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Closed circuit system in laparoscopy: SARS-CoV-2 pandemic

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ABSTRACT

Background: There is a big concern regarding transmission of Severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) during laparoscopy and using energy devices through the carbon dioxide (CO₂) pneumoperitoneum. So, we decided to use a novel indigenous innovative closed-circuit system (CCS) to avoid this contamination in operation theatre.

Methods: We set out to do a prospective study in the safety of this innovative closed-circuit system in elective surgeries over 3 consecutive months of May to July 2020, during the peak of SARS-CoV-2 pandemic in a tertiary teaching hospital. We recruited 52 patients undergoing elective laparoscopic surgery in a single laparoscopy unit. The Coronavirus disease 2019 (COVID-19) status was unknown, so we presumed all patients to be potential carriers of SARS-CoV-2. However, we followed the Indian council for medical research (ICMR) and Government of Karnataka (GOK) guidelines of clinical screening before surgery. We observed the postoperative outcome regarding COVID-19 symptoms in Health care workers (HCW) involved in the operation theatre. If required, we do a real time reverse transcription polymerase chain reaction (RT-PCR) to find the true positives.

Results: Of the total 52 (basic and advanced) laparoscopic surgeries performed during this period, only 2 (3.84%) patients turned positive in the postoperative period. They developed COVID-19 symptoms and were tested positive by RT-PCR. None (100%) of the HCW developed any symptoms of COVID-19.

Conclusion: Closed circuit system is a safe and promising technique during laparoscopy.

Keywords: SARS-CoV-2, Laparoscopy, CCS, Pneumoperitoneum, Energy device, COVID-19

INTRODUCTION

The return of the old enemy "Severe acute respiratory syndrome- coronavirus 2 (SARS-CoV-2)" in a more powerful way has hit the world hard (Figure 1). Healthcare system is an epi-centre of this challenge. Many studies have shown the presence of human immunodeficiency virus (HIV), human papillomavirus (HPV), hepatitis B surface antigen (HBsAg) and hepatitis C virus (HCV) in the cautery smoke.¹⁻³ Research has shown the presence of SARS COV-2 in feces, blood, peritoneal fluid and mucosa.⁴ SARS-CoV-2 Ribonucleic acid (RNA) has been found in the feces of infected patients.⁵ So there is a

significant theoretical risk of generating aerosol contaminated SARS-CoV-2 while using energy source (Harmonic>>>ligasure>>cautery>standard), so in the Carbon dioxide (CO₂) venting in laparoscopy. Laparoscopy/minimal access surgery (MAS) is the preferred method for most abdominal surgeries for obvious benefits. Healthcare workers (HCW) on the frontline in Operation theatre (OT) are at great risk. Many countries around the world had stopped elective operations as laparoscopy being an aerosol generating procedure (AGP) was a big concern. We in India too followed a similar path, but we had a worry of "safety versus economy".

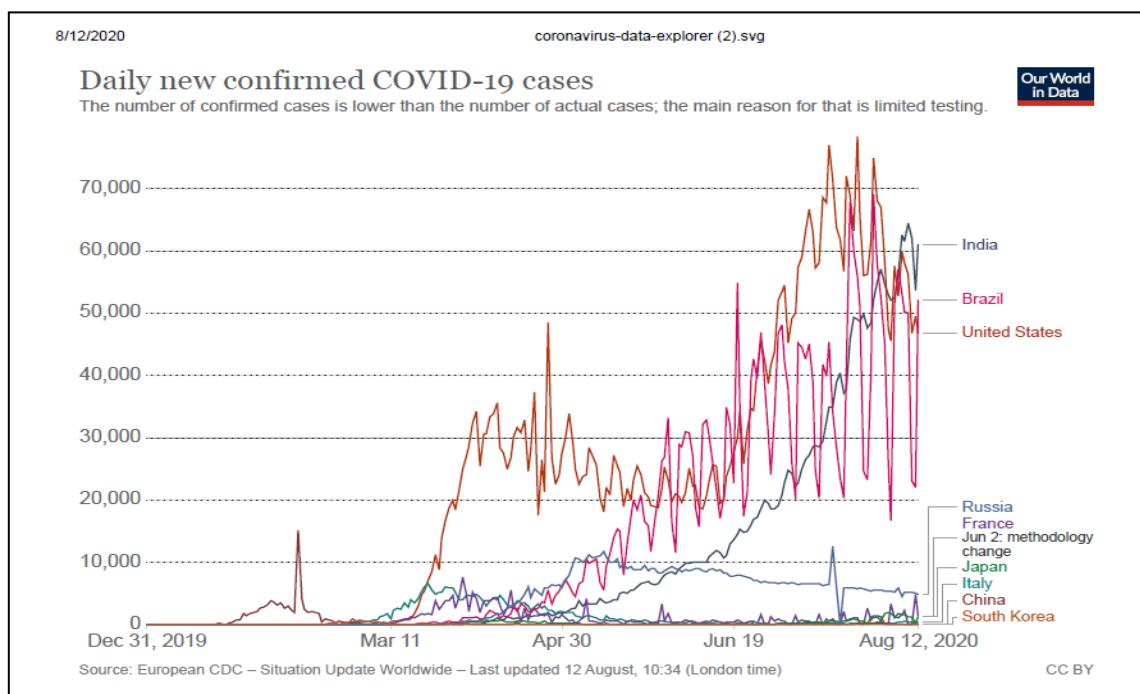


Figure 1: Daily confirmed cases around the world.

