around the world. Elective surgery was canceled or postponed and the threshold for emergency surgery was increased in some hospitals worldwide.[1] While the disruption of surgery was often due to hospital capacity and infection transmission concerns, there was also uncertainty regarding the perioperative risks of patients with severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[2–5] Early reports from the pandemic showed that COVID-19 is truly a systemic disease with complications including pulmonary, gastrointestinal, thromboembolic, renal, and other system-specific complications,[6–9] with concerns that surgery might trigger or worsen these complications in patients with SARS-CoV-2 infection. As such, major surgical societies urged surgeons to provide surgical care that takes into consideration their local epidemiological, logistic, and patient-related factors.[10–14] Most of these guidelines were created with a pragmatic approach based on expert opinion and the limited available data at that time.

An initial report from our COVIDSurg multicenter international study that included 1128 patients from 235 hospitals in 24 countries suggested a high risk of mortality and pulmonary complications in patients with severe SARS-CoV-2 infection undergoing surgery during the early phases of the pandemic.[15] Smaller studies from the Netherlands and Italy showed similarly high mortality and complications rates in patients undergoing surgery with SARS-CoV-2 infection.[16,17] Another recent report found a high risk of mortality and perioperative complications in SARS-CoV-2 positive patients undergoing emergency surgical procedures at 2 centers in New York.[18] However, multicenter data on outcomes of patients undergoing surgery with a peri-operative SARS-CoV-2 infection in the USA remains scarce.

In this study, we aimed to evaluate the 30-day postoperative outcomes of patients undergoing surgery with a peri-operative SARS-CoV-2 infection across different hospitals in the USA during the early to mid-phases of the pandemic.

## METHODS

We report this study in compliance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines for observational cohort studies.[19] The study has been registered in ClinicalTrials.gov (Identifier: NCT04323644).[20]

### Study Population, Setting, and Design

This is a multicenter prospective cohort study conducted as part of the ongoing international multicenter COVIDSurg study.[21] Only routine, deidentified data were collected. We included all patients aged ≥17 years undergoing any surgical operation between January 1 and June 30, 2020 with perioperative SARS-CoV-2 infection (confirmed within 7 days before or 30 days after surgery) in 70 USA hospitals across 27 states. The index procedure was

defined as the procedure closest to the time of confirmation of SARS-CoV-2 infection.

## Study Variables and Outcomes

The diagnosis of SARS-CoV-2 infection was based on either quantitative reverse transcription polymerase chain reaction testing or chest computed tomography scan, when deemed appropriate by the participating hospital. The timing of SARS-CoV-2 diagnosis was recorded as either preoperative or postoperative. Patient characteristics included age (grouped as 17–29, 30–49, 50–69 and ≥70 years), sex, and American Society of Anesthesiologists (ASA) physical status classification (grades 1–2 vs grades 3–5). Clinical symptoms present at the time of hospital admission were recorded. Preoperative physiological variables included respiratory rate, heart rate, and systolic blood pressure. Operative variables included case booking status (elective or emergency), primary procedure performed, anesthesia used (local, regional, or general), and grade of surgery (minor vs major; classified according to the Bupa schedule of procedures).[22] Comorbidity variables were recorded as follows: 1) No comorbidities, 1 comorbidity, and 2 or more comorbidities. 2) Respiratory comorbidity (asthma or chronic obstructive pulmonary disease [COPD]). Revised Cardiac Risk Index (RCRI) was used as a measure of preoperative cardiac risk.[23] The local principal investigator for each participating hospital was asked to confirm data completeness and that all eligible patients had been entered into the database. Study data were collected and managed using REDCap electronic data capture tool hosted at University of Birmingham, UK, followed by secure data transfer to the Massachusetts General Hospital, Boston, US.

The primary outcomes were 30-day mortality and pulmonary complications (defined as pneumonia, acute respiratory distress syndrome, or unexpected postoperative ventilation). Unexpected postoperative ventilation was defined as requiring non-invasive ventilation, invasive ventilation, or extracorporeal membrane oxygenation after initial extubation following surgery; or patient could not be extubated as planned after surgery. Secondary outcomes were 7-day mortality, hospital length of stay, and 30-day pulmonary embolism, re-operation, and intensive care unit admission.

