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Original Article

A Prospective Study to Identify Rates of SARS-CoV-2 Virus in the Peritoneum and Lower Genital Tract of Patients Having Surgery: An Observational Study

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ABSTRACT **Study Objective:** The risks to surgeons of carrying out aerosol-generating procedures during the coronavirus disease 2019 (COVID-19) pandemic are unknown. To start to define these risks, in a systematic manner, we investigated the presence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus in the abdominal fluid and lower genital tract of patients undergoing surgery.

Design: Prospective cross-sectional observational study.

Setting: Single, large United Kingdom hospital.

Patients: Total of 113 patients undergoing abdominal surgery or instrumentation of the lower genital tract.

Interventions: We took COVID-19 swabs from the peritoneal cavity and from the vagina from all eligible patients. Results were stratified by preoperative COVID-19 status.

Measurements and Main Results: In patients who were presumed COVID-19 negative at the time of surgery, SARS-CoV-2 virus RNA was detected in 0 of 102 peritoneal samples and 0 of 98 vaginal samples. Both cohorts included 4 patients who were antibody positive but nasopharyngeal swab test negative at the time of surgery. Peritoneal and vaginal swabs were also negative in 1 patient who had a positive nasopharyngeal swab immediately before surgery.

Conclusion: The presence of SARS-CoV-2 RNA in the abdominal fluid or lower genital tract of presumed negative patients is nil or extremely low. These data will inform surgeons of the risks of restarting laparoscopic surgery at a time when COVID-19 is endemic in the population. Journal of Minimally Invasive Gynecology (2021) 28, 1633−1636. © 2021 AAGL. All rights reserved.

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As health services around the world emerge from the first wave of coronavirus disease 2019 (COVID-19) infections, the ability to resume normal work patterns becomes of paramount importance. Surgeons in particular need to be able to deliver effective and safe treatments to patients and reduce the inevitable backlogs that have developed.

Laparoscopy and other surgical procedures such as colposcopy and hysteroscopy are essential parts of the management of cancer patients. Laparoscopic and robotic surgery are associated with reduced hospital stays and reduced complication rates compared with open surgery [1]. Colposcopy and hysteroscopy are essential parts of the diagnostic process for gynecologic cancer [1,2].

However, the safety of these procedures, which when combined with electrosurgery, are known to be aerosol generating [3], is unclear, thus leading to a profusion of

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Ethical approval was obtained from Frenchay Research Ethics Committee (20/SW/0088) and informed written consent obtained from all patients before the collection of swabs and data.
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conflicting guidance (reviewed in [4]). The presence, although not necessarily infectivity, of other virus particles, including hepatitis B virus, has been confirmed in laparoscopic aerosols [5], but evidence for the presence of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) virus is mixed [6] with some single case reports of positive peritoneal fluid [7], whereas others report negative findings [8]. Consequently, there has been a call from some quarters to abandon minimal access surgery in all patients [4].

In the United Kingdom, the National Health Service (NHS), similar to many other healthcare systems, has attempted to stratify patients by introducing cohort status dependent on preoperative cohort status [9]. Inclusion in the lowest risk cohorts includes preoperative isolation and COVID-19 testing before admission. Despite this risk stratification, many centers continue to manage these patients as potentially high risk and have been reluctant to return to the use of minimal access surgery for these groups.

We, therefore, set out to systematically evaluate the risk of SARS-CoV-2 virus present in the peritoneal fluid and vagina of patients of apparent low-risk. Although the presence of virus would not necessarily confirm infectivity, the absence of virus RNA would provide reassurance that the risks of undertaking aerosol-generating procedures would be low in these groups.

Materials and Methods

Study Population

Patients were enrolled into the study at Saint Mary's Hospital, Manchester Royal Infirmary, and Wythenshawe Hospital, all part of Manchester University Foundation NHS Trust, between June 7 and July 29, 2020. The study was registered with the National Institute of Health Research register of COVID-19–related trials. Ethical approval was obtained from Frenchay Research Ethics Committee (20/SW/0088) and informed written consent obtained from all patients before the collection of swabs and data. The study was sponsored by Manchester University NHS Foundation Trust.