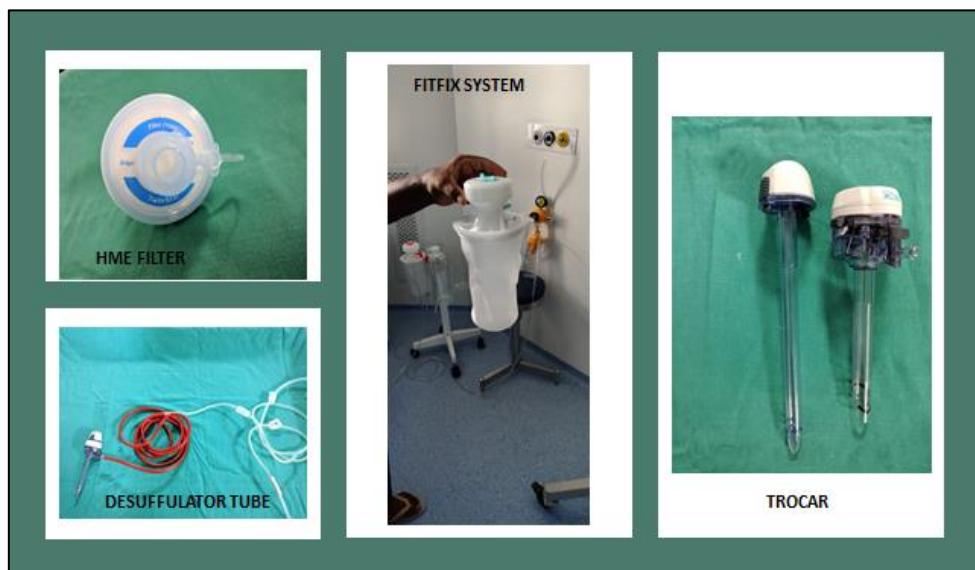


Figure 2: Various components of the closed-circuit system.

Source: operation theatre of SJNAHS.

Elective surgeries should be commenced once Coronavirus disease 2019 (COVID-19) curve shows a continuous decline for 15 days. The Association of Surgeons of India (ASI) consensus guidelines, suggested this.⁶ But is this practical? These challenges invited me to create a novel, safe, cost effective (<₹ 500) system using standard available materials in the operating theatre to release CO₂. In an Indian perspective where testing all is far from reality. Also, the concerns of false negatives of rapid antigen (Ag) test (₹ 800) and the Government of Karnataka/Indian council of medical research (GOK/ICMR) guidelines prevented us from routine real

time-polymerase chain reaction (RT-PCR) testing (₹ 4500) in the early part of the pandemic. Following Standard operating procedure (SOP) like using N95 mask, Personal protective equipment (PPE) and Viser may not be practical in smaller centres in a third world country. The non-availability of routine negative pressure or High efficiency particulate air (HEPA) filters in OT is also worrying. Considering these various factors we had to find a safe, cost effective and novel system which suits our need. So, the Closed-circuit system (CCS) is the promising future and the new normal in laparoscopy.

METHODS

This was a prospective randomized study conducted for 3 months dating May to July 2020 during the peak of the SARS-CoV-2 pandemic. It was conducted in the department of general surgery at St. John's Medical college and hospital, Bengaluru, India. We recruited a sample size of 52 patients. All patients undergoing elective laparoscopic surgery (basic and advanced) from a single unit were included in this study. It involved both sexes randomly. The aim of this research is to study the safety of HCW using the new innovative closed-circuit pneumoperitoneum system in laparoscopic surgery during the current global pandemic of SARS COV-2. Patients in whom laparoscopy is contraindicated was excluded from this study. The COVID status was unknown (not tested by RAT or RT PCR), so we presumed all patients to be potential carriers of SARS-CoV-2. However, we followed the ICMR and GOK guidelines of clinical screening before surgery. A informed written consent was taken after explaining the procedure.

The laparoscopy procedure itself involved three surgeons with different experience. The standard technique was used to create pneumoperitoneum by Hasson or Veeres needle. The pneumoperitoneum is created to the desired pressure (low versus standard i.e., 12 versus 15 mmHg). To keep the insufflation pressures low, the anesthetist will give deep muscle relaxation. The ports are placed as per standard technique and their numbers varied based on the type of surgery. For this study we always used corrugated

disposable plastic trochars (Figure 2), the corrugation ensures the trochars fit snug and leakage is less.