## State-level Variations

State variations in 30-day mortality were examined at 3 levels: 1) regional (eg Northeast vs West), 2) time of first COVID-19 pandemic peak [early (<May 2020) vs. late (≥May 2020)] obtained through the Johns Hopkins University Coronavirus Information Center,[24] and 3) presence of a statewide elective surgery cancelation order obtained from official state and national agencies (Supplemental Digital Content 2, Table 1, http://links.lww.com/SLA/D521) and its impact on mortality in patients who underwent elective surgery.[25–27] Whether the elective surgeries were performed in those states before or after the cancelation orders was undetermined.

## Statistical Analysis

Descriptive statistics were used to report the study outcomes. For continuous data, mean and standard deviation were used to report normally distributed data, whereas median and inter-quartile ranges were used for non-normally distributed data. Normality was determined using histogram. Predictors of 30-day mortality were evaluated among patients with a peri-operative diagnosis of COVID-19 using univariable then multivariable logistic regression analyses comparing those who died vs those who survived at 30 days. An additional sub-analysis was performed to compare survivors vs nonsurvivors among patients with a preoperative diagnosis of COVID-19. For univariable analyses, chi-squared or Fisher exact tests were used to compare categorical variables as appropriate. For continuous variables, unpaired *t* test or Wilcoxon rank sum tests were used as appropriate to compare patient mean difference or mean ranks, respectively. In the multivariable logistic regression analyses, covariates that occurred before the outcome of interest were included in the logistic regression model a priori. These include demographics, comorbidities, and procedure characteristics. Model fitness was evaluated using a calibration plot.

The Benjamini–Hochberg method[28] was performed to control for false discovery rate, the probability of making a Type I error (false positive rate), that may have resulted from multiple comparisons of mortality, when appropriate.

Two-side *P* value with a level of significance of 0.05 was used. All statistical analyses were performed using StataCorp. 2017. *Stata Statistical Software: Release 15*. College Station, TX: StataCorp LLC. Maps were produced using Tableau Desktop version 2020.3.4.

## Ethical Oversight

The study was approved as a clinical audit (registration number CARMS-15986) at the lead center (University Hospital Birmingham, UK). Massachusetts General Hospital was the lead center in the USA and responsible for coordinating obtaining Institutional Review Board ethical approval and Data Use Agreement from each participating center before collecting and uploading their data.

# RESULTS

## Participant Characteristics

A total of 1581 patients were included. More than half the patients were male (n = 822, 52.0%) and older than 50 years (n = 835, 52.8%) [Supplemental Digital Content 2, Table 2, http://links.lww.com/SLA/D521]. Most patients (n = 1103, 73.1%) had high ASA grade (3 to 5) and 804 patients (50.9%) had 2 or more comorbidities. Most patients had at least 1 symptom on hospital admission (n = 1010, 63.9%). Most procedures (n = 1261, 79.8%) were emergent, with laparotomy being the most common (n = 538, 34.1%) [Supplemental Digital Content 2, Table 7, http://links.lww.com/SLA/D521]. Procedures performed were mainly for benign or obstetric (rather than cancer) indications (n =1153, 72.9%).

## Overall Outcomes

At 30-days postoperatively, 174 patients (11.0%) died and 622 (39.5%) developed pulmonary complications, specifically pneumonia (22.8%) and acute respiratory distress syndrome (15.3%) [Table 1]. Of those who developed pulmonary complications, the 30-day mortality rate was 24.4%. Pulmonary embolism occurred in 41 patients (2.6%). The unplanned hospital length of stay admission and reoperation rates were 5.5% and 19.8%, respectively. The median hospital length of stay (inter-quartile range) was 6 (2, 16) days.

## State-level Variation of Outcome

Figure 1 and Supplemental Digital Content 2, Table 3, http://links.lww.com/SLA/D521 shows the 30-day mortality rate across the different states. Mortality was higher in Northeastern states vs Western states (13.5 vs 7.5%, $P = 0.020$) and in states with early vs late first pandemic peak (13.9 vs. 8.6%, $P < 0.001$). Elective surgery cancelation orders at the state level were not associated with decreased mortality in those states. However, in an additional sub-analysis, the presence of elective cancelation orders was associated with lower odds of mortality in patients who underwent elective surgery (odds ratio 0.14 [0.03–0.61], adjusted $P = 0.04$) [Supplemental Digital Content 2, Tables 4 and 5, http://links.lww.com/SLA/D521].

