

## ORIGINAL PAPER

## Obstetrics &amp; Gynaecology

# Is it safe to perform elective gynaecologic surgery during the two peaks of COVID-19 pandemic?

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**Abstract**

**Purpose:** In December 2019, the COVID-19 pandemic started in China and spread around the World. Operations were postponed in most surgical clinics to reduce the risk of contamination and increase the number of beds available in hospitals. We investigate whether elective gynaecologic surgery is safe or not under safety measures.

**Methods:** A total of 765 patients were operated on electively between 15 March and 30 October 2020 at our inpatient gynaecology clinic. We took the SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) test of the nasopharyngeal swab before and after the surgery. Patients were questioned for COVID-19 symptoms by phone calls on the 7th, 15th, 30th and 60th days postoperatively.

**Results:** The average age of patients was  $45.6 \pm 11(19-81)$ . Sixty-two (8.1%) operations were performed due to gynaecologic malignancies. Three patients (0.39%) were detected as SARS-CoV-2 RT PCR positive within 7 days after surgery. The patients did not need ICU admission or any further treatments.

**Conclusion:** Our study offers a novel perspective on elective surgery during a pandemic. The risk assessment of patients should be meticulously done and substantiated on objective variables. According to our study, in a carefully selected patient population, operating under appropriate precautions, elective gynaecologic surgical procedures during the two peaks of the COVID-19 pandemic do not pose a risk to the patients.

## 1 | INTRODUCTION

In December 2019, the first clinical case was presented as viral pneumonia from Wuhan, the capital city of China's Hubei Province.<sup>1</sup> Two months later, on 12 February 2020, the World Health Organization (WHO) entitled the novel virus as Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), causing Coronavirus Disease 2019 (COVID-19), responsible for severe pneumonia and multiple symptoms such as diarrhoea, myalgia, headache, anosmia and ageusia.<sup>2</sup> On 11 March, approximately 118 000 cases in 114 countries and 4291 COVID-19-related deaths worldwide were reported, and WHO declared the outbreak to be a pandemic.<sup>3</sup>

In Turkey, on 9 March 2020, a 44-year-old-man was hospitalised with fever and cough after traveling abroad. He became Turkey's first official case, which was announced on 11 March, simultaneously as WHO's pandemic declaration.<sup>4</sup> The virus spread rate in Turkey was about the same as the World's, and the number of cases reached 476 601 within 3 months.

Besides the prevention methods were considered with the onset of the pandemic, there were concerns among the surgeons about the effects of surgery on COVID-19. The findings of some studies suggested that SARS-CoV-2 increases circulating pro-inflammatory cytokines and chemokines.<sup>5,6</sup> Consequently, higher levels of cytokines are correlated with the severity of the

COVID-19.<sup>1</sup> Furthermore, surgery induces an early systemic inflammatory response and causes immune function impairment.<sup>7,8</sup> Surgical patients who had COVID-19 have higher mortality rates than those who had only COVID-19.<sup>9</sup> In the light of these reports, elective and non-urgent surgeries were postponed in many countries and Turkey.

Postponing surgery was thought to be essential to reduce the possibility of infection related to hospitalisation and surgery and was also critical in increasing the number of available beds and staff in the hospital. In addition, operating rooms could be transformed into intensive care unit (ICU) beds to meet the increased ventilator requirement.

On the other hand, it is widely assumed that rescheduling elective surgeries will have a noticeable impact on the waiting lists of all surgery clinics. Moreover, delaying surgical procedures for an undetermined time negatively impacts patients' underlying health situation and psychology, particularly for patients with malignancy.<sup>10</sup> Even in benign diseases, postponement of operations may lead to workforce loss and a decrease in the patients' quality of life.

The goal of the present article is to summarise our experience with elective gynaecologic surgeries during the two waveforms of the COVID-19 pandemic. In the present article, we describe the preoperative preparations of patients, the preventive measures were presented, which were taken by both health-care providers and patients, and the information was given about the postoperative time, especially complications, more precisely SARS-CoV-2 infection.

## 2 | MATERIALS AND METHODS

Seven hundred and sixty-five patients underwent elective gynaecologic surgery from 15 March to 30 October 2020, at Kartal Dr Lütfi Kırdar City Hospital, Istanbul, Turkey, involved in this retrospective study. Emergency surgeries, outpatient procedures and SARS-CoV-2 RT-PCR positive surgical patients were excluded from the study. The Ministry of Health and the Ethics Committee of the Kartal Dr Lütfi Kırdar City Hospital approved the study. (No. 2020/514/192/30).