Now setup the simple innovative closed circuit (Figure 3) system before starting surgery. The suction pressure on the de-sufflation tube can be adjusted with the pressure gauge in the circuit (Figure 4). This is kept low to avoid bowel injury during de-sufflation at the end of surgery.

We strongly advise minimal use of energy source to avoid aerosol generation. Use the maximum or cutting mode on the foot peddle wherever possible. Exchange instruments minimally, this mitigates gas leak during exchange of instruments. At the end of operation ensure decompression of gas fully before specimen retrieval. This is done through the port over the liver or direct the port against the anterior abdominal wall. This ensures we don't accidentally damage bowel which could be sucked through the deflation port. From the fit-fix system it is connected to the wall mounted scavenging system in each OT which is a one way exhaust system which is vented to the atmosphere (25 cycles/hour). We also added a small modification to this system, a Y connector (figure 4) for sucking out fluid during laparoscopy into the fit-fix system. This contains a chemical which form a coagulum as soon it comes in contact with peritoneal fluid like blood, bile, enteric content. This allows the technician to dispose the biowaste containing the virus into the bin with ease and avoiding contact. Figure 5 shows live setup seen during a laparoscopic Transabdominal preperitoneal (TAPP) hernia surgery in the OT.

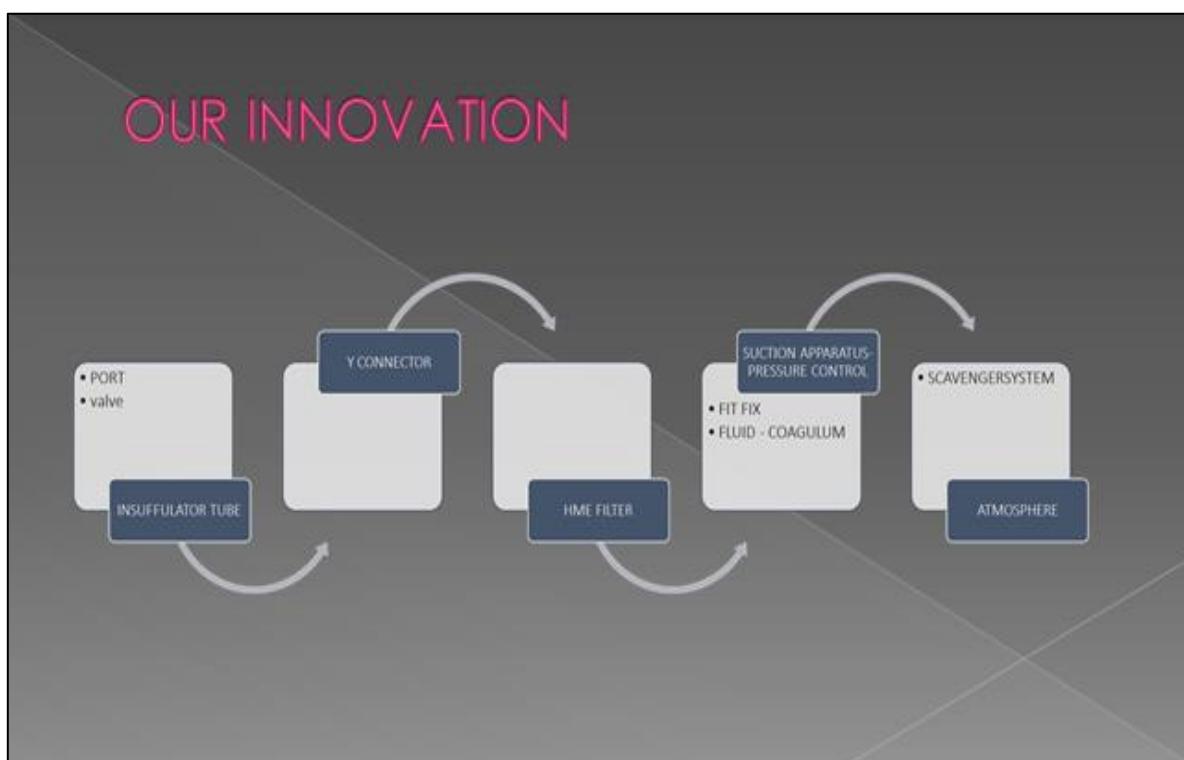


Figure 3: Line diagram of the closed-circuit system.

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 bar diagram and 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 4: CCS connected to the scavenging system on the wall through the fit-fix seal.

Source: operation theatre of SJNAHS.