Inclusion and Exclusion Criteria

Patients were eligible if they were undergoing abdominal surgery including laparoscopy, laparotomy, and cesarean section or undergoing instrumentation of the lower genital tract including but not limited to colposcopy, hysteroscopy, and the insertion of an intrauterine device. All patients had a nasopharyngeal COVID-19 swab taken within 48 hours of the procedure.

Patients were excluded if there was evidence of fecal or amniotic contamination of the peritoneal cavity before the swab was taken.

Study Procedures

When applicable, patients had one or both of the following samples collected. A vaginal COVID-19 swab was taken from all 4 vaginal fornices, before any vaginal prep, catheterization, or vaginal instrumentation.

An abdominal COVID-19 swab was taken as soon as the abdominal cavity was opened. The swab was taken from the pelvis and the paracolic gutters. For laparoscopic cases, the swab was inserted through a 5-mm operating port, manipulated using laparoscopic forceps to ensure it was applied firmly to peritoneal surfaces, and then removed immediately through the laparoscopic port.

Samples were collected in viral transport medium and tested for the presence of SARS-CoV-2 RNA by reverse transcriptase–polymerase chain reaction using the Cobas SARS-CoV-2 RNA assay (Roche Diagnostics, Burgess Hill, UK).

Clinical Risk Groups

For the purposes of analysis patients were classified into the 3 risk groups defined by NHS England [9]. Many United Kingdom centers have adopted these risk groupings as a mechanism for cohorting patients within hospitals. For this study, the 3 groups were therefore defined as the following:

Green (COVID-19 clear). Patients who self-isolate for 14 days before admission, undergo negative nasopharyngeal swab within 48 hours of admission (and in the case of patients being admitted to level 2 and 3 care also undergo negative chest imaging) and are treated by teams of clinicians only caring for patients who are designated green.

Amber (undifferentiated). Patients who have not self-isolated but are asymptomatic at the time of admission, undergo negative nasopharyngeal testing within 4 hours of admission or have suspicious but not diagnostic chest radiologic findings.

Blue (COVID-19 positive). Patients who have had positive COVID-19 nasopharyngeal testing, or who have symptoms or radiological findings in keeping with current acute infection.

Clinical COVID-19 Testing

All patients recruited underwent standard screening for active COVID-19 infection using combined nose and throat swabs, tested for SARS-CoV-2 RNA by reverse transcriptase–polymerase chain reaction.

While the study was recruiting, SARS-CoV-2 antibody testing became available for some patients, and these results, when available, were collected from the patient record along with other clinical details.

Population Infection Rates Estimation

Estimates of the incidence of COVID-19 positivity during the study were derived from United Kingdom government websites.

Sample Size and Statistical Analysis

Because this was an observational study, a formal power calculation was not possible. The number to be recruited

was therefore estimated using a Bayesian approach. The number needed for the study was defined as the number needed to convince most of the clinicians that the rate of COVID-19 positivity in a particular cohort is sufficiently low and that the benefits of surgery outweigh the risks.

Polling a panel of surgeons revealed that a rate of 0/100 for any particular risk group would be sufficiently low risk to convince surgeons that this was a safe procedure. A total number of 100 cases was therefore selected for the study.

Data were analyzed using Microsoft Excel (Microsoft Corp., Redmond, WA).

Data were reported in line with STROBE guidance for the reporting of cross-sectional observational studies [10].

Results

A total of 113 patients were recruited, of whom 102 and 98 had a peritoneal and/or vaginal swab taken, respectively. Only 1 of 113 patients had a positive nasopharyngeal swab before surgery. This patient was asymptomatic at the time of admission for elective cesarean section, underwent the procedure as planned, and remained well in the postoperative period.

Peritoneal Swab Cohort

Peritoneal sampling was carried out in 102 patients at the time of surgery. Clinical characteristics of this cohort are shown in Table 1. During the study period, there was only 1 patient undergoing surgery who had evidence of acute infection (blue risk). A total of 78 were managed as amber risk and 23 as green risk. Of this cohort who underwent testing, 4 of 31 (13%) showed evidence of SARS-CoV-2 antibody suggesting previous infection.

Of 102 peritoneal swabs, 0 were positive for SARS-CoV-2 virus RNA. This included the 1 patient who had a positive nasopharyngeal swab immediately before a cesarean section.

