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Original Research Article

Comparison of clinical safety of minimal access surgery/laparoscopy versus open surgery in terms of patient outcomes and risk to theatre staff during the COVID-19 pandemic

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ABSTRACT

Background: The COVID-19 pandemic has greatly affected surgical practice in all parts of the world because the safety of minimal access surgery (MAS) was questioned during the COVID-19 pandemic due to increased concern with regard to disease spread. This study assessed the available evidence on the safety of laparoscopy as compared to open surgery during the COVID-19, explored the possible precautions to be taken to prevent exposure of the operating team to the viral infection. The objective of this study was to access the clinical safety of laparoscopy as compared to open surgery during the COVID-19 pandemic.
Methods: This study was a retrospective study conducted during the COVID-19 pandemic in the Department of Surgery, GMC, India, from January 2020 to January 2021. The various outcomes assessed included: burden of covid-19 infection among the patients, deaths due to COVID-19, infection acquired by staff, length of hospital stay and post-discharge symptomatology among patients.
Results: There was no statistically significant difference in terms of median age of patients (p=0.853), gender (p=0.835), American Society of Anesthesiologists (ASA) status (p=0.876), urgency of operation (p=0.074), total time in theatre complex (p=0.163) or total number of theatre staff involved (p=0.831). The length of stay in the hospital was significantly shorter in the laparoscopic as compared the open group (3.5 versus 9 days; p=0.011).
Conclusions: Based on our review, we concluded that if recommended guidelines are followed and proper precautions are taken, laparoscopic surgery is safe for patients and theatre staff during the COVID-19 pandemic. Only on the basis of COVID-19, laparoscopy should not be replaced by laparotomy. If laparoscopy is strongly indicated in patients, it can be used with precautions because of its benefits over open surgery.

Keywords: Aerosols, American Society of Anesthesiologists, COVID-19 pandemic, Open surgery, Minimal access surgery

INTRODUCTION

Minimal access surgery (laparoscopic surgery) is nowadays an established procedure for a number of elective and emergency gastrointestinal (GI) operations. The advantages of minimal access surgery over open surgery are well established and include less incidence of wound infection, faster recovery of bowel function, a shorter duration of hospital stay and earlier restoration of normal activity. But minimal access surgery is associated with longer operative times and that too depends on the expertise of operating surgeon.[1]

In the light of the current COVID-19 pandemic, the initial cautionary surgical guidance was to avoid minimal access surgery (laparoscopic surgery) due to the potential risk of

aerosol generation with pneumoperitoneum leading to spread of virus and risk to the operating team, OT staff and patients.[2]

The evidence for risk of transmission of COVID-19 infection to staff as a result of minimal access surgery (laparoscopy) is still not established. This was impressed upon in a statement from the Association of Laparoscopic Surgeons of Great Britain and Ireland (ALSGBI). Moreover, the clinical safety of patients undergoing laparoscopic GI surgery during the pandemic remain undefined and has not been properly established till now.[3]

Aims and objectives

The aim of the study was to evaluate the clinical safety of minimal access surgery (laparoscopic) as compared to open surgery in terms of patient outcomes and risk to theatre staff during the COVID-19 pandemic.

METHODS

This study was a retrospective study conducted during the COVID-19 pandemic in the department of surgery, Government Medical College and hospital, Jammu, India, from January 2020 to January 2021. A sample size of 80 patients was included in this study.

Inclusion criteria

The inclusion criteria included patients with pre-operative COVID-19 RT-PCR negative results who were to undergo either emergency or elective gastrointestinal surgery.

The data of all the patients including demography, any comorbidity, perioperative and survival data were collected from medical records and supplemented with patient symptoms in the postoperative period which were reported at telephone follow up. An informed written consent was taken from all the patients before surgery. Patients were divided into two groups: the minimal access surgery group (laparoscopic) and open surgery group for comparison. The various outcomes which were assessed included: burden of COVID-19 infection among the patients, deaths due to COVID-19 (patient mortality), infection acquired by staff, length of hospital stay and post-discharge symptomatology among patients.

Exclusion criteria

The exclusion criteria included patients undergoing vascular, urological, obstetric and gynecological surgeries.

