Results of COVID-minimal Surgical Pathway During Surge-phase of COVID-19 Pandemic

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Objective: The outcomes of patients treated on the COVID-minimal pathway were evaluated during a period of surging COVID-19 hospital admissions, to determine the safety of continuing to perform urgent operations during the pandemic.

Summary of Background Data: Crucial treatments were delayed for many patients during the COVID-19 pandemic, over concerns for hospital-acquired COVID-19 infections. To protect cancer patients whose survival depended on timely surgery, a ‘‘COVID-minimal pathway’’ was created.

Methods: Patients who underwent a surgical procedure on the pathway between April and May 2020 were evaluated. The ‘‘COVID-minimal surgical pathway’’ consisted of: (A) evolving best-practices in COVID-19 transmission-reduction, (B) screening patients and staff, (C) preoperative COVID-19 patient testing, (D) isolating pathway patients from COVID-19 patients. Patient status through 2 weeks from discharge was determined as a reflection of hospital-acquired COVID-19 infections.

Results: After implementation, pathway screening processes excluded 7 COVID-19-positive people from interacting with pathway (4 staff and 3 patients). Overall, 122 patients underwent 125 procedures on pathway, yielding 83 admissions (42 outpatient procedures). The median age was 64 (56–79) and 57% of patients were female. The most common surgical indications were cancer affecting the uterus, genitourinary tract, colon, lung or head and neck. The median length of admission was 3 days (1–6). Repeat COVID-19 testing performed on 27 patients (all negative), including 9 patients evaluated in an emergency room and 8 readmitted patients. In the postoperative period, no patient developed a COVID-19 infection.

Conclusions: A COVID-minimal pathway comprised of physical space modifications and operational changes may allow urgent cancer treatment to safely continue during the COVID-19 pandemic, even during the surge-phase.

Keywords: cancer, COVID-19, COVID-minimal surgical pathway

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In response to the COVID-19 pandemic, hospitals around the world dramatically reduced the volume of hospital care provided for non-emergent conditions. These reductions were necessary to create capacity to care for COVID-19 patients, and concerns over potential COVID-19 exposure in the hospital. Ultimately, the vast majority of elective and semi-elective treatments, including surgical procedures, were delayed or deferred. Unfortunately, not all treatment delays are without consequences. Delaying surgical treatment for some cancer patients, could compromise cure rates.[1–3] As a result, several oncology and surgical organizations released guidance to assist hospitals in identifying patients in whom surgical delay should be minimized.[4,5] Therefore, most hospitals sought to continue performing a limited number of surgical procedures during the pandemic, to care for patients whose survival or permanent function was jeopardized by delay (commonly referred to as ‘‘urgent’’ procedures).

The cancer patient population may be at particularly high risk for medical care during the COVID-19 pandemic. Many cancer patients are elderly, with multiple medical conditions, putting them at high risk for a complicated course should they become infected with COVID-19.[6] Beyond matching the high-risk profile, a cancer history may further accentuate the hazards of COVID-19. For example, the COVID-19 and Cancer Consortium, found that among 928 COVID-19 patients with cancer, 13% of the cases were fatal.[7] There has also been concern that perioperative the period may be a particularly vulnerable time for COVID-19 infection, which has been supported by a number of case series.[8–10] In fact, within an international collaborative of perioperative COVID-19 infections, 24% of patients died within 30 days of surgery.[11] As a result, patients have been forced to face competing threats during the pandemic, trying to understand whether their disease or their treatment represents the lesser risk.

In an effort to protect patients from hospital-acquired COVID-19 infections, a ‘‘COVID-minimal surgical pathway’’ was developed to minimize the exposure of cancer patients to people, locations, and materials that posed the highest risk to transmit a coronavirus infection.[12] The COVID-minimal surgical pathway is a culmination of best practices surrounding risk-reduction for virus transmission (symptom screening, distancing, mask wearing, etc), preoperative patient COVID-19 testing, and a rigorous process to physically separate, to the greatest degree possible, surgical pathway patients from people, space and materials that were in contact with the COVID-19 population. The following report outlines the outcomes of patients that underwent a surgical procedure on the pathway for confirmed or suspected malignancy.