**TABLE 1.** Outcomes of Patients with Peri-operative SARS-CoV-2 Infection in the USA

| Outcome | Value |
|---|---|
| 30-day mortality, n (%) | 174 (11.0) |
| 7-day mortality, n (%) | 47 (3.0) |
| Pulmonary complications, n (%) | 622 (39.5) |
| ARDS, n (%) | 241 (15.3) |
| Pneumonia, n (%) | 359 (22.8) |
| Unexpected postoperative ventilation, n (%) | 461 (29.2) |
| 30-day mortality in those with pulmonary complications, n (%) | 152 (24.4) |
| Pulmonary embolism, n (%) | 41 (2.6) |
| HLOS, median (IQR) | 6 (2, 16) |
| Unplanned ICU admission, n (%) | 86 (5.5) |
| 30-day re-operation rate, n (%) | 310 (19.8) |

ARDS indicates acute respiratory distress syndrome; HLOS, hospital length of stay; ICU, intensive care unit; IQR, inter-quartile ranges.

### Predictors of 30-day Mortality

On univariable analyses, patients who died were more often older than 70, male, had higher ASA grades, and more comorbidities than those who survived [Supplemental Digital Content 2, Table 2, http://links.lww.com/SLA/D521]. They were also more likely to undergo emergency and cancer surgery under general anesthesia.

On multivariable analyses, independent predictors of 30-day mortality were age $\geq$70 years (2.46 [1.65–3.69], $P < 0.001$), male sex (2.26 [1.53–3.35], $P < 0.001$), ASA grades 3–5 (3.08 [1.60–5.95], $P = 0.001$), malignant disease (2.97 [1.58–5.57], $P = 0.001$), emergent surgery (2.44 [1.31–4.54], $P = 0.005$), preoperative white blood cell count $\geq$11 K/$\mu$L (odds ratio 2.16 [1.48–3.14], $P < 0.001$), respiratory comorbidities (2.08 [1.30–3.32], $P = 0.002$), and higher Revised Cardiac Risk Indices (1.20 [1.02–1.41], $P = 0.025$) [Fig. 2]. The state or region in which the procedure was performed did not predict mortality. Supplemental Digital Content 2, Figure 1, http://links.lww.com/SLA/D521 shows a good model calibration which reflects a good model performance.

Among patients with a preoperative diagnosis of COVID-19, patients who died were more often older than 70 and had a higher RCRI than those who survived [Supplemental Digital Content 2, Table 6, http://links.lww.com/SLA/D521].

## DISCUSSION

This study shows that the 30-day mortality and pulmonary complication rates of patients with perioperative SARS-CoV-2 undergoing surgery in the USA in the early to mid-phases of the pandemic were significantly elevated but not as elevated as the data reported internationally from an earlier phase of the pandemic. Specifically, an earlier report from our COVIDSurg Collaborative which included similar patient population undergoing surgery during the early phase of the pandemic (January to March 2020) from across the world, showed higher mortality (23.8% vs. 11.0%) and pulmonary complications (51.2% vs 39.5%) rates than the results in this study.[15] However, the mortality we report here is still higher than that historically reported for emergency surgery prior to the pandemic in countries with high Human Development Index (4.5%).[29] Similarly, the pulmonary complication rates we report here are higher than those reported in non-COVID-19 patients prior to the pandemic (7.0%–11.0%).[30–32] The mortality of patients who developed pulmonary complications in our cohort was notably elevated. Based on our results, we recommend careful consideration for postponing elective surgery and adopting nonoperative management in the USA during the pandemic, when reasonable and feasible per local conditions, especially for patients at risk for or with confirmed SARS-CoV-2 infection.[15,33,34]

When examining state-level variation in outcomes, our study suggested a higher patient mortality in participating hospitals located