The list of theatre staff members developing COVID-19 symptoms within 14 days of surgery was collected from theatre in-charge office. Staff members included were surgeons, anesthetists and paramedical staff members including nurses and support workers). If a staff member was sick and developed COVID-19 related symptoms and was involved in both open and laparoscopic surgeries, the sickness was assigned to the laparoscopic case. The follow up of the patients was done by telephonic consultation after they were discharged from the hospital.

RESULTS

A total of 490 procedures were performed at Government Medical College, Jammu, India including 400 general surgery cases, out of which 110 were elective and 290 were emergency cases. A total of 100 cases were diagnosed as COVID-19 positive cases by reverse transcription polymerase chain reaction (RT-PCR).

Preoperative and intraoperative data

The median age at the time of operation was 50 years (range: 8-80 years) and 35 patients (43.75%) were female. The indications, urgency and approaches to operations performed are presented in Table 1.

Out of 80 patients, 22 (27.5%) patients underwent elective operations and 58 (72.5%) patients underwent emergency operations. The laparoscopic group consisted of 26 (32.5%) patients and open surgery group consisted of 54 (67.5%) patients. Two laparoscopic cases were converted to open surgery (conversion rate was 2out of 26; 7.69%). The median number of theatre staff involved was 5 (4-10).

Preoperative RT-PCR tests for SARS-CoV-2 were performed in all the patients, and all of them were negative. All patients underwent a preoperative chest radiograph, 2 chest radiograph (2.5%) findings had indeterminate results for COVID-19, and rest of the results were deemed negative. A total of 31 (38.75%) patients underwent preoperative computed tomography (CT) thorax, out of which 1 (1%) was indeterminate result and 29 (36.25%) patients had negative results. Therefore, there were no preoperative diagnosed cases of COVID-19 infection.

On comparison of minimal access surgery (laparoscopic cases) vs open surgery cases, it was concluded that there was no statistically significant difference in terms of median age of patients (p=0.853), gender (p=0.835), American Society of Anesthesiologists (ASA) status (p=0.876), urgency of operation (p=0.074), total time in theatre complex (p=0.163) or total number of theatre staff involved (p=0.831). Table 2 represents a detailed comparison of minimal access surgery cases (laparoscopic) and open cases during the intraoperative and post-operative period.

Table 1: Indications, type of surgery, approach and total number of patients.

Indications	Elective/emergency n (%)	Laparoscopic/open N (%)	Total* N (%)
Cancer	15 (50)/15 (50)	10 (33.3)/20 (66.6)	30 (37.5)
Acute appendicitis	3(10.7)/23 (92)	10 (35.7)/16 (61.5)	26 (32.5)
Small bowel obstruction	1 (10)/9 (90)	3 (30)/7(70)	10 (12.5)
GI perforation	0/8 (100)	2 (25)/6 (75)	8 (10)
Restoration of GI continuity	2 (100)/0	0/2 (100)	2 (2.5)
Diverticular disease	0/1 (100)	0/1 (100)	1 (1.25)
Large bowel obstruction	0/2 (100)	0/2 (100)	2 (2.5)
Abdominopelvic abscess	1 (100)/0	1 (100)/0	1 (1.25)
Total*	22 (27.5)/58 (72.5)	26 (32.5)/54 (67.5)	80 (100)

GI = Gastrointestinal; *Percentages with respect to total cohort (n=80)

Table 2: Comparison of laparoscopic and open surgery cases during the intraoperative and post-operative period.

Variables	Laparoscopic (n=26) (%)	Open (n=54) (%)	P value*
Median age at time of surgery (in years)	50.0	53.5	0.853
Gender (male/female)	18/8 (69.2/30.8)	30/24 (55.5/44.5)	0.835
Comorbidity			
Hypertension	8 (30.7)	14 (25.9)	0.845
Ischaemic heart disease	1 (3.8)	2 (3.7)	0.013
Chronic heart failure	1 (3.8)	0	0.565
Cerebrovascular disease	0	3 (5.5)	0.012
Diabetes mellitus	4 (15.3)	4 (12.9)	0.051
Chronic kidney disease (CKD)	0	3(5.55)	0.185
Cancer	10 (38.4)	20 (37)	0.143
COPD	1 (3.8)	0	0.586
Bronchial asthma	3 (11.5)	6 (11.1)	0.045
Chronic smoker	2 (7.7)	7 (12.9)	0.645
ASA physical status			
I	6 (23)	15 (28)	0.764
II	8 (30.7)	18 (33.3)	
III	4 (15)	12 (22)	
IV	2 (8)	6 (11)	
Indications for surgery			
Benign disease	19 (73)	40 (74)	0.031
Malignant disease	7 (27)	14 (26)	
Urgency			
Elective	8 (30.7)	20 (37)	0.063
Emergency	18 (69.3)	34 (63)	
Median time in theatre complex	285 min	350 min	0.163
Median number of theatre staff involved	5	6	0.831

