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Original Research Article

Safe laparoscopy during COVID-19 pandemic by SARS-CoV-2: bio innovation of the closed-circuit system

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ABSTRACT

Background: Severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) transmission during laparoscopy while using energy devices through the carbon dioxide pneumoperitoneum is a big concern in operation theatre. So, we had to alter the way we vent carbon dioxide through a closed-circuit system (CCS) to avoid contamination.
Methods: We did a prospective study in the safety of the CCS during elective laparoscopic surgeries. We had recruited 184 patients from a single unit in three quarters. The first quarter had 52 patients where the SARS-CoV-2 status was unknown as rapid antigen test (RAT) and reverse transcription polymerase chain reaction (RT- PCR) was not done as per government guidelines. So, we presumed all patients to be potential carriers. Later in the 2nd and 3rd quarter we had recruited 132 patients; all were tested by RAT/RT-PCR and positive patients were excluded from our study. Postoperatively we observed for COVID-19 symptoms in our health care workers (HCW) and confirmed by RT-PCR.
Results: Of the total 184 laparoscopic surgeries performed during this period, only 2 (1.09%) patients developed COVID-19 symptoms and this was in the 1st quarter when routine testing by RT-PCR was not done. None (100%) of our HCW developed symptoms of COVID-19.
Conclusions: Closed circuit system is an innovative and safe technique during laparoscopy. We strongly recommend RT-PCR for COVID-19 before elective surgery.

Keywords: SARS-CoV-2, Laparoscopy, CCS, Pneumoperitoneum, Energy device

INTRODUCTION

Healthcare system is an epicentre of "severe acute respiratory syndrome-Coronavirus-2 (SARS-CoV-2)" pandemic. Many countries have already witnessed the second wave and India experienced it recently. There are predictions of the 3rd wave in August or September in the Indian subcontinent. Studies in the past have shown the presence of human immunodeficiency virus (HIV), papillomavirus (HPV), hepatitis B virus (HBV) and hepatitis C virus (HCV) in the cautery smoke.[1-3] SARS-CoV-2 has been isolated in faeces, blood, peritoneal fluid and intestinal mucosa.[4,5] So there is a significant theoretical risk of generating aerosol contaminated SARS-CoV-2 while using energy devices during laparoscopy. Routinely we release carbon dioxide (CO2) during laparoscopy to avoid fogging of the lens, thus endangering HCW in the operation theatre (OT). As a result, laparoscopy an aerosol generating procedure (AGP) was stopped in most countries. We too in India had stopped operating based on the ICMR guidelines. The Association of Surgeons of India (ASI) consensus guidelines suggested elective surgeries to commence once the curve shows a continuous decline for 15 days.[6] Likewise there has been other recommendations and guidelines for practicing safe laparoscopy during the pandemic.[7-9] There are also concerns of false negatives reports (21-54%) with RAT and RT-PCR.[10] Following

Standard operating procedure like using N95 mask, personal protective equipment (PPE) and visor may not be practical in smaller rural centres in a third world country. These challenges invited us to create a novel, safe and cost-effective CCS. This could enable us to continue operating safely during the pandemic and later.

METHODS

This prospective randomised study was conducted in the laparoscopy unit from May 2020 to January 2021. Our sample size was 184 patients, 52 in 1st quarter and 132 in 2nd/3rd quarter. Based on the literature and assuming standard deviations, we calculated a sample size of at least 50 subjects in each quarter. The aim of this research was to assess the safety of HCW using the CCS during laparoscopy. During the first quarter between May to July 2020, patients were admitted 24 hours prior to surgery. The COVID status was unknown as RAT/RT-PCR testing was not done but clinical screening was performed as per ICMR and government (GOK) guidelines. So, we presumed all patients to be potential carriers of SARS-CoV-2. However, in the 2nd and 3rd quarter between August 2020 to January 2021, patients were admitted 2 days preoperatively, their COVID status checked by RT-PCR and elective surgery performed only with a negative report. The exclusion criteria were, patients in whom laparoscopy was contraindicated and COVID positive. A written informed consent was taken after explaining the procedure. Laparoscopy procedures involved three surgeons with different experience. The standard technique was used to create pneumoperitoneum by Hasson or Veeres needle. To keep the insufflation pressures low, the anaesthetist gave deep muscle relaxation. The ports were placed by standard techniques and their numbers varied based on the type of surgery. We always used corrugated disposable plastic trocars (Figure 1), the corrugation ensures the trocars fits tight and avoids peri tubal leak. We setup the simple innovative CCS before starting surgery. The fit-fix system was connected to the wall mounted scavenging system in each OT which is a one-way exhaust into the scavenging pit, which is vented to the atmosphere at 25 cycles/hour. The suction pressure in the circuit is kept low to avoid bowel injury, adjusted through the pressure gauge (Figure 2 and 3). We strongly advise minimal use of energy source and use maximum mode on the foot peddle to minimise aerosol generation, exchange instruments minimally to mitigate gas leak. At the end of operation, place the port over the liver or under the parity and decompress gas fully before specimen retrieval to avoid bowel injury. We added a small modification to this system, a Y connector (Figure 3 and 4) to suck out fluid during laparoscopy into the fit-fix system. Statistical analysis was done using the Statistical package for social sciences (SPSS) version 16. Inferential statistics used were the chi-square and t test for comparison. Standard pie charts were used to describe the results. Multivariate regression analysis was performed to ascertain the influence of safety of CCS on the outcome of SARS-CoV-2 infection in HCW.