Until May, standard protocols for testing COVID-19 had not been defined preoperatively; therefore, the diagnosis was made through patient history and detailed physical examination. After the second part of May 2020, appropriate tests were enabled. Subsequently, the government and the hospital's infectious disease committee advised specific preoperative workups.

### 2.1 | Preoperative preparation

Before elective surgery, all patients were individually educated about the risks and contagion of the virus. Recommendations were given on how to be prepared for surgery and what to pay attention in their social lives to protect against the virus. The

#### What's known

During the COVID-19 pandemic, elective surgeries were postponed for various reasons. However, postponing operations for an undetermined time would cause an increase in the health problems of the patients in the long term. Moreover, the backlog of the workload in hospitals would rise after the pandemic.

#### What's new

In our study, we presented our elective gynaecologic surgery experience during the COVID-19 pandemic. We performed elective operations on non-COVID-19 patients, and we gave information about the clinic features of the patients who were diagnosed with COVID-19 after the operation.

Our study offers a perspective on elective gynaecologic surgery during the two peaks of a pandemic. According to our study, in a carefully selected patient population, operating under appropriate precautions does not pose a risk to the patients.

instructions for protecting against viral infection were explained about the operation process and, more importantly, postoperative time. In case the patient declined the operation, a follow-up plan was scheduled.

Patients were questioned for symptoms of COVID-19 or close contact with any COVID-19 infected persons before the procedures and referred to the COVID-19 outpatient clinic in the event of suspicious cases. If the patients were diagnosed with COVID-19, they would be re-evaluated for surgery after 28 days from the diagnosis (Figure 1).

Other than the informed consent specific to the scheduled operation, an informed consent form for COVID-19 was created consisting of five parts. The risk of nosocomial SARS-CoV-2 contraction, the general risks of the COVID-19, risk of possible future delays in routine or emergency care, the responsibility of notifying any symptoms to attending surgeon or other health-care professionals about the virus before or after the operation were the main components of the written informed consent form. Best- and worst-case scenarios were clarified for a patient-oriented shared decision-making model. Additionally, and more importantly, patients were encouraged to ask questions expressed fears, concerns and preferences.

Three days and one day before the operation day, we took the SARS-CoV-2 Reverse Transcriptase (RT) Polymerase Chain Reaction (PCR) test of the nasopharyngeal swab. In the case of a positive test or suspicion of COVID-19, computerised tomography (CT) scan of the thorax was carried out before the procedures. When the first SARS-CoV-2 RT-PCR testing was negative, the necessity of self-isolation until hospitalisation was explained to the

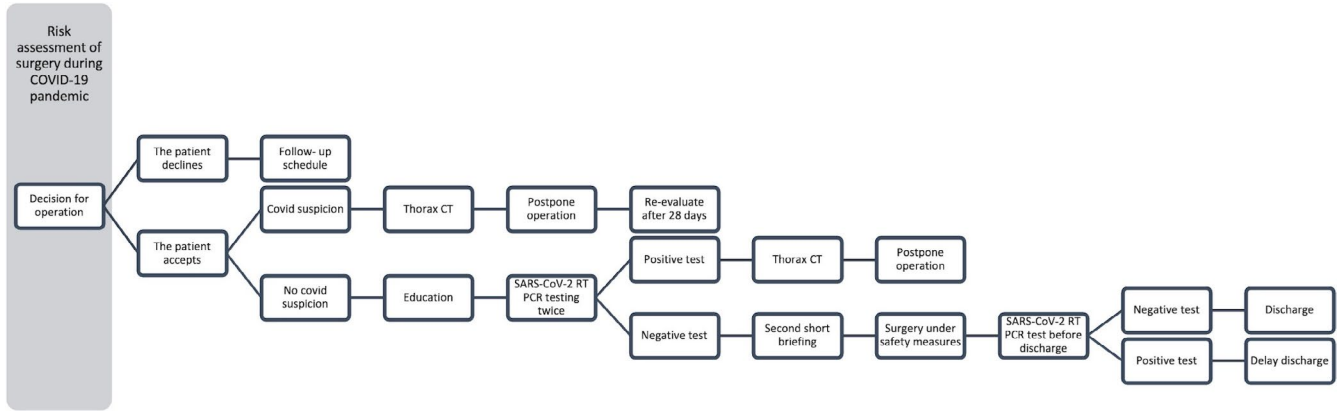


FIGURE 1 Pre and postoperative stages

patient. After the second SARS-CoV-2 RT-PCR test negativity, a second brief presentation was given about safety measures on the day before the operation.