ASA = American Society of Anaesthesiologists; COPD: chronic obstructive pulmonary disease
*Mann-Whitney test for quantitative and ordinal data, Pearson chi-square test for categorical data

Table 3: Various variable outcomes in laparoscopic and open surgery group.

Variables	Laparoscopic (n=26)	Open (n=54)	P value*
Mortality	0	5 (9.25%)	<0.001
Number of staff infected (<2 weeks)			
Surgeons	2	2	0.321
Anaesthetist	0	1	0.354
Paramedical staff	6	4	0.643
Total staff members	8	7	0.331
Postoperative COVID-19	0	10 (18.5%)	<0.001

Continued.

Variables	Laparoscopic (n=26)	Open (n=54)	P value*
Median length of stay in days	3.5	9	0.011

*Mann-Whitney test for quantitative and ordinal data, Pearson chi-square test for categorical data

The postoperative follow-up of the patients was done over a period of 6 weeks (42 days). There was a total of five mortalities (6.25%). All five patients were above the age of 50, and had undergone an emergency open procedure for benign disease. These patients were postoperatively diagnosed with COVID-19 infection. However, no mortality was noticed in the laparoscopic group.

A total of 15 staff members including four surgeons, one anesthetist and ten para-medical staff members developed COVID-19 symptoms within 2 weeks of surgery. If we compare the incidence of COVID-19 infection among staff members we found that there was no statistically significant difference between the minimal access surgery group (laparoscopic) and open groups with respect to total numbers of staff members infected overall (8 versus 7; p=0.31), among surgeons (2 versus 2; p=0.356), among anesthetists (1 in open group) or among paramedical staff (6 versus 4; p=0.570).

On postoperative follow-up, 15 patients (18.75%) underwent a SARS-CoV-2 RT-PCR test. A total of seven cases (8.7%) were found positive for COVID-19. Out of 20 patients (25%) who underwent a postoperative chest radiograph, 5 (6%) cases were found to have indeterminate results and 15 (19%) patients had negative chest radiograph results. A postoperative CT thorax was advised in 10 (12.5%) patients out of which 4 had positive results (5%), 3 patients had indeterminate results (3.75%), and 3 patients had negative results (3.75%). On the basis of a positive result in either RT-PCR tests for SARS-CoV-2, chest radiograph or CT thorax, 10 patients (12.5%) were diagnosed postoperatively with COVID-19 infection. All patients who developed COVID-19 infection in the postoperative period belonged to the open surgery group.

The median length of stay in the hospital stay (Table 3) was 4.0 days and was significantly shorter in the laparoscopic as compared the open group (3.5 versus 9 days; p=0.011).

Out of a total of 80 patients, follow-up of 70 (81%) patients was done by telephonic consultation, 2 (1%) patients refused to participate in follow up, 6 (10%) patients could not be contacted and 2 patients were still in hospital (3%). Among the 70 patients who were followed up, if we compare minimal access surgery (laparoscopic) vs open surgery (24 versus 46 patients), we found that there was no significant difference in the prevalence of abdominal pain (10 versus 22; 38.4% versus 40.7%), dyspepsia (11 versus 24; 42.5% versus 44.4%), diarrhea (4 versus 9; 15.3% versus 16.6%), fever (5 versus 8; 19.2% versus 46.2%), dyspnea (1 versus 5; 3.8% versus 9.2%), ageusia (3 versus 7; 11.5% versus 12.9%), cough (2 versus 4; 7.6% versus 7.40), headache (2 versus 5; 7.6% versus 9.2%), pharyngitis (1 versus 3;3.8 versus 5.5%), arthralgia (2 versus 4; 7.6% versus 7.4), myalgia (3 versus 7; 11.5% versus 12.9), anosmia (2 versus 5; 7.6% versus 9.2%).