METHODS

Patients

Patients with confirmed or suspected cancer, whose clinical scenario met the current departmental criteria for appropriateness of surgery (ie, ‘‘urgent’’ status) were eligible. More specifically, to preserve critical resources to care for surging COVID-19 populations

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and to prevent hospital-acquired COVID-19 infections, surgeons were only permitted to perform surgical procedures in patients felt to be risking survival or permanent function by delay. Appropriateness of surgery was determined by leadership within the department of surgery (Division Chief, Chair of surgery) in consultation with multidisciplinary oncology teams and were contingent on availability of mission-critical resources (such as personal protective equipment, ventilators, staff, etc). Triage practices were consistent with guidance provided by major surgical organizations.[4,5] In general, patients whose survivorship or permanent function were felt to be at risk by delay of surgery by 3 months (our modeled duration of surge-related delay, at time pathway implemented) were eligible, and final approval given by a triage committee comprised of clinicians managing the pathway. However, from this eligible population, patients who were felt to be likely to require prolonged ventilator support, have prolonged needs for intensive care unit (ICU) care were deferred.

Participation in the pathway was open to all surgical services that perform surgical procedures for diagnosed or suspected cancer. Service lines with the most cancer patients qualifying as "urgent" included otolaryngology, gynecologic-oncology, thoracic oncology, surgical oncology, and urology. A weekly triage conference coordinated requested access to the pathway, as capacity was limited. The pathway was opened to patients on April 3rd, 2020 and the experience during the surge is reported through May 31, 2020. All but 4 of the patients came to the hospital on the day of surgery (2 of whom were admitted the night before for optimization).

COVID-minimal Surgical Pathway

The COVID-minimal surgical pathway was conducted as described previously.[12] The objective of the pathway was to minimize the risk of hospital-acquired COVID-19 infection by preventing patients on the pathway from encountering people, places or materials likely to transmit a coronavirus infection. Preoperative visits to the hospital were minimized. Initial consultations took place via telemedicine. Patients had previously been coming to the hospital for a preadmission testing visit, during which blood would be drawn, electrocardiogram performed, and the anesthesia team would evaluate. This visit was eliminated, and the activities instead took place on the day of surgery.

First and foremost was an effort to adhere to the evolving best practices for COVID-19 prevention (eg, hand washing, distancing, wearing masks). In addition, staff members (eg, nurses, nursing assistants, unit clerks, surgeons) were screened for symptoms and fever before engaging in patient care on the pathway. Key nursing leaders were engaged to disseminate best practice advisory to their teams, and to highlight the priority of pathway integrity, to create a culture around COVID-19 safety. To document compliance, nurses were asked to log their temperatures at the beginning of shift, in a paper-based ledger system. Asymptomatic staff were not routinely screened for COVID-19 infections. Within 48 hours before surgery, patients were screened for COVID-19 symptoms, had their temperature taken and underwent preoperative COVID-19 testing. The day of surgery, patients were screened again for symptoms and had their temperature taken on entry into the hospital. Visitors were excluded from the hospital along the entire pathway. Once patients passed the screening station at the entrance of the hospital, patients were directed through the hospital (eg, admitting, preoperative holding, operating rooms, recovery area, and inpatient units) to locations that were as geographically remote as possible from areas that were being used to care for patients with confirmed or suspected COVID-19 infections (ie, separate corridors of operating rooms from COVID-19, separate recovery area, separate floors). By clustering pathway patients together, they were in effect isolated from patients who did not have a negative COVID-19 test (ie, pathway patients did not mix with "COVID-19 unknown" patients).

Preoperative Patient Testing

The pathway policy was for all patients to undergo testing for COVID-19 within 48 hours before surgery. The testing platform varied during this time frame in response to evolving technology and availability of reagents. Initially, the patients were tested using an Food and Drug Administration-approved in laboratory assay developed in-house, but ultimately platforms offered by Cepheid, ThermoFisher, Hologic, and Becton Dickinson were utilized. Patients would come to 1 of 3 drive-up testing sites in which a deep nasal swabbing was performed.

Screening Outcomes

The outcomes of staff-screening for temperature and symptoms were determined by surveying the unit managers (individual staff member status was not tracked). Outcomes of patient screening before their procedure (ie, how many patients were excluded by testing and symptom screening) were determined by surveying surgical teams and unit managers.

Follow Up

Follow up was conducted through chart review and patient phone calls by the quality assurance team. The patient's status was determined during their hospitalization and through their first 2 weeks after discharge from the hospital. The time frame was chosen because the vast majority of patients with symptomatic COVID-19 infections will develop symptoms within 2 weeks of exposure,[6,13] and transmission could occur at any point during their hospitalization. Specific outcomes that were determined included: (1) evidence of COVID-19 symptoms (fever, cough, shortness of breath, gastrointestinal distress) during the first 2 weeks after discharge, (2) documented COVID-19 testing, (3) documented COVID-19 infection, (4) evaluation in the Emergency Department, (5) hospital readmission, and (6) death. Follow-up was obtained on 121 (99.2%) of patients (1 patient lost to follow-up after outpatient surgery).