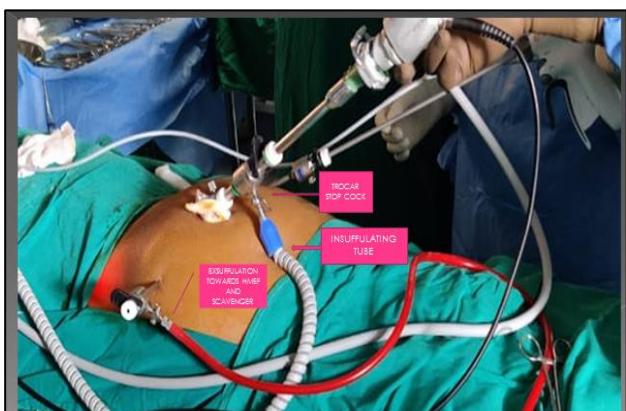


Figure 5: Live setup seen during a TAPP hernia repair.

Source: operation theatre of SJNAHS.

RESULTS

The age of patients involved in the study ranged from 17 to 55 years with the mean age being 42 years. The male to female distribution was unevenly distributed with a male predominance. During these 3 months period we did a total of 52 laparoscopic surgeries using this novel innovative closed-circuit system involving basic and advanced laparoscopy. The type of surgeries and their number is shown in the pie chart below (Figure 6).

We also show the break up of laparoscopic surgeries and their numbers during the heights of the pandemic in India of individual months of May, June and July (Figure 7). It was during this period, the Government of India (GOI),

GOK and ICMR had a lot of dilemmas regarding guidelines, to allow elective surgery, routine testing by RAT/RT PCR. This was also associated with paucity of available kits.

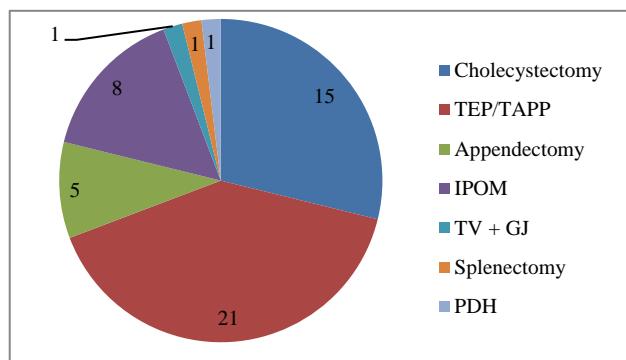


Figure 6: Distribution of laparoscopy surgery from May to July 2020.

All patients were inpatients, admitted 24 hours prior to surgery. Most (92.3%) were discharged within 24 hours following surgery except 4 (7.69%) who underwent advanced laparoscopic surgery. None were treated on a day care basis. Of the delayed discharged patients, one (1.92%) patient who underwent laparoscopic cholecystectomy had a difficult laparoscopy due to adhesions, he had a CBD injury which was repaired laparoscopically. Two patients developed significant COVID symptoms in the postoperative period with high grade fever, shortness of breath. There was significant drop in oxygen saturation to 75% in one patient who underwent laparoscopic TAPP and another patient who underwent laparoscopic appendectomy to 68%. Both were shifted to our COVID-19 suspect Intensive care unit (ICU) and they were swabbed by nasal and nasopharyngeal swab. Twelve hours later the RT PCR was reported as positive for SARS-CoV-2 and the patients were shifted to the COVID-19 ICU. Arterial blood gas (ABG) did confirm respiratory acidosis. Their chest X-ray showed bilateral infiltrates of their lower zone lung fields. They were treated with High flow nasal canula (HFNC) oxygen, Non-invasive ventilation (NIV), Hydroxychloroquine (HCQS). Both recovered well after a protracted course of 8 and 12 days respectively in ICU.

They were shifted to the ward after testing negative by RT-PCR in ICU, then discharged 24 hours later from hospital. On follow up there are doing fine. The pie chart below shows the details of this (Figure 8).

None of our doctors and related HCW associated with these patients during this period developed symptoms of COVID-19. As per the procedure performed we were at high risk for exposures to SARS-CoV-2 virus i.e., laparoscopy (AGP). As per ICMR/GOK guidelines we did not test our medical personnel involved in these 2 cases for COVID-19 by RT-PCR/Rapid Ag, because none of them developed any COVID-19 related symptoms.