DISCUSSION

The current COVID-19 pandemic has drastically changed our clinical practice. Starting from the onset of the pandemic, various guidelines have been published but they are limited due to lack of clinical evidence. Since it is a continuously evolving situation, therefore establishing clinical evidence remains a challenge. In our study, we have addressed some of the concerns regarding minimal access surgery as compared to open surgery in view of COVID-19 pandemic. On comparison we found that minimal access surgery (laparoscopic surgery) is associated with a shorter duration of hospital stay, lower postoperative COVID-19 infection rates, and a lower mortality rate as compared with open surgery. It can thus be concluded that by reducing the duration of hospital stay, minimal access surgery (laparoscopic surgery) reduces the exposure of postoperative patients to COVID-19 infection in the hospital and thus leading to better outcomes.[4]

In our hospital, the first COVID-19 positive patient was diagnosed on 18th November 2019. Subsequently, the number of COVID-19 cases increased. During the initial phase of the pandemic, the main aim was directed towards maximising hospital capacity, strengthening infrastructure and increasing manpower to cope up with the surge in COVID-19 admissions. The nonclinical staff was also deployed in helping clinical departments to strengthen the manpower. The various additional measures taken in the operation theatre included: decreasing the number of theatre staff numbers, use of personal protective equipment (PPE kits), surgical caps, N95 masks, goggles, plastic aprons and fluid-resistant gowns, double gloving for surgeons and anaesthetists, and shoe covers, reduction of pneumoperitoneum pressures to 12 mmHg, use of balloon laparoscopic ports and filtered smoke extractors, and closed-system aspiration of pneumoperitoneum prior to specimen retrieval or port removal.[5] During the initial phase of the pandemic, an important anticipation was that any patient or staff member may carry SARS-CoV-2 at any time as there was a high incidence of infection in the community.

Recent studies show that SARS-CoV-2 RNA can also be detected in the peritoneal fluid of COVID-19 positive patients.[4,6] Simultaneously, recommendations from various expert departments advise very cautious and selective use of minimal access surgery (laparoscopic surgery) due to increased risk of spread of SARS-CoV-2 virus through aerosols.[7,8] The spread of blood-borne viruses (e.g.; human papillomavirus and human

immunodeficiency virus) through aerosols generated from surgical smoke or plume has been well established, reports of transmission of COVID-19 virus through surgical smoke are rare and are not exclusive to minimal access surgery. So far, there is no evidence that SARS-CoV-2 can be transmitted from a covid positive patient to staff through laparoscopic smoke, plume or through pneumoperitoneum. However, absence of evidence does not equate to evidence of absence and for this reason we resorted to the use of protective measures. Since in open surgery there is more manual contact with the peritoneal fluid and hence more exposure and also there is more exposure of peritoneum to the atmosphere, so it can be inferred that the risk of transmission of SARS-CoV-2 during open surgery is relatively high as compared to laparoscopic surgery.[9,10] On the contrary, minimal access surgery creates a contained environment and hence may pose a lower risk to the theatre staff. It can be logistically inferred that the institutional precautions taken during the surgery and described above have synergistically reduced the risk of SARS-CoV-2 transmission between patients and the theatre staff. These precautions are in accordance to the measures as described by the European and American endoscopic surgery recommendations.[11]

Minimal access surgery (laparoscopy) or open surgery (laparotomy)

Elective surgery should be avoided in patients who are COVID-19 positive if it is medically justified that the surgery can be postponed.[12,13] It has been noted that postoperative pulmonary complications occur in half of patients with perioperative COVID-19 positive status, and is associated with increased mortality. Moreover, there is a risk of viral transmission to operating team, theatre staff members and other patients during surgery and hospital stay.[14,15] Patients requiring emergency surgery or oncological surgery for any malignancy should always be considered whether the patient is COVID-19 positive or a COVID-19 suspect.[16]