Vaginal Swab Cohort

Vaginal sampling was carried out in 98 patients at the time of surgery. Clinical characteristics of this cohort are shown in Table 2. During the study period, there was only 1 patient undergoing surgery who had evidence of acute infection (blue risk). A total of 75 were managed as amber risk and 22 as green risk. Of this cohort who underwent testing, 4 of 32 (13%) showed evidence of SARS-CoV-2 antibody suggesting previous infection.

Of 98 vaginal swabs, 0 were positive for SARS-CoV-2 virus RNA. This included the 1 patient who had a positive nasopharyngeal swab immediately before a cesarean section.

Discussion

In this study, we were unable to detect any SARS-CoV-2 RNA in either the abdominal cavity or the vaginal fluids of a prospective series of more than 100 patients undergoing surgery.

Table 1

Patient characteristics (peritoneal cohort)

Characteristic		Number
Total cohort		102
Age, yrs, median (range)		36 (20–83)
Ethnicity		
	White	70
	BAME	32
BMI, kg/m^2	<25	31
	25–40	59
	>40	1
	Not known	11
Operative procedure	Cesarean section	72
	Cancer surgery	19
	Other	11
Antibody testing	Not tested	71
	Negative	27
	Positive	4
COVID-19 cohort*	Green	23
	Amber	78
	Blue	1

BAME = black, Asian, and minority ethnic; BMI = body mass index; COVID-19 = coronavirus disease 2019.
* COVID-19 cohort as defined by NHS England [9].

Table 2

Patient characteristics (vaginal cohort)

Characteristic		Number
Total cohort		98
Age, yrs, median (range)		35 (20–81)
Ethnicity		
	White	67
	BAME	31
BMI, kg/m^2		
	<25	28
	25–40	59
	>40	2
	Not known	9
Operative procedure	Cesarean section	71
	Cancer surgery	21
	Other	6
Antibody testing	Not tested	66
	Negative	28
	Positive	4
COVID-19 cohort*	Green	22
	Amber	75
	Blue	1

BAME = black, Asian, and minority ethnic; BMI = body mass index; COVID-19 = coronavirus disease 2019.
* COVID-19 cohort as defined by NHS England [9].

Specifically, the numbers of patients who were designated green (n = 27) and amber (n = 84) included in this study provide reassurance that the risks in these 2 groups are extremely low and that surgery in patients who have tested negative preoperatively could be undertaken safely, including minimal access surgery as appropriate.

We were unable to detect virus in the 4 of 32 (13%) patients who had positive antibody titers and the 1 patient who had active infection at the time of surgery. These numbers remain too small to make strong recommendations, but we will continue to recruit these subgroups of patients for further study.

Although the detection of virus particle in vaginal and abdominal fluids would not necessarily indicate infectivity as virus may be destroyed through the process of heating required to generate a surgical plume or aerosol, the absence of virus particle in vaginal and abdominal fluids tested in this study is reassuring.

This study was carried out at a time when the community incidence rate of COVID-19 infection was estimated to be stable at 0.02% [11]. This rate of infection would seem to represent the ongoing endemic rate that is likely to persist for at least a period of months.

Our study was weighted toward the inclusion of patients undergoing cesarean section as this is currently the most common abdominal operation carried out in our institution. Nevertheless, we were able to include patients undergoing other procedures including oncology surgery and emergency general surgical procedures. There is no reason to suppose that the population included in this study is particularly different from the general obstetric, gynecologic, or surgical population.

This study did not include any patients in whom there was fecal contamination of the abdominal cavity at the time of surgery. Further studies are now underway to address this and also to assess the risk in patients who are asymptomatic and symptomatic COVID-19 positive and those who have positive antibodies.

In summary, we have demonstrated that undertaking abdominal and gynecologic surgery, including laparoscopic surgery, in patients who have been COVID-19 tested preoperatively, whether they have been self-isolating or not, must be considered a low-risk procedure. These data will allow surgeons, and their teams, to make informed decisions about returning to laparoscopic surgery, the role of filtration devices, and the need for personal protective equipment in low-risk patients who comprise most of the patients currently awaiting a surgical procedure.

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