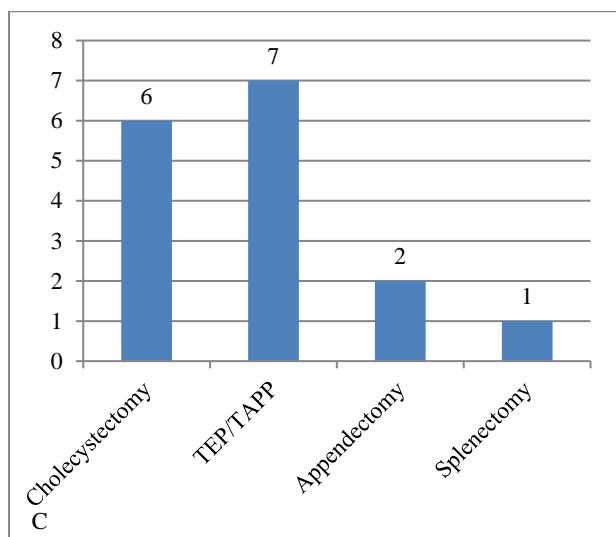
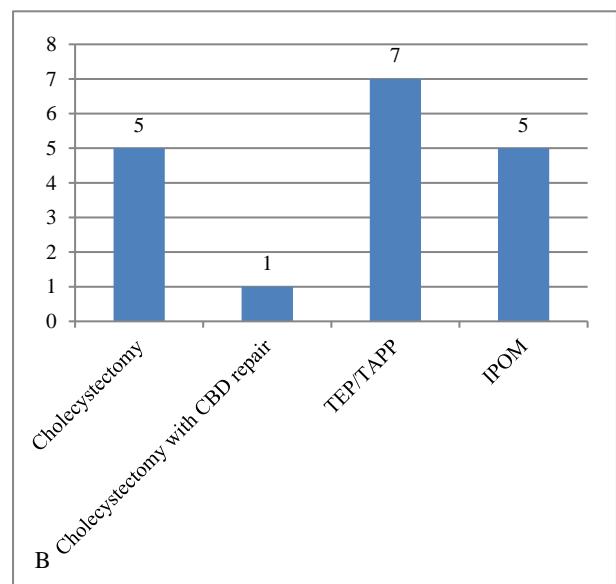
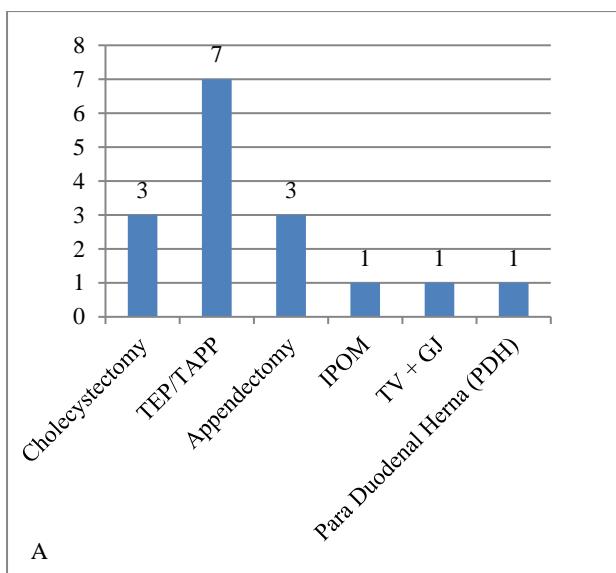


Figure 7: Distribution of laparoscopy surgery in (A) May 2020, (B) June 2020, (C) July 2020.

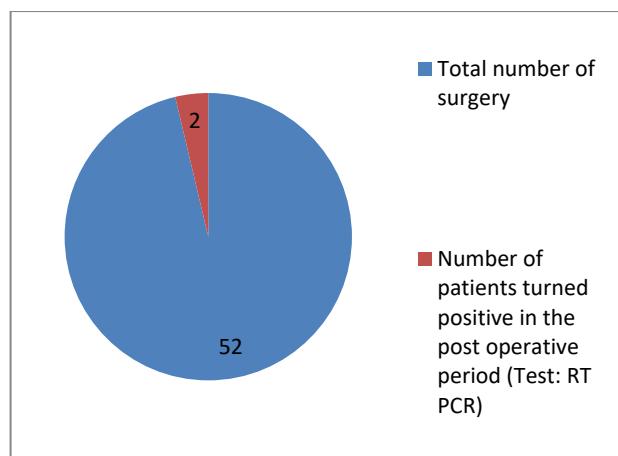


Figure 8: Positive patients.

DISCUSSION

Laparoscopy is a bane or a boon during this SARS-CoV-2 pandemic! Minimally invasive surgery or laparoscopy represent the standard of care for most abdominal surgeries because of the proven and obvious benefits. Laparoscopy during this pandemic will decrease the length of stay as compared with open surgery. This will increase the availability of beds which is a limited resource. Laparoscopy is less traumatic compared with a laparotomy so if a patient is infected with COVID-19, a minimally invasive surgery with reduced hospital stay and faster recovery will help the limited resources during this pandemic. Laparoscopy allows for a self-contained operative field so reduces exposure of HCW. For this reason, in the 1990s during the start of acquired immunodeficiency syndrome (AIDS) epidemic, laparoscopic surgery was strongly encouraged over open surgery in patients infected with the HIV.^{7,8}