Currently there is not a clear-cut preference for minimal access surgery (laparoscopy) or open surgery (laparotomy). Minimal access surgery (laparoscopy) may expose health care workers to a small increased risk of COVID-19 infection; but, this potential risk can be reduced by taking proper precautions and using personal protective measures. It has been established that in the postoperative period, a patient having undergone open surgery has more negative cardiac and pulmonary side effects than a patient having undergone minimal access surgery (laparoscopy).[17] Also, these patients have a longer duration of hospital stay and a longer recovery period. In a patient who is COVID-19 positive with potential pulmonary complications, this especially is not desirable. On the other hand, in a COVID-19 positive patient with many pulmonary complaints there may be worsening due to creation of pneumoperitoneum and Trendelenburg position during laparoscopic procedure.[18]

From the above discussion, it can be inferred that the choice to perform a minimal access surgery (laparoscopy) or laparotomy should not depend on the COVID-19 status of the patient. Due to lack of conclusive evidence and the expected very low risk of transmission of infection during laparoscopy, it can be concluded that COVID-19 is not a contraindication for laparoscopic surgery. The choice of surgical approach should be based on the clinical profile of the patient, indication of surgery, and experience of the surgeon.

Safety measures to be taken

Prevention of pneumoperitoneum dispersion

Pneumoperitoneum dispersion is to be avoided as much as possible to prevent aerosols from entering the operation theatre area. The trocars should be closed at the time of introduction and the Veress needles should be closed during removal. The use of trocars with intra-abdominal seal can help in preventing aerosol dispersion. Pneumoperitoneum and surgical smoke should be completely evacuated, before the end of surgery or before any laparoscopic surgery is to be converted to open surgery, use of a filtration device has been proven to be very useful. Evacuation of pneumoperitoneum and smoke should be done through a closed system to prevent any dispersion of aerosols.[19]

The various filtration devices which are available include HEPA (high-efficiency particulate arrestance) filters and ULPA (ultralow particulate arrestance) filters. HEPA (high-efficiency particulate arrestance) filters can eliminate 99.97% of particles of size larger than 0.3 µm and ULPA filters have an efficiency of 99.999% for removing particles of size larger than 0.1 µm and some can remove even up to 0.01 µm. It should be noted that in HEPA and ULPA filters, the virus filtration is based on particle size and till now, the efficacy of filters on virus filtration has not been established in clinical studies. Therefore, use of a filter is advocated in addition to a closed suction system, and CO_2 should not be allowed to directly enter the operation theatre complex through the filter.[14,20]

Another important aspect of pneumoperitoneum is intra-abdominal pressure. Zheng et al and SAGES have advocated that the intraperitoneal pressure should be kept at the lowest possible levels without compromising the surgical field in order to reduce the risk of transmission.[21] Theoretically, it can be attributed to the fact that with less high intraperitoneal pressure, the aerosols will leave the peritoneal cavity with less force upon dispersion of pneumoperitoneum. But this concept is based on little clinical evidence as studies in this aspect are obsolete. It is recommended that surgery should be performed with the lowest intraperitoneal pressure possible, but at the same the surgical field should not be compromised. At the same time, it should be kept in mind that low pressure might lead to complications, and hence

the operating surgeons should not deviate from their normal practice and should keep the risk benefit ratio in their mind.[15]

Operating technique

Electrocautery and ultrasonic surgery are important sources of energy used in laparoscopy and they cause potential smoke generation. Therefore, prolonged use at one site and using high voltage may result in additional smoke generation. Since ultrasonic energy creates low-temperature vaporization, therefore cellular material in surgical smoke may remain infectious.[22] But it has got only a theoretical value as studies in this aspect are lacking. Therefore, both electrocautery and ultrasonic surgery are considered safe to use as potential negative effects do not outweigh the very small reduction of viral transmission. Another important aspect during the surgical technique is the Trendelenburg position which may negatively affect pulmonary function and cardiac circulation, especially in COVID-19 patients. Hence the duration of Trendelenburg position should be kept as short as possible provided it is surgically justified.[5,8]