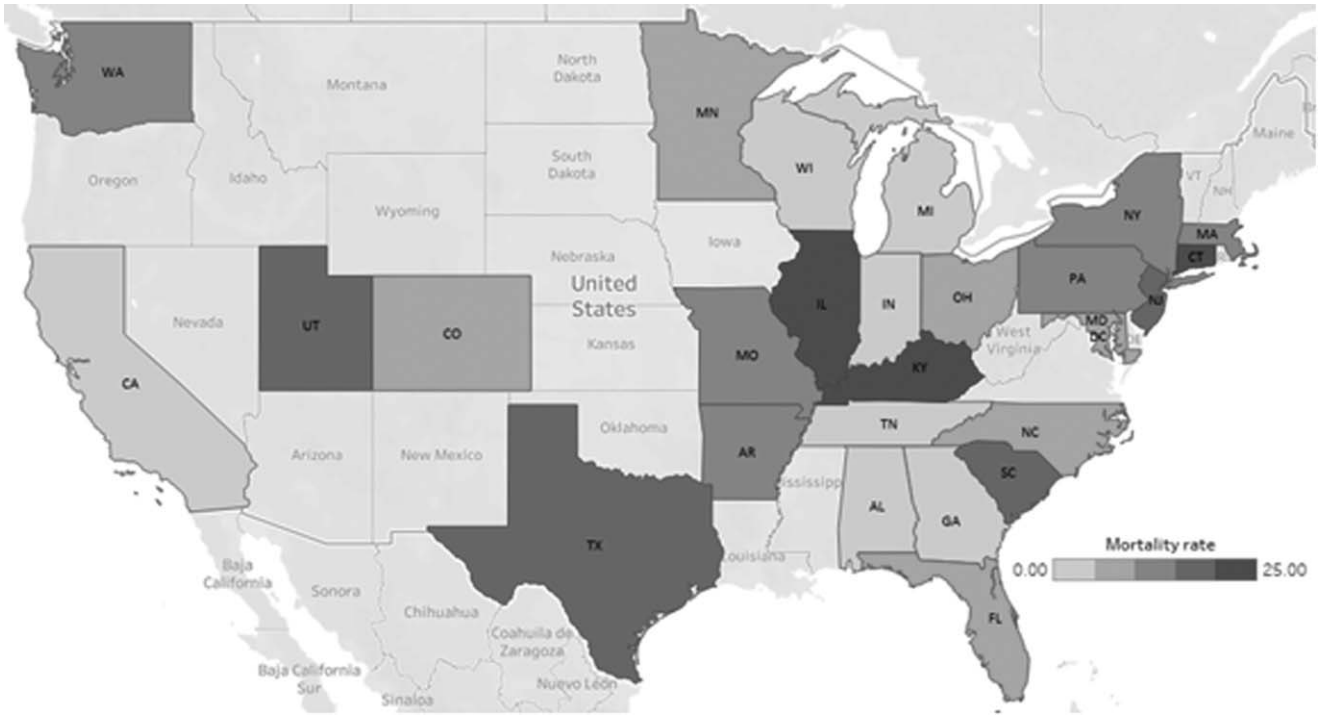


**FIGURE 1.** Mortality risk (%) of COVID-19 patients undergoing surgery by USA state.

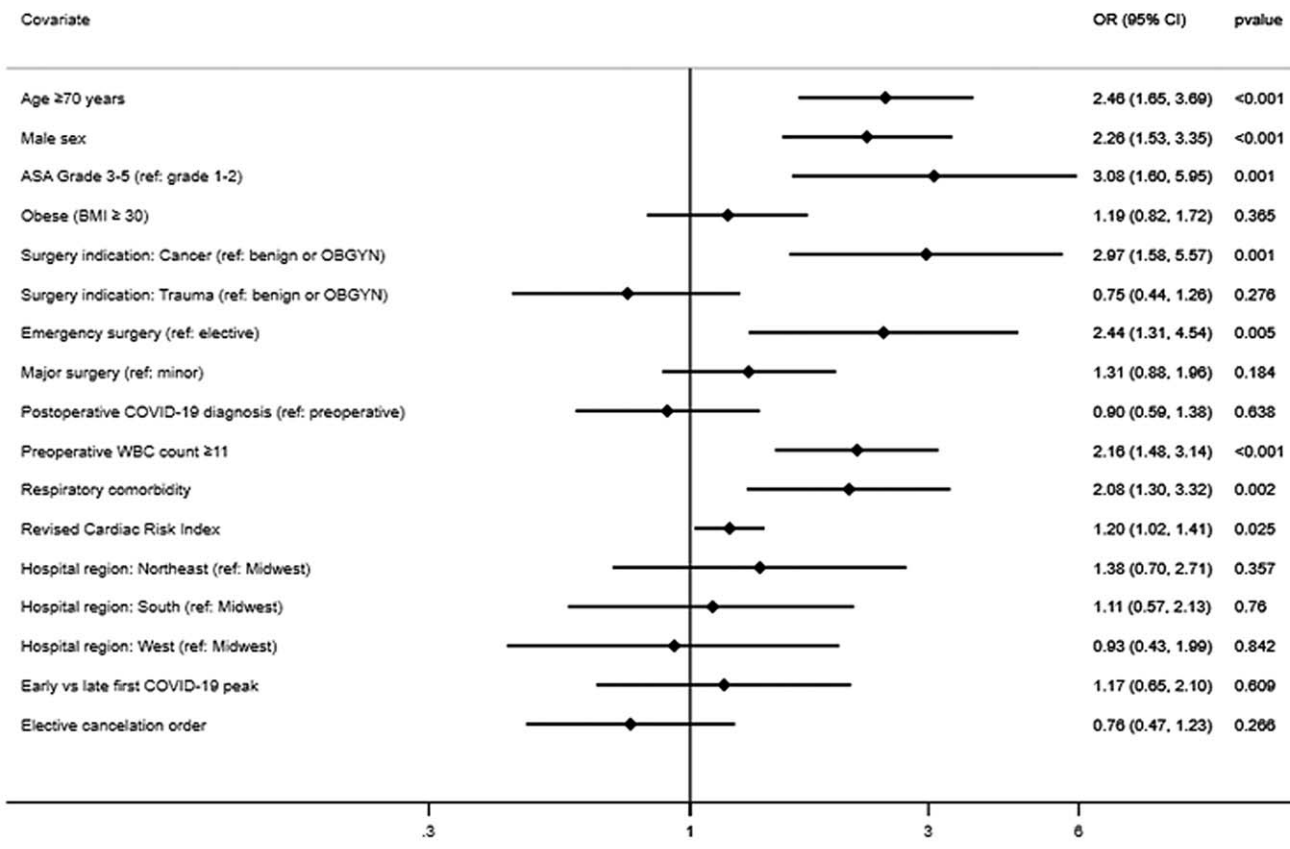


**FIGURE 2.** Multivariable logistic regression of predictors of mortality in patients with peri-operative SARS-CoV-2 diagnosis in the USA. **The Brier score: 0.08; Pearson goodness-of-fit (Hosmer-Lemeshow goodness-of-fit) test: 0.20; AUROC (95% CI): 0.82 (0.78–0.85).*

in Northeastern states compared to other regions and in states with early vs late first pandemic peak. However, these results did not impact mortality after adjusting for other covariates in the multivariable analysis. Although it is possible that the uncertainties that surrounded COVID-19 and its optimal management in the early phases of the disease, and the variation of timing of disease peaks across the states contributed to the variation in outcome, it raises the question of whether this is due to changes in the disease acuity in later stages of the pandemic. This is further supported by the fact that states with early COVID-19 peaks showed higher crude rates of mortality of surgical patients. On the other hand, this study showed that states with elective surgery cancelation orders, while not having a lower mortality overall, had lower odds of mortality in patients undergoing elective surgery than states without such orders. This finding needs further exploration to better understand the interplay between the perioperative risk of elective surgery versus the risks associated with delay of surgical treatments during the pandemic.[35]

In addition, our data identified age $\geq$70 years, male sex, ASA grades 3 to 5, cancer surgery, emergent surgery, preoperative WBC count $\geq$11 K/uL, respiratory comorbidities, and higher RCRI as independent predictors of 30-day mortality. These findings have significant implications for surgical practice in the USA and elsewhere as they suggest caution is warranted when operating on this subset of high-risk patients.