In 1996, Coetoeus et al showed the presence of breathable aerosols and cell size fragments in the cautery smoke during laparoscopy. The presence of Hepatitis B virus (HBV)/HCV/HIV/HPV Deoxyribonucleic acid (DNA) in surgical smoke has been well proven in multiple studies.¹⁻³ HPV transmission during anogenital surgery is most widely reported in the literature. Liu et al outlined four articles linking surgical smoke to the transmission of HPV (type 6,11,13), progressing to oropharyngeal squamous cell carcinoma.⁹⁻¹² These cases occurred in otherwise fit healthcare professionals performing gynaecological surgery with no other risk factors for the disease. The HPV genotypes in the infected healthcare professional were identical to those identified in the patient.¹³ Ilmarinen et al found that one in five surgeons, and three in five nurses, tested positive for HPV after performing operations for laryngeal and urethral papillomas. The HPV genotypes in the infected healthcare professional were identical to those identified in the patient.¹⁴ Baggish et al captured HIV proviral DNA in the inner lumen of smoke evacuation tubing after in vitro laser vaporization of cultured HIV cells.¹⁵ Kwak et al. further revealed that HBV was present

in surgical smoke. HBV was detected in 10 of the 11 samples of surgical smoke in their study. This may suggest that bloodborne viruses may be present within surgical smoke. The recent global pandemic has also raised concerns regarding surgical smoke (CO₂) because several molecular studies have shown the presence of SARS COV-2 in stool (29%), peritoneal fluid, feces (15%), Gastrointestinal tract (GIT) mucosa.⁴ Surgical smoke is the iatrogenic aerosol formed as a result of tissue vaporization during usage of energy sources like cautery, harmonic scalpel or ligasure. It is released when energy generating device raise the intracellular temperature to at least 100 degrees. Composed of 95% of water and 5% of a suspension containing solid particle or liquid or gas, organic pollutants (hydrocarbons, hydrocyanic acid, aldehydes), biological pollutants such as cells (some cancerous), bacteria and fragments of viral DNA. The stagnant heated volume of gas in the abdominal cavity which may subsequently allow for a concentrated aerosolization of the virus. The aerosol produced during surgery particularly when 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, but documented cases are rare.¹⁶⁻¹⁸ SARS-CoV-2 was detected in peritoneal fluid at a higher concentration than in respiratory tract.⁵ Viral isolation, which would have provided stronger evidence of infectivity, could not be performed. This present paper represents a warning for increasing the level of awareness and protection for surgical staff especially in emergency surgery situations even in the absence of intestinal perforation or ischemia.⁵ Since we are in a pandemic of a highly contagious virus, it is better to be proactive and exercise safeguards.

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 in the enterocytes of the intestinal mucosa.¹⁹ ACE2 expression is approximately 100-fold higher in the gastrointestinal tract (mainly colon) than in the respiratory system. To highlight this point, let me quote a relevant fact, The Royal College of Surgeons in association with the endoscopic surgeons of United Kingdom had stopped all elective colon surgeries during the pandemic.

The Association of surgeons (ASI) in its consensus guidelines published in international journal of surgery (IJS), June edition had advised elective surgeries should be commenced once COVID-19 curve shows a continuous decline for 15 days.⁶ In a country like India, is this possible? We have to balance economy with safety. This raised a question in my mind of how to innovate a cost effective but safe system so as to continue operating during this pandemic. Why? Because SARS-CoV-2 has come to stay and it doesn't seem to go away very soon. So during

the month April 2020 when the entire country went into lockdown, we researched to find this novel closed circuit system.

Aerosols are generated while using various energy source devices. The table below shows the harmonic scalpel produces smoke containing bigger size particles and this could be detrimental to health care workers during venting of CO₂ in laparoscopy.²⁰

Device	Plume
Electrocautery	< 0.1 microns
Laser ablation	0.3 microns
Ultrasonic scalpel	0.35–6.5 microns

Figure 9: Relative size of surgical smoke.

Though our study was mainly concerned with abdominal elective laparoscopic cases, a note on the various other manifestation of COVID-19 with or without respiratory symptoms should be noted. COVID-19 can present with abdominal pain with or without respiratory symptoms. SARS-CoV-2 infection could lead to an acute abdomen-like presentation in the absence of identifiable surgical causes. To highlight this view, the flow chart shows the various presentations of acute abdomen (Figure 10). So, we have to exercise caution when evaluating an acute abdomen in ER. So, if we offer laparoscopy in emergency, the same precautions should be taken as elective surgeries.

For MIS procedures, use of devices to filter released CO₂ for aerosolized particles should be strongly considered was advised by SAGES and EAES.²¹ Currently the most effective smoke evacuation system is the triple-filter system, which includes a prefilter that captures large particles, a Ultra low particulate air (ULPA) filter, and a special charcoal that captures the toxic chemicals found in smoke. Readily available ultrafiltration device like the CONMED airseal (figure 11), Stryker pneumoclear insufflator are in the market. However, they are expensive and not universally available.