Figure 1: The various indigenous individual components used in the assembly of the CCS.

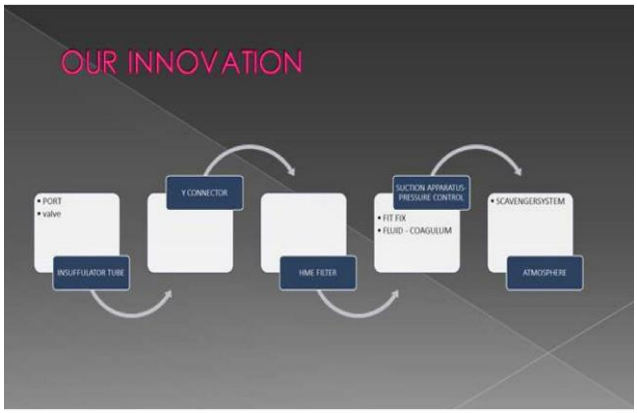

Figure 2: Line diagram of our innovation of setting up the CCS during laparoscopy.

Figure 3: Figur 3: Assembled closed circuit system with a Y connector. One limb is connected to desufflate CO_2 pneumoperitoneum and the other to the fit fix seal for aspirated fluid (blood/bile/pus). This in turn connects to the scavenging system on the wall whose suction pressure can be regulated through the pressure gauge.

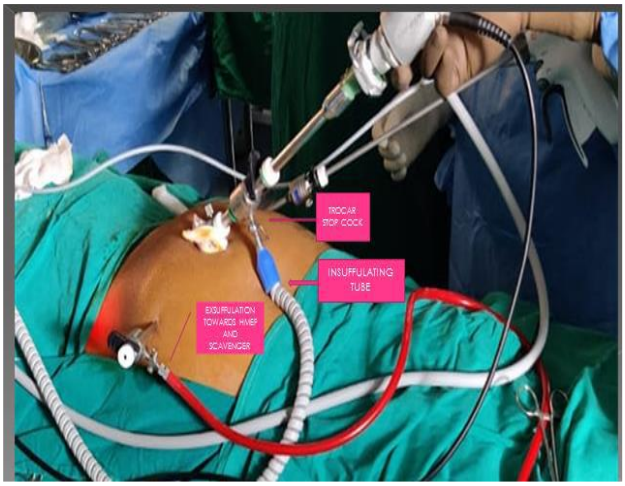

Figure 4: Live setup of the CCS seen during a laparoscopic TAPP hernia surgery.

RESULTS

The age of patients ranged from 17 to 55 years with a mean of 42 years. The sex distribution was uneven with a male predominance. We had performed 184 laparoscopic surgeries in 9 months using the CCS. The distribution of surgeries and their numbers are shown below (Figure 5 A, B, D).

During the first quarter, 92.3% patients were discharged within 24 hours following surgery except 7.69% who underwent advanced laparoscopic procedures. Of the delayed discharges, one (1.92%) patient had a difficult laparoscopic cholecystectomy secondary to adhesions. He had a bile duct injury which was repaired laparoscopically. Two patients (3.84%) in this group developed significant COVID symptoms in the postoperative period with high grade fever, shortness of breath and drop in oxygen saturation (Figure 5 C). Both were shifted to our COVID suspect intensive care unit (ICU) and were swabbed. RT PCR was reported positive for SARS-CoV-2 and were shifted to COVID ICU. Arterial blood gas (ABG) confirmed respiratory acidosis. The CT scan showed bilateral infiltrates in the lower zone lung fields. They were treated with high flow nasal cannula (HFNC) oxygen, non-invasive ventilation (NIV), hydroxychloroquine (HCQS). Both recovered well over a course of 8 and 12 days respectively. They were shifted to the ward after testing negative by RT-PCR and discharged 24 hours later. On follow up they are doing fine. In the 2nd and 3rd quarter, 82.57% were discharged within 24 hours after surgery and 17.42% discharged later being advanced laparoscopy. In this group no patient developed COVID symptoms postoperatively. During the entire study period, none of our doctors and related HCW (100%) associated with care of these patients developed symptoms of COVID-19. So, we did not test them by RT-PCR as per existing ICMR/GOK guidelines.