Surgical team

The number of staff members should be kept to a minimum in order to minimize the risk of transmission of infection. Since intubation and extubation is considered as a high-risk aerosol-forming procedure, therefore a minimum number of staff members should be present preferably only the anesthetist and the technician. The rest of surgical team members should enter the theatre room only after intubation has been completed.[12,17]

PPE

As per WHO guidelines, protective measures and proper precautions should be taken for every contact with a COVID-19 positive patient or a suspect. N95/FFP_2 masks are helpful in reducing the risk of transmission of corona virus to health care workers, but small particles of size (<0.1 µm) may not be filtered by these masks. There is a lack of consensus regarding the use of a positive pressure mask, personal HEPA filter, FFP_2, or FFP_3 mask among various institutions across the globe.[8,10] As per WHO recommendations a FFP_2/N95 mask should be used for aerosol-forming procedures or if they are not available then FFP_1 masks can be used. Triple layered surgical masks are recommended in all other conditions.[15] As discussed earlier, the spread of the COVID-19 virus during minimal access surgery (laparoscopy) has not yet been established, and the risk is considered very small because the aerosols do not originate from the respiratory tract. From these data, it is currently recommended to use at least a triple layered surgical mask during laparoscopic procedures. PPE kit should consist of at least a water-repellent apron, a triple layered surgical mask, tightly fitting goggles or a face shield, and gloves.[13] The use of shoe covers is advocated in some guidelines; however, this is not considered necessary if operating clogs are used which are cleaned after surgery.[20]

Operating room

A dedicated operating room for COVID-19 positive or suspected patients should be established to reduce the risk of transmission. Some guidelines advocated maintaining a negative pressure in the OR to prevent viral transmission to the outside rooms but practically it is not possible to achieve a negative pressure in the operating room. Because of this drawback, no suggestions regarding positive or negative pressure in the operating room are made.[17] There should be an adequate waiting time between surgeries after a COVID-19 positive or suspected patient has been operated to eliminate the possible viral particles in the air. In various studies, this time varied from 30 minutes (99% effectiveness) to 60 minutes (dilution to 0.0000002%).[18,19] In Dutch class 1 operating rooms, air is changed continuously at least 20 times per hour and in addition to it, it is also filtered using HEPA filter.[21] It is therefore recommended that the time required to remove aerosols from the air should be taken into account and accordingly the guidelines should be formulated. Although our study addresses pertinent issues regarding risk to theatre staff with open and laparoscopic surgery during the COVID-19 pandemic. However, there are several limitations that needs to be acknowledged. Firstly, this is a retrospective study in an environment where daily practice and guidelines have been subject to change, and also a relatively small single-centre cohort of 80 patients has been taken into account. In this study, out of 26 laparoscopic procedures 10 procedures were performed for acute appendicitis, which may partly account for the shorter length of hospital stay observed in laparoscopic surgery as compared to open surgery. Furthermore, perioperative SARS-CoV-2 RT-PCR testing was not universally available due to limited testing resources. The limited sensitivity of available SARS-CoV-2 RT-PCR tests also meant that this could not be used as a standalone criterion for excluding SARS-CoV-2 infection. Finally, symptomatology was included in an attempt to provide a more complete picture of patient risk but is inherently prone to recall bias and is limited by the lack of pathognomonic COVID-19 symptoms. Keeping in mind the above limitations, this study provides pragmatic evidence during the COVID-19 pandemic in a government hospital in India.

CONCLUSION

Based on our review, we concluded that if recommended guidelines are followed and proper precautions are taken, laparoscopic surgery is safe for patients and theatre staff during the COVID-19 pandemic and maintains an advantage in terms of length of hospital stay as compared to open surgery. During this pandemic, there is a need for guidance of all health care workers regarding the importance of taking appropriate measures in order to

prevent viral transmission during laparoscopic surgery. But currently there is lack of evidence from literature on how to precisely deal with this problem. Since there is generation of aerosols during laparoscopy, there is a potential small risk of viral transmission. However, this risk is not considered significant. This review describes the various practical preventive measures that need to be taken to minimize this small risk of viral transmission during laparoscopy. Only on the basis of COVID-19, laparoscopy should not be replaced by laparotomy if there is no other clinical indication. If laparoscopy is strongly indicated in patients, it can be used with precautions because of its benefits over open surgery.

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