## 2.2 | Operation safety measures

On the operation day, the safety measures started with the transport of the patient. The transportation staff and all the medical staff in the operating room wore double examination gloves, hooded protective gowns, rubber boots, safety glasses, protective shields, FFP2 or N95 respirators, and standard surgical masks. The patients were transported directly from their room to the operating theatre to avoid any risk of contamination.

The surgeries were performed in an isolated operating room consisted of a chief surgeon, an assistant surgeon, one resident, a chief anaesthesiologist, an assistant anaesthesiologist, one scrub nurse and one circulating nurse. The surgeons and nurses entered the operating room after the anaesthesiologist invited them.

Either by laparoscopy or laparotomy, electrocautery was used minimally to reduce the smoke development. If essential, electrocauterisation was not prolonged in one location and not used with high voltage settings. Additional safety measures were taken to minimise the exposure of aerosols during the laparoscopic procedures. All instruments and suction systems were checked before laparoscopy. The abdomen was insufflated through the Verres needle, the intra-abdominal pressure was maintained at the possible lowest level, and the Verres needle was closed during removal. Suitable holes were created to ensure leak-free trocars, and at the introduction, the trocars were ascertained to be closed. Instrument changing was kept at minimum. Before the end of the surgery or converting to laparotomy, pneumoperitoneum and smoke were evacuated through a closed suction system.

After the operation finished, the patients recovered in the operating room, and same as before surgery, directly transferred to their room, bypassing the postoperative unite. After surgery, a patient-controlled analgesia device was applied to relieve pain and minimise contact with the medical staff. No companions or visitors

were allowed in the inpatient clinic to reduce the risk of SARS-CoV-2 infection after the operation.

After each operation, all operating theatre surfaces were disinfected with diluted chlorine bleach ( $\geq 500$  ppm).<sup>11</sup> The subsequent surgery patient was taken to the operating room 30 minutes after the end of the disinfection.

The Enhanced Recovery after Surgery protocol (ERAS) was applied after operations.<sup>12</sup> The patients were encouraged for early mobilisation at the sixth postoperative hour. On the first postoperative day, the patients were transferred to another newly disinfected and well-ventilated room. The discharge was decided when the patient was able to take care of herself since our aim was the continuation of social isolation as much as possible after the discharge. Specifically, the importance of not accepting any visitors in their homes during the recovery period was explained repeatedly.

Six hours before discharge, the last SARS-CoV-2 RT PCR test was taken from the patients. If the test was positive, the discharge was postponed, thorax CT was carried out, the Infectious Disease consultation was requested, and the patients were kept under surveillance for at least 5 more days to detect possible symptoms.

After discharge, patients were questioned for COVID-19 symptoms by phone calls on the 7th, 15th, 30th and 60th days postoperatively. Moreover, another investigator checked the patient recordings about COVID-19 on the Public Health Management System.

Demographic information, surgery type and time, preoperative diagnosis and postoperative complications were taken from electronic medical records.

Continuous variables were presented as mean, standard deviation and range. Categorical variables were expressed as frequencies and percentages. All statistical analyses were performed with SPSS<sup>®</sup> version 23.0 software (SPSS<sup>®</sup>, Chicago, Illinois, USA).

## 3 | RESULTS

A total of 804 operations on 765 patients were performed between 15 March and 30 October 2020 at our inpatient clinic. The data of

three participants were excluded from the analysis because of non-COVID-19 related deaths within 2 months after surgery.

Preoperatively, all patients were SARS-CoV-2 RT PCR negative in this study. The average age of patients was  $45.6 \pm 11(19-81)$ . The most common indication for surgery was abnormal uterine bleeding (25.3%), unresponsive to conservative medical management. Patients' clinical characteristics, including age, medical comorbidities, previous abdominal surgeries and surgery indications, were displayed in Table 1.

Sixty-two (7.7%) operations were performed due to gynaecologic malignancies. Additionally, 74 (9.7%) surgeries were planned for the excision of premalignant lesions. Independently from precancerous and malignancy procedures, 412 (51.4%) underwent hysterectomy for benign gynaecologic diseases. The distribution of surgical procedures was detailed in Table 2.