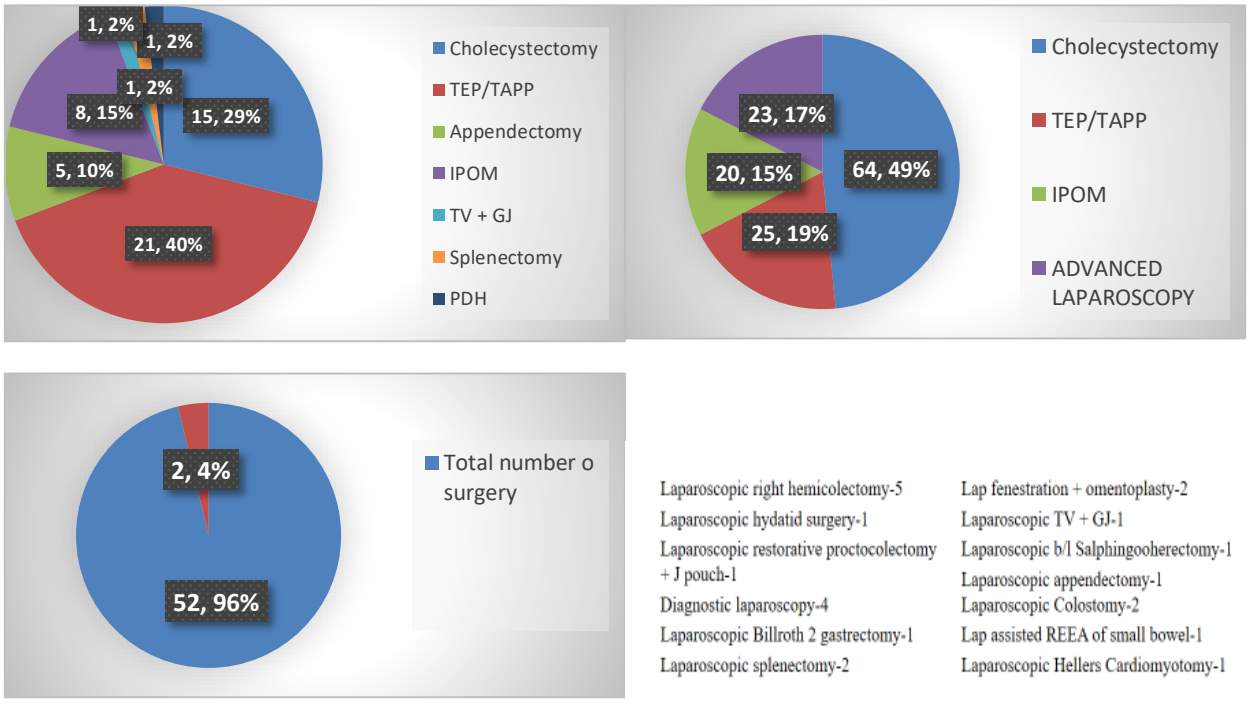

Figure 5: Results from the study. (A) Distribution of laparoscopy surgery from May to July 2020; (B) distribution of laparoscopy surgery from August 2020 to January 2021; (C) pie chart showing the positive patients: May to July 2020; (D) advanced laparoscopy surgery from August 2020 to January 2021.