Considering these various factors we had to find a safe, cost effective and novel system which suits our need. So the CCS was devised with the existing materials in the operation theatre as the promising future and the new normal in laparoscopy. With this we went ahead with elective laparoscopy cases during the months of May to July, 2020 when the pandemic was at its peak in the Indian subcontinent.

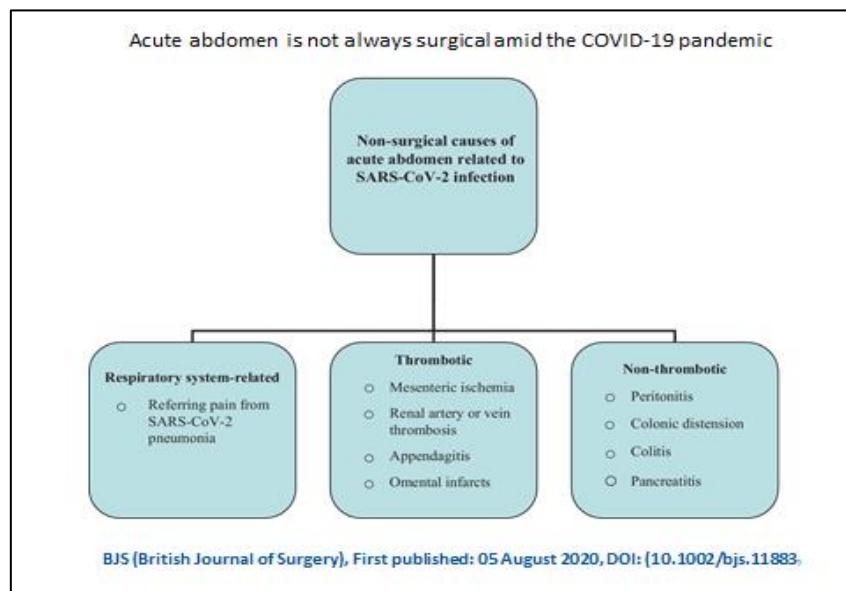


Figure 10: Non-surgical causes of acute abdomen.



Figure 11: CONMED airseal: a ultrafiltration device.

Source: Copyright 2020 CONMED Corporation.

We recruited 52 cases during this period of both basic and advanced laparoscopy. We had a lot of dilemmas regarding guidelines, to allow elective surgery, routine testing by RAT/RT-PCR. This was also associated with paucity of available kits. In our series 92.3% were discharged within 24 hours following surgery except 7.69% who underwent advanced laparoscopic surgery. Two patients i.e., 3.8% developed significant COVID-19 symptoms in the postoperative period with high grade fever, shortness of breath. There was significant drop in oxygen saturation, so they were shifted to ICU for further care. Twelve hours later their RT-PCR was reported as positive for SARS-CoV-2. The blood gases showed respiratory acidosis and their chest X ray show bilateral infiltrates in the lower zone lung fields. They were treated with High flow nasal canula (HFNC) oxygen, NIV,

HCQS. Both recovered well after a protracted course of 8 and 12 days respectively in ICU. They were shifted to the ward after testing negative by RT-PCR in ICU, then discharged. Both recovered well without much sequelae. On follow up they are doing fine. The doctors and related HCW associated with these patients during this period did not have any COVID-19 symptoms. As we know laparoscopy is a aerosol generating procedure and the health care workers involved were at high risk for contracting the SARS-CoV-2. As per ICMR/GOK guidelines, as none of them developed symptoms, we did not test them for COVID-19 by RT-PCR or RAT. This reaffirms the safety of our innovative closed-circuit system for routine use during laparoscopy. As a modification we also added a Y connector tubing for sucking out peritoneal fluid which as we know is also rich in the contagion virus.

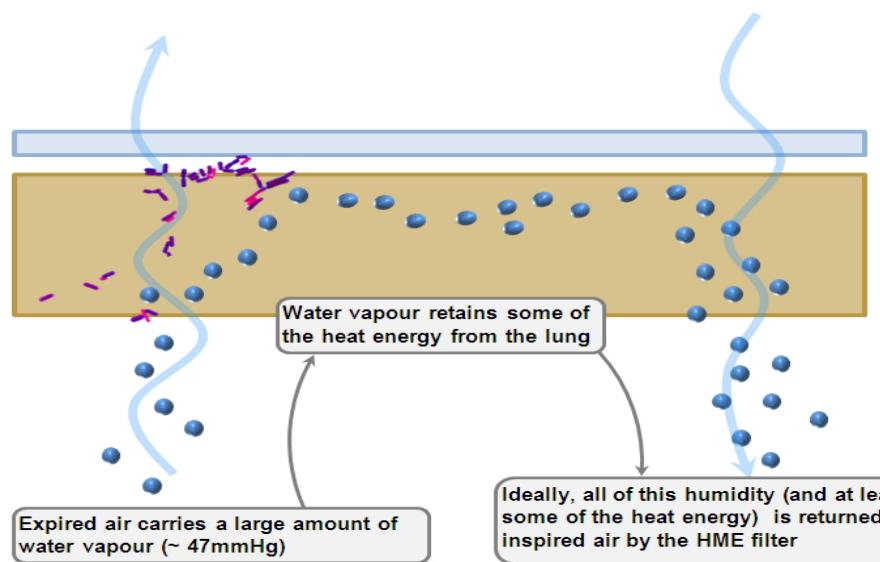


Figure 12: Mechanism of action of HME or HMEF filter.