Hospitalized COVID-19 Population

The Yale New Haven Hospital tracked the prevalence of COVID-19 patients among the hospital population during the pandemic. The Yale New Haven Hospital is comprised of 2 campuses in New Haven Connecticut, which are separated by 0.8 miles. The larger campus had an average census of 844 admitted patients over the study period, and the smaller campus had an average census of 343 patients. The pathway was located on the smaller campus. A broad spectrum of adult care is offered at both campuses, including medical and surgical ICUs, and there is a high degree of overlap between the physicians practicing at both campuses. During the pandemic, there was no deliberate attempt to direct or restrict the flow of admissions of COVID-19 patients to either campus (in fact the smaller campus ended up with a higher prevalence of COVID-19 patients). Certain tertiary services, such as extracorporeal membraned oxygenation, were only offered at the larger campus.

The project was evaluated by the Yale IRB and felt to represent quality assurance and not research, and as such, consent was not needed.

RESULTS

Before Pathway Implementation

In the week before initiating the pathway, there was a median of 143 hospitalized COVID-19 positive patients, representing 14% of the hospital census. During the week, 39 patients were admitted from

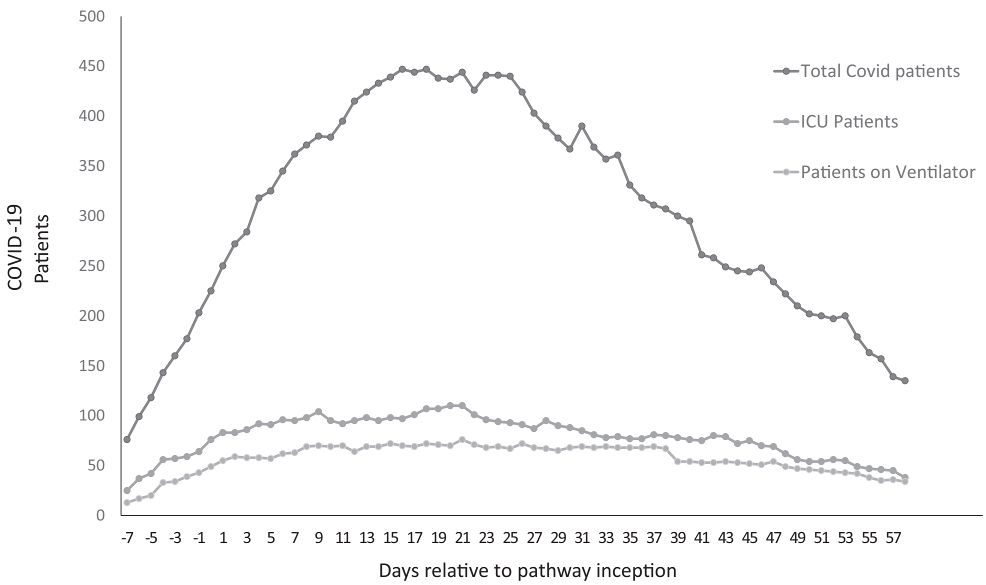

FIGURE 1. Prevalence of COVID-19 patients within the hospital around the time of the COVID-19 minimal surgical pathway implementation. On the *x*-axis are days relative to the initiation of the pathway (negative numbers being before implementation, positive numbers being after). Total admissions are shown in blue line, whereas patients in the ICU are in orange and patients on ventilators in gray ICU indicates intensive care unit.

home for surgical procedures by the services that routinely operate for cancer. Two of the 39 patients (5.1%) were diagnosed with COVID-19 in the first 2 weeks of the postoperative period (which inspired the pathway's creation).

COVID-19 Census Surge

The census of admitted COVID-19 patients, including need for ICU and ventilator use is plotted over time in Figure 1. During the 2-month period, the median number of admitted confirmed COVID-19 patients at Yale New Haven Hospital was 331 (interquartile range 246–409). At the peak of the surge, 447 confirmed COVID-19 patients were hospitalized, representing 36.5% of all the admitted patients.

TABLE 1. Profile of Pathway Patients

Age – median (IQR)	64 (56–79)
Sex = female	71 (57%)
Preoperative testing interval	
Same day as surgery	11
Day before surgery	95
24–48 h before surgery	19
Procedure for cancer*	113 (90%)
Procedures by Surgical Service†	
Otolaryngology	44
Gynecology Oncology	37
Urology	17
Surgical Oncology	12
Thoracic	12
Other	2
Robot-assisted procedure	36 (29%)
Admitted after surgery	83 (66%)
Outpatient	42
Length of stay‡-median (IQR)	3 days (1–6)

*Several patients were presumed to have cancer, underwent surgery on the pathway, but were subsequently found not to have cancer.
†Among the most common procedures performed included laparoscopic total abdominal hysterectomy, omentectomy, colectomy, pulmonary lobectomy, nephrectomy, neck dissection, prostatectomy, thyroidectomy, endoscopy.
‡Length of stay only includes of admitted patients.
IQR indicates interquartile range.