DISCUSSION

Laparoscopy with its obvious advantages represent the standard of care for most abdominal surgeries. The presence of HBV/HCV/HIV/HPV deoxyribonucleic acid (DNA) in surgical smoke during laparoscopy has been well proven in multiple studies.[1-3] Laparoscopy allows a self-contained operative field, so reduces exposure of HCW. For this reason, in the 1990's during the start of acquired immunodeficiency syndrome epidemic, it was strongly encouraged in patients infected with the HIV.[11,12] Studies have linked surgical smoke to the transmission of HPV (types 6, 11, 13), progressing to oropharyngeal squamous cell carcinoma.[13-16] The recent global pandemic has raised concerns regarding surgical smoke because several molecular studies have shown the presence of SARS COV-2 in peritoneal fluid, faeces, gastrointestinal tract mucosa.[4] Surgical smoke is the iatrogenic aerosol formed due to tissue vaporization while using energy devices. It is released when these devices raise the intracellular temperature to at least 1000° F. It composes 95% water and 5% suspension containing solid particle/liquid/gas, organic pollutants (hydrocarbons, hydrocyanic acid, aldehydes), biological pollutants such as cells, bacteria and fragments of viral DNA. The stagnant heated volume of gas in the abdominal cavity subsequently allows for a concentrated aerosolization of the virus. The aerosols produced during surgery vary in size from 0.1 micron in electro cautery to 6.5 microns in ultrasonic scalpel. Using low temperature ultrasonic devices, may not effectively deactivate the cellular components of a virus. So, the possibility of disease transmission through surgical smoke does exist in humans.[17-20] SARS-CoV-2 enters cells via the angiotensin-converting enzyme 2 (ACE2) receptor, which is widely expressed not only in pulmonary alveolar cells but also on the enterocytes.[21] ACE2 expression is approximately 100-fold higher in the gastrointestinal tract mainly colon than in the respiratory system. In view of this, Royal College of Surgeons in association with the endoscopic surgeons of United Kingdom had stopped all elective colon surgeries. This study presents caution, awareness, innovation and protection of surgical staff. Since we are in a pandemic of a highly contagious virus, it is better to be proactive and exercise safeguard. We had a lot of dilemmas regarding guidelines, performing routine elective surgery, routine testing by RAT/RT PCR during the first quarter of our study. Most patients were discharged early. In the early postoperative period, two patients developed significant COVID symptoms and were treated successfully. However, in the 2nd and 3rd quarter of our study none of the tested patients developed covid symptoms. As we know laparoscopy is an aerosol generating procedure and the HCW were at high risk of contracting the SARS-CoV-2. However, none of our HCW associated with these patients developed covid. This reaffirms the safety of our innovative CCS for routine use during laparoscopy. In laparoscopy, use of devices to filter released CO_2 for aerosolized particles was strongly advised by SAGES and EAES.[22] Currently the most effective smoke evacuation system is the triple-filter system, which includes a prefilter that captures large particles, an ultra-low particulate air filter (ULPA) and a special charcoal that captures the toxic chemicals found in smoke (conmed, air seal, Stryker pneum-oclear).[23] However, they are expensive and not universally available. A third world country like India with a large rural and semi urban population could not afford it. Some of them have incorporated the insufflation, desufflation and pressure monitoring tubing in the same system (ConMed Air Seal) while others have a dual lumen tubing of insufflation with evacuation in the same system (PneumoClear). The disadvantage of using them in the same nozzle is CO_2 recirculation, this may increase the theoretical risk of concentrating the virus further. This is not a limitation in our system. When comparing these various readily available smoke evacuators in the market with our system, it is simple, easy and quick to assemble, disposable after single use, efficient in smoke evacuation too. There are other studies which use only the heat and moisture exchanger (HME/HMEF) filter in the circuit.[24-26] This has been filtering HBV (42 nm) and HCV (30 to 60 nm) with an efficacy of 99.9%. SARS-CoV-2 has a larger diameter of 70 to 90 nm, so we expect a similar or better filtration efficacy. In our study we have used this along with the other components to increase the safety. Some researchers only use sodium hypochlorite a virucidal agent, while others have combined both in the circuit.[27-28] Also, to note, in all these systems CO_2 pneumoperitoneum which is filtered in the circuit is released inside the theatre itself. Though the filters are very efficient, theoretically a small risk still persists of contamination. However, our CCS is unique because from the port to the scavenging system of each operation theatre, it is a totally closed circuit with no CO_2 gas leak. We added a Y connector modification connecting the fit fix system to the CCS to suction peritoneal fluid like blood, bile, enteric content which could be rich in virus.[29] The canister contains a chemical which forms a coagulum as soon it comes in contact with it. This allows the technician to dispose the bio-waste containing the virus into the bin with ease and avoiding contact. Fit fix system can be used safely for multiple cases till the container gets filled as it has a one-way valve. Once the canister is full, the unique technology of "flow stopper" stops aspirating automatically. The entire cost of this circuit is only ₹500. There are a few limitations in this study. It would have been ideal to have tested all patients preoperatively by RT-PCR so as to ensure safety of patients and HCW. But the existing ICMR and GOK guidelines during the first quarter would not permit this. Now preoperative testing is the standard of care in all elective surgical patients. A valid question that could be raised is lack of regular testing of HCW by RT-PCR. This was considered nonessential, if clinical symptoms were absent. Another valid limitation, we did not have separate operating teams for emergency and elective surgeries. It could have been ideal to completely segregate these two subsets of HCW from the safety

point of view. However, HCW taking care of proven positive patients were not involved with routine patient care till they completed their mandatory quarantine period and tested negative before getting back to work.

CONCLUSION

COVID-19 has come to stay, so we have to find ways to ensure safety of patients and HCW. As the contagion with new mutations producing more virulent delta and lambda variants, we cannot exclude the possibility of bio aerosol-based transmission of this deadly disease in laparoscopy. So, this novel indigenous cost-effective CCS is a safe and innovative technique. This has become the standard of care at our institution across all departments where aerosol generating procedures are done. Patients undergoing elective surgery as a prerequisite must be tested negative for COVID-19 by RT-PCR.

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