Figure 2 shows changes in the number of cases per week during the pandemic. Between 30 March and 22 May 2020, the mean number of operations per week was two, and the minimum and the maximum number of operations per week were 1 and 4, respectively.

Table 3 provides details about the operative and postoperative variables and complications especially SARS-CoV-2 contagion. The detection time of SARS-CoV-2 infection was divided into three periods: 1 to 14, 15 to 30, 30 to 60 days after the operation. Our results showed that seven (0.89%) patients were positive for testing SARS-CoV-2 RT PCR within the first month after surgery. Three patients

(0.39%) were detected as SARS-CoV-2 RT PCR positive within 7 days after surgery. Twenty-two patients (2.9%) became SARS-CoV-2 RT PCR positive between the first and second months following the operation.

Three patients were kept under surveillance for 5 more days after their tests were positive. The clinical features of the three patients were detailed in Table 4. The common symptoms such as fever, cough, sore throat, dyspnoea, headache, myalgia, gastrointestinal symptoms, anosmia or ageusia were not detected during these 5 days. Although thorax CTs revealed bilateral ground-glass opacities, their transcutaneous hemoglobin oxygen saturations were remained normal in room air. ICU admission was not required, and at the end of the 5-day observation, patients were discharged by notifying the home health-care services.

## 4 | DISCUSSION

The goal of the present article was to investigate whether it is safe or not to perform elective surgeries during the COVID-19 pandemic under safety precautions. Our results showed that the incidence of early postoperative COVID-19 was 0.39%. All the SARS-CoV-2 RT PCR positive patients after elective surgery in this study were asymptomatic and did not require ICU admission. In contrast with our results, Lei et al suggested that asymptomatic patients with

TABLE 1 Clinical features of surgical patients

|                            |                   |
|----------------------------|-------------------|
| Age                        | 45.6 ± 11 (19-81) |
| Medical Comorbidity        | 304 (39.8%)       |
| Diabetes Mellitus          | 80 (10.5%)        |
| Hypertensive diseases      | 151 (19.8%)       |
| Cardiovascular disease     | 43 (5.6%)         |
| Respiratory disease        | 52 (6.8%)         |
| Previous malignancy        | 36 (4.7%)         |
| Previous abdominal surgery | 342 (45%)         |
| 1                          | 200 (26.2%)       |
| 2                          | 92 (12%)          |
| 3                          | 32 (4.2%)         |
| 4 and more                 | 19 (2.4%)         |
| Surgery indications        |                   |
| Abnormal uterine bleeding  | 193 (25.3%)       |
| Pelvic pain                | 127 (16.6%)       |
| Myoma uteri                | 96 (12.5%)        |
| Adnexal mass               | 88 (11.5%)        |
| Premalignant lesions       | 74 (9.7%)         |
| Pelvic organ prolapse      | 68 (8.9%)         |
| Malignancy                 | 62 (8.1%)         |
| Urinary incontinence       | 54 (7%)           |

Note: Values are n, n/total (%) or mean ± standard deviation (minimum-maximum).

TABLE 2 Categories of surgery

|  |             |
|--|-------------|
| Hysterectomy                                     | 412 (51.4%) |
| Laparotomy                                       | 214 (26.7%) |
| Laparoscopy                                      | 149 (18.6%) |
| Vaginal  | 49 (6.1%)   |
| Conisation/LEEP                                  | 72 (8.9%)   |
| Hysteroscopy                                     | 56 (6.9%)   |
| Operations for urinary incontinence              | 54 (6.7%)   |
| Myomectomy                                       | 41 (5.1%)   |
| Ovarian cystectomy                               | 39 (4.8%)   |
| Salpingo-oophorectomy                            | 27 (3.3%)   |
| Malignancy operations                            | 62 (7.7%)   |
| Cytoreductive surgery                            | 21 (2.6%)   |
| Radical hysterectomy with pelvic lymphadenectomy | 19 (2.3%)   |
| Malignancy detected by frozen section            |             |
| Laparoscopy                                      | 12 (1.4%)   |
| Laparotomy                                       | 10 (1.2%)   |
| Sacro-spinous ligament fixation                  | 11 (1.3%)   |
| Dermoid cyst excision                            | 10 (1.2%)   |
| Bartholin's cyst excision                        | 9 (1.1%)    |
| Sacral colpo hysteropexy                         | 8 (1%)      |
| Combined operations                              | 34 (4.2%)   |

Note: Values are n, n/total (%), LEEP, loop electro excision procedure.