Pathway Patients

A total of 122 patients underwent 125 surgical procedures during this 8-week period, including 83 in which the patients were admitted, and 42 outpatient procedures. The median age was 64 years of age (interquartile range 56–79) and 71/122 (58%) patients were female (Table 1). The most common procedures were related to malignancy of the uterus, colon, genitourinary tract, lung or head and neck. Of the admitted patients, the median length of stay was 3 days (interquartile range 1–6 days).

Patient Outcomes

Follow up was available on 99% of patients (121/122). Postoperative COVID-19 testing was performed after 27 of the procedures, none of which were positive (Table 2). Overall 9 patients were evaluated in the emergency department after their surgical procedure and 8 patients were readmitted to the hospital. After clinical review of patient medical record and phone call follow ups, there were no suspected or confirmed post-operative COVID-19 infections (0/124 procedures - 0%).

Exclusion of High-risk Contacts by Pathway Process

During the surge period, 2 patients were excluded because of preoperative of positive COVID-19 screening, and a third patient by their temperature screening at entry to the hospital. A total of 4 staff members developed symptoms at home and were diagnosed with COVID-19 during the surge period. These staff were not symptomatic or febrile while interacting with pathway. No staff member came to the hospital and was found to be febrile at check-in to their unit.

DISCUSSION

The current results suggest that the performance of surgery using a COVID-minimal surgical pathway carries a low risk of hospital-acquired COVID-19 infection, even in the setting of surging COVID-19 populations. The implications of this finding are significant, as the successful implementation of the pathway could allow hospitals to minimize COVID-related therapeutic delays in patients whose survival is dependent on timely surgical care.

The pathway was created to address a perceived risk of nosocomial infections among patients coming to the hospital for urgent surgical procedures. Although the true nosocomial risk was

TABLE 2. Postoperative Results*

Postoperative diagnosis of COVID-19	0 (0%)
COVID-19 test in postoperative period†	27 (22%)
Evaluated in Emergency Department during postoperative period	9
Readmissions to hospital‡	8
Deaths in perioperative period	0

*Total of 125 procedures were performed in 122 patients. One patient was lost to follow up after an outpatient procedure (N = 124 procedures in 121 patients).

†Three of these tests were patients who had multiple procedures, and the test was a preoperative test for a subsequent procedure. All readmitted patients were tested for COVID-19.

‡Causes for readmission included: drug reaction (patient had fever and rash on admission, COVID-19 negative), hydronephrosis, small bowel obstruction, fall, atrial fibrillation, deep venous thrombosis.

unknown at the pathway's inception, initial concerns have been supported by recent reports outlining the danger of COVID-19 infection in the perioperative period. Recognizing the considerable variability across reports from different regions, approximately 5% of patients recovering from surgery during the pandemic have been diagnosed with COVID-19 infections.[14–16] This rate is similar to what was observed at the current hospital the week before implementation of the pathway (2/39 patients developed COVID-19 infections after surgery). The impact of preventing COVID-19 infections is significant. Of patients that develop a COVID-19 infection during the perioperative period, the mortality seems to be quite high (around 25%[11,17]), emphasizing the critical need to protect patients.

The risk of hospital-acquired COVID-19 infection likely parallels the prevalence of COVID-19 within the treating the hospital and surrounding communities. To this end, a recent multi-institutional analysis of surgical procedures in children found that roughly 50% of patients from a single county around Philadelphia severely impacted by COVID-19 developed perioperative infections (compared to 1.5% for hospital's overall infection rate).[18] In this regard, the current study examined a surge that took place in one of the more severely affected parts of the United States. During the time period in which the pathway was implemented, Connecticut ranked fifth in the United States in terms of the prevalence of COVID-19 infections (12,055 per million people), and eighth in terms of total mortalities (3,972).[19]

The COVID-minimal surgical pathway was neither novel nor innovative. The pathway essentially represented a commitment to adhere to the evolving best practices and a common-sense approach of isolating noninfected patients from infected patients.[20,21] That being said, the implementation of the pathway was neither simple nor easy. The pathway was devised and implemented at a time of great uncertainty. Recovery rooms were being converted to ICUs. Staff and clinicians were being relocated across the hospital, many serving in unique roles, not uncommonly outside of their formal training. Implementation required extremely high levels of interprofessional engagement, identification and preservation of physical care spaces, and complex schedule coordination and bed management. This effort would not have been possible without an effective strategy, implemented with a process that respected the disrupted environment, within a culture of patient-centeredness. Perhaps the most salient observation from the pathway outcomes is that the significant sacrifices and effort required to formally commit time, space, and resources to the pathway – seem to be justified.