While our study presents several strengths including a large sample size and a wide representation from 70 hospitals across more than half the number of USA states, it is not without limitations. First, our cohort is heterogeneous, with both symptomatic and asymptomatic patients undergoing surgery at various hospitals and states, with different capacities, patterns of practice, and quality of care profiles. Second, the absence of a non-COVID-19 control group prevents any efforts at confirming or refuting the hypothesis that these complications are COVID-19 specific. Third, as with any regression analysis, residual confounders might still exist. Specifically, other predictors of mortality described in the literature such as race, ethnicity, medications received (eg, steroids) were not evaluated in this study. Fourth, the occasional use of computed tomography scan for diagnosis of COVID-19 is likely to detect patient who are already suffering pulmonary complications which may bias estimates of the reported rates of pulmonary complications for patients with COVID-19 undergoing surgery. Fifth, variation in hospital-specific policies with regards to preoperative testing and elective surgery cancelation or delay invariably exists and this heterogeneity could limit generalizability of the study findings. Finally, patients were enrolled from a limited number of hospitals/states which could also limit the generalizability of the study findings.

## CONCLUSIONS

USA patients with perioperative SARS-CoV-2 infection have a high risk for postoperative mortality and pulmonary complications. This is especially important in elderly male patients with comorbidities undergoing emergency or cancer surgery. Although we observed variation in outcomes across states, this variation is likely due to different timing of the pandemic and different patient and procedure profiles across these states. This study provides further evidence supporting careful consideration to delaying elective surgery and

adopting nonoperative management, when reasonable as an alternative, for emergency surgery during active phases of the pandemic.

**Authors' contributions:** see Supplemental Digital Content 1, http://links.lww.com/SLA/D520

**Author access to data:** the corresponding author has full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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