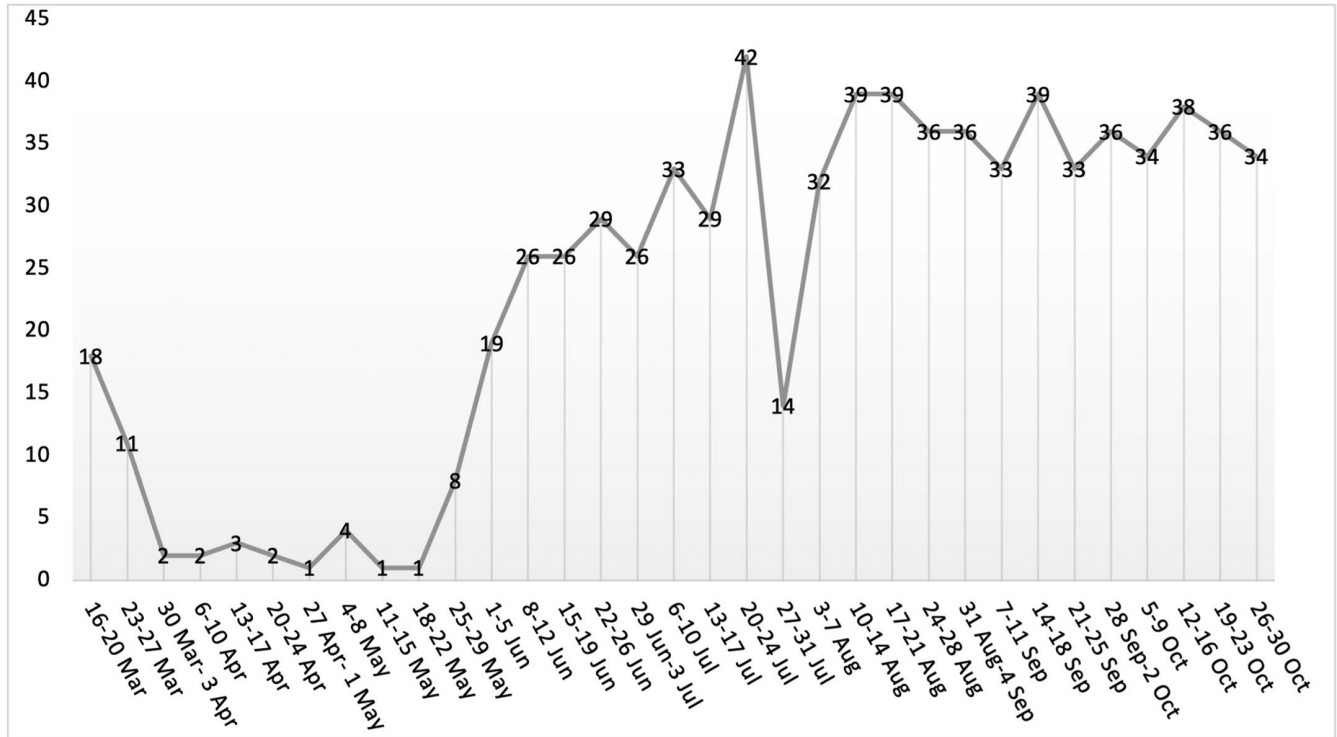


FIGURE 2 Weekly numbers of operated patients

TABLE 3 Operative and postoperative variables and complications

|                              |                       |
|------------------------------|-----------------------|
| Operation time (minutes)     | 89.8 ± 53.1 (16-403)  |
| Hospitalisation time (hours) | 91.6 ± 42.2 (2-417)   |
| Preoperative Hb              | 12.2 ± 1.5 (4.7-16.1) |
| Postoperative Hb             | 11.7 ± 1.5 (5.9-15.9) |
| Complications                |                       |
| Soft tissue infection        | 4 (0.5%)              |
| Hematoma                     | 4 (0.5%)              |
| Urinary tract injury         | 10 (1.3%)             |
| Bowel injury                 | 6 (0.8%)              |
| COVID-19 contagion           | 8 (1%)                |
| 1st-14th days                | 3 (0.39%)             |
| 15th-30th days               | 4 (0.5%)              |
| 30th-60th days               | 22 (2.9%)             |

Note: Values are n, n/total (%) or mean ± standard deviation (minimum-maximum), Hb, haemoglobin.