The concept of the COVID-minimal surgical pathway is a local response to a global problem. Because the pathway is a delicate balance between resource availability and the relative impact of surging COVID-19 patients, each hospital represents a unique circumstance. As a result, the pathway would look quite different from hospital to hospital and, depending on the surge-status, potentially different from week to week. Our 2-campus model allowed for more movement within the hospital, but also created distinct logistical challenges, such as procuring the materials and equipment needed to care for some of the surgical patients. In the end, the campus that was home to the COVID-minimal surgical pathway had a higher prevalence of COVID-19 patients (peak prevalence of 45% of admitted patients vs 34% at larger campus), which did not preclude the pathway from protecting patients. Ultimately, the ability to maintain separation of staff and patients according to COVID-19 status was likely more important than the prevalence of COVID-19 patients.

LIMITATIONS

There is no way to definitively establish negative COVID-19 status among the patients that were followed. Patients were not routinely tested for COVID-19 in the post-operative period. Even if all patients had been tested, the COVID-19 testing platforms have false negative rates that can vary considerably (ie, 20%–38%) depending on the patient's disease phase.[22] Although patients were followed for clinical change, we cannot exclude the possibility that patients acquired an asymptomatic COVID-19 infection during their hospitalization.[23] Therefore, it may be more accurate to conclude that surgical procedures on the COVID-minimal pathway were able to be performed with low risk of developing a symptomatic COVID-19 infection.

Without a control group, it is impossible to know the true impact of the pathway (ie, what would have happened if the pathway was not created). We are left to compare our observed infection rate of 0% to contemporary reports, and surgical outcomes at our hospital the week before pathway implementation (COVID-19 infection rates around 5%[14–16]).

It is also not possible to know which components of the pathway were most impactful. Preoperative testing was likely extremely important. For example, a multi-institutional study in children having surgery that included preoperative COVID-19 testing found a postoperative infection rate of around 1%.[18] However, it is important to note that the screening processes embedded in our pathway (ie, checking for symptoms, temperature) excluded 5 additional people (1 patient and 4 staff) from interacting with the pathway beyond those detected by preoperative testing. These exclusions are critical, as a single individual with an undiagnosed COVID-19 infection can transmit to 10 or more other individuals in the hospital setting.[14]

CAUTIONS ON INTERPRETATION

At the time of the pathway's creation and implementation, surgical activity was being drastically reduced around the world (eg, 85% reduction at our hospital during the surge), to both protect patients and conserve resources (eg, blood products, ventilators) needed to care for COVID-19 patients. It is unclear how the pathway would perform at larger scale. It would not be appropriate to interpret these results to obviate the need for surgical volume restriction during a pandemic. Although we believe there are potential opportunities to extend these findings (ie, surgical procedures for other indications, other types of treatment) and at different scales as resources allow, the pathway would have been unlikely to have been sustainable without some degree of reduction in clinical activity. Results from this pilot have been key in planning our pandemic recovery phase and preparing for subsequent surges. This pathway was implemented in Connecticut, which at the time, had a seemingly high compliance with best practices (sheltering in place, wearing of facemasks, restriction of visitors). In future iterations of this model, it may be beneficial to be more explicit regarding expectations of behavior outside of the hospital before and after surgery (eg, quarantine).

Finally, this pathway was designed to manage the COVID-19 pandemic. It is unclear if the outcome of the pathway would be the same in the setting of a different contagion. The concept of designing a pathway around current best-practices, and attempting to isolate patients coming in contact with people, locations, and materials that also contact infected patients, will likely be important. However, as each infection has distinct nuances regarding detection and transmissibility, it is not possible to know the safety of providing care on such a pathway for other types of infections.

CONCLUSIONS

The culmination of best practices and isolation efforts into a COVID-minimal surgical pathway seems an effective strategy to protect surgical patients from hospital-acquired COVID-19 infections, even as COVID-19 patients were surging. These findings may reassure hospitals and patients that it is possible to safely conduct a limited flow of surgical procedures at a time when the hospital is committing space and resources to care for a rapidly expanding COVID-19 population.

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