Along with the new closed-circuit system, we also had to change or reemphasize a few concepts of performing laparoscopy as the new normal during this pandemic. Keep a low pressure for pneumoperitoneum, so the chimney effect of leakage is minimized. Exchange of instruments should be minimal so the sudden bursts of pneumoperitoneum from trocar valves is minimized. To ensure utmost care is taken to evacuate pneumoperitoneum completely before retrieval of specimen. While doing so to avoid bowel injury during closed circuit suction, keep trocar away from bowel over liver or under the parity.

There are a few studies which have used only the Heat and moisture exchanger (HME/HMEF) filter in their circuit.²²⁻²³ A small note on how these filters work, a countercurrent mechanism (Figure 12). HMEF filter, also known as Swedish nose is a light weight disposable device used with mechanical ventilator. This has been filtering HBV (42 nm) and HCV (30 to 60 nm) very well with efficacy of 99.9%.²⁴ SARS COV-2 has a larger diameter of 70 to 90 nm, so we expect a similar or better filtration efficacy. Also, the cost of it varies from ₹ 90 to ₹ 160 in the Indian market, quite cheap. Our system is unique compared to this and others because from the site of the port to the scavenging system of each operation theatre, it is totally a closed circuit with no CO₂ gas leak.

Also, the Y connector modification which we added to this closed circuit system to suction peritoneal fluid is readily available in the market. This too is cost effective at ₹ 600 to ₹ 900 in the Indian market and this can be used for multiple cases till the container gets filled. It is safe to use for multiple cases because it has a one-way valve (Non-return valve (NRV)). This fit-fix system has a canister which contains a chemical and forms a coagulum when it comes in contact with blood, bile or enteric content.²⁵ Once the canister is full the unique technology of "flow stopper"

stops aspirating automatically. This then can be easily disposed without any contact by the OT personnel.

There are a few limitations in this study. It would have been ideal to have preoperatively tested all patients for COVID-19 by RT-PCR so as to ensure safety of patients and HCW. But the existing guidelines in the early part of the pandemic in India through ICMR and GOK did not permit us to do routine testing. We strictly followed the clinical guidelines set by the same agencies then to ensure safety. However now routine testing is a must in all elective patients before surgery. Also, a point in question that could be raised is regular testing of the HCW for COVID-19 involved in the study, which was not done. This was considered not required if clinical symptoms of COVID-19 were absent. We would consider this as a valued limitation because, some HCW involved here were working in all wards except COVID-19 including attending emergencies. During emergency surgery of COVID-19 suspect patients, the entire team operated wearing the full PPE kit. We did not have a separate emergency and elective operating team for this. As is obvious, this is not practical. We were already short staffed during the peak of this pandemic. Even now we don't have separate teams for this. Ideally it may help to completely isolate these two subset of HCW from the safety point of view. However, we would like to add, HCW involved in the care of proven positive COVID-19 patients were not part of this study.

CONCLUSION

COVID-19 crisis is redesigning the world, we as surgeons are to discover new roads to keep our journey on. As the new contagion will live longer, we cannot exclude the possibility of bioaerosol based transmission of this deadly disease in laparoscopy (AGP). So this novel innovative indigenous cost effective CCS is a safe and promising

technique during elective laparoscopy surgeries till we have definite answers of safety to all aerosol generating procedures.

Recommendations

With this prospective study in a tertiary care hospital doing a good number of basic and advanced elective laparoscopic surgeries routinely and during this SARS-CoV-2 pandemic, our recommendations for safety of HCW are as follows: closed circuit system (CCS) is a must, fix HME or HMEF filters to the Co2 desuffulation tube, deep muscle blockade to lower pressure, avoid frequent change of instruments, minimal use of energy devices, using a simple Y connector in the closed circuit to the FitFix system will suck peritoneal fluid. This is a added benefit because it avoids contamination, deflate fully after finishing the procedure and before specimen retrieval, use a appropriate one way suction scavenging system in theatre, use of standard PPE/N95/Viser irrespective of the COVID-19 status, to screen all surgery patients by RAT/RT PCR is ideal (GOK/ICMR is accepting now) and if positive and the elective surgery is not life threatening to postpone. However, if it is emergent or semi-urgent to discuss with patient and make a informed decision. We make this statement though we have proved the safety of CCS during laparoscopy.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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