COVID-19 undergoing surgery tend to have worse outcomes. Especially respiratory problems, ICU admission and overall mortality seem to be higher.<sup>9</sup> Lei et al gave the operation decision due to lack of COVID-19 symptoms, whereas we performed the SARS-CoV-2 RT PCR twice before surgery. Physical examination and questioning about the symptoms are crucial in detecting COVID-19; however, we think testing for COVID-19 before planning an elective operation is valuable and should not be omitted.

On the other side, overall Turkey's COVID-19 incidence for the same time interval was 0.46%.<sup>13</sup> One possible explanation for the lower incidence of the elective surgery group is that the patients were individually educated about the virus and transmission ways before the surgery. Physical distancing, hand hygiene, avoiding touching nose, mouth, and eyes, disinfecting surfaces before touching, using a mask and face shield were the most emphasised measures to minimise or prevent the risk of virus spreading.

Most interestingly, in the same patient group, the incidence of COVID-19 reached 2.9% between 1 and 2 months after the operation. The second peak of the virus in Turkey and the timescale of these patients' positivity detection were mainly the same. On the other hand, the early postoperative positivity of the virus was completely independent of the virus' peaks. We can suggest that in the early postoperative period, the patients strictly applied the recommended safety measures; however, they might have neglected these critical preventive measures after the recovery period. The results lead us to the importance of preventive measures during a pandemic.

When we look back in the World's history, we mainly come across two pandemics in particular. The 1889 pandemic lasted 3 years, the influenza pandemic of 1918, known as Spanish flu, lasted 2 years, and both of them occurred in the three waveforms.<sup>14,15</sup> At the time of writing this article, more than a year had passed since the first patient was diagnosed with COVID-19. Although the vaccine has been introduced and administered, there is still no indication that the pandemic has come to an end.

During the pandemic period, a total of 82 000 surgical cases per week were postponed in Turkey. 39.3% of postponed gynaecologic

TABLE 4 Clinical characteristics of three patients with COVID-19

|                         | Patient 1          | Patient 2                      | Patient 3                      |
|-------------------------|--------------------|--------------------------------|--------------------------------|
| Age                     | 77                 | 57                             | 46                             |
| Operation type          | Debulking surgery  | TAH with BSO                   | TAH with BSO                   |
| Operation (minutes)     | 127 min            | 101 min                        | 63 min                         |
| Hospitalisation (hours) | 174 h              | 158 h                          | 150 h                          |
| COVID-19 detection day  | 2nd day after op.  | 2nd day after op.              | 1st day after op.              |
| Comorbidity             | HT                 | HT                             | None                           |
| Surgery indication      | Ovarian malignancy | Symptomatic, large myoma uteri | Symptomatic, large myoma uteri |

Abbreviations: BSO, bilateral salpingo-oophorectomy, HT, hypertensive disease; TAH, Total abdominal hysterectomy.

surgeries were malignancy operations, and 81.6% were surgeries for benign gynaecologic diseases.<sup>16</sup> Even with benign diseases, delays in treatment may cause deterioration in the patient's current condition, disability, workforce loss. The postponement of surgery during the COVID-19 pandemic created the need to use alternative medical treatments. The efficacy of alternative medical treatments evaluated by surveying and the severity of symptoms remained unchanged in 60% of the patients and had worsened in 27%.<sup>17</sup> According to calculations made with modelling, after a 12-week delay of surgeries, despite a 20% increase in the workforce, the accumulated workload can be compensated in 45 weeks.<sup>16</sup> Based on this modelling, a pandemic that could last up to a year will likely take more than 3 years to eliminate the workload that will arise.

In Turkey, the Ministry of Health commissioned two hospitals to continue performing essential operations in Istanbul during the pandemic. Other than these two medical facilities, all hospitals, including private hospitals, provided free service for patients with COVID-19. Patients requiring surgery were referred to those two chosen hospitals. One of these two centres serving Istanbul with a population of 15.5 million was our hospital, Kartal Dr Lütfi Kırdar City Hospital. Therefore, the patients had been meticulously evaluated to determine the necessity of surgery, and the risk assessment of patients was individualised based on objective variables.

Our hospital was a new hospital, started to provide service in October 2019, and has a capacity of 1105 beds, including 183 ICU beds and 45 operating theatres. Owing to be a new hospital, the number of patients waiting for surgery was low, and on account of the high capacity and low patient volume, it provides a convenient opportunity for proper disinfection.

In our study, between 15 March and 29 May 2020, 45 patients were operated on under WHO's guidance, with all personal protective equipment due to lack of standard protocols for testing COVID-19. The Ministry of Health of Turkey decided to postpone elective surgery on 27 March, and from 30 March to 25 May 2020, only malignancy operations were performed. The total number of malignancy operations was 62 (7.7%) in this study. Although elective surgeries were delayed, all hospitals continued to perform cancer surgeries. For this reason, even though our hospital is a tertiary referral centre, our number and rate of cancer surgeries are not higher than what it is expected to be.

As a tertiary referral centre, we perform a high number of laparoscopy. Following the pandemic outbreak, many surgeons were doubtful about performing laparoscopy due to airborne transmission risk. The underlying reasons for that doubt are the SARS-CoV-2 RNA has been identified in samples from the respiratory tract, faeces, blood, saliva, urine, lymph and peritoneal fluid,<sup>18,19</sup> and the transmission route of the virus is the inhalation of droplets or viral contact with the mucous membranes such as oral, nasal or ocular mucous membrane.<sup>20</sup> Furthermore, pneumoperitoneum desufflation can contaminate the operating theatre with blood and bodily fluids, and aerosols are more concentrated in pneumoperitoneum.<sup>21</sup> Over and above, electrocautery can create surgical smoke particle-sized 0.07-6.5 microns. This particle can contain viral particles as HIV, poliovirus or HPV.<sup>22</sup> When all this information is evaluated together, there is a theoretical risk of contagion of the virus with the smoke and aerosol during laparoscopy.

On the other hand, Cheng and colleagues identified SARS-CoV-2 in environmental samples; however, the same authors did not detect SARS-CoV-2 in air samples in the very same area.<sup>23</sup> Similarly, in another study involving 75 465 COVID-19 cases, airborne transmission of the virus was not reported.<sup>24</sup> We cannot ignore the fact that laparoscopy has fewer adverse cardiac and pulmonary side effects, and patients have a shorter recovery period and hospitalisation time. Using personal protective equipment, checking instruments and suction systems before the operation, preventing gas leakage from Vessel needle or trocars, maintaining pneumoperitoneum at the lowest levels, using electrocautery minimally and evacuating the gas with a closed suction system after the operation or in case of converting to laparotomy are facile and feasible precautions.<sup>25</sup> In conclusion, these safety measurements are also effortless methods that can prevent all the theoretical ways of virus transmission described above.

Our study has two main limitations that must be acknowledged. First, we did not know the number of elective surgeries cancelled due to COVID-19. It could be expedient to compare the incidence of COVID-19 in the gynaecologic surgical patient population. Another limitation is that we performed the SARS-CoV-2 RT PCR test 3 days and 1 day before hospitalisation and the day of discharge. The median incubation period for SARS-CoV-2 is 5.1 days, and the probability of false-negativity of SARS-CoV-2 RT PCR ranges from 68% to 100% and



differs according to the swab sample collecting day.<sup>26</sup> Moreover, the false-negativity reduces 8 days after the infection, on an average of 3 days after the onset of symptoms.<sup>27</sup> In line with these information, it could not be concluded whether the infection was contracted in the hospital or had not been detected with the tests before the surgery.

Although these limitations, our study cannot be ruled out entirely. Our study gives information on the incidence and the clinical features of the patients with COVID-19, which were detected after surgery during the two peaks of the COVID-19 pandemic in Turkey. We think that our study can provide selective information with a large number and variety of patients to make surgery decisions in possible future pandemics.

## 5 | SUMMARY & CONCLUSION

In our study, we presented our elective gynaecologic surgery experience during the COVID-19 pandemic. We performed elective operations on non-COVID-19 patients, and we gave information about the clinic features of the patients diagnosed with COVID-19 after the operation.

Taken together, our study offers a perspective on elective gynaecologic surgery during the two peaks of a pandemic. According to our study, in a carefully selected patient population, operating under appropriate precautions does not pose a risk to the patients.

### ACKNOWLEDGEMENTS

None.

### DISCLOSURE

None of the authors has any conflict of interest to disclose.

### DATA AVAILABILITY STATEMENT

Data are available on request from the authors.

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