

Effect of the COVID-19 Pandemic on the Management of Acute Cholecystitis and Assessment of the Crisis Approach: A Multicenter Experience in Egypt

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Abstract

Introduction: The covid-19 pandemic has had a drastic impact on all medical services. Acute cholecystitis is a serious condition that accounts for a considerable percentage of general surgical acute admissions. Therefore, the Royal College of Surgeons' 'Commissioning guidance' recommended urgent admission to secondary care and early cholecystectomy. During the first wave of hospital admissions associated with COVID-19, most guidelines recommended conservative treatment in order to limit the admission rates and free up spaces for COVID-19-infected patients. However, reviews of this approach have not been widely done to assess the results and, in turn, planning our future management approach when future pressures on in-patient admissions are inevitable.

Methods: Our study included all acute cholecystitis patients who needed surgical intervention in one Centre in the UK over three distinct periods (pre-COVID-19, during the first lockdown, and lockdown ease). Comparison between these groups were done regarding intraoperative and postoperative results.

Results: The conservative management led to a high rate of readmission. Moreover, delayed cholecystectomy was associated with increased operative difficulties such as extensive adhesions, intraoperative blood loss, and/or complicated gall bladder pathologies such as perforated or gangrenous gall bladder (29.9%, 16.7%, and 24.8%, respectively). The resulting postoperative complications of surgical and nonsurgical resulted in a longer hospital stay (13.5 d).

Conclusion: The crisis approach for acute cholecystitis management failed to deliver the hoped outcome. Instead, it backfired and did the exact opposite, leading to longer hospital stays and extra burden to the patient and the healthcare system.

KEYWORDS

acute cholecystitis, COVID-19, crisis approach

1 | INTRODUCTION

All over the world it is recognized that some patients with gallstones generate multiple admissions and combined planned and unplanned visits to the hospital with considerable patient, health service, and societal burden. Acute cholecystitis is an emergency condition, typically arising from gall bladder stones and often leading to unplanned surgical admissions and inpatient surgical intervention. Thousands of people develop symptoms of acute cholecystitis annually across the world, with a resulting high management cost. In 2012, the US reported that 215,995 patients were diagnosed with acute cholecystitis, resulting in a direct cost of US \$9.3 billion.¹ In the UK, acute cholecystitis accounts for approximately one-third of all unplanned general surgical admissions. Historically, UK centers have reported a variable percentage of units able to perform laparoscopic cholecystectomy to these patients in the first 10 d of presentation, ranging from 0%–35%.²

According to the Royal College of Surgeons' Commissioning guidance, early management of acute cholecystitis, in particular, is the key to prevent further development of more serious complications that can lead to mortality (up to 10%). Therefore, urgent admission to secondary care is recommended once the diagnosis is confirmed.³ Once admitted, cholecystectomy should be performed as soon as possible. The National Institute for Health and Care Excellence guidelines recommended that, after the onset of acute cholecystitis, cholecystectomy should be performed within 1 wk^{4,5} Conservative management is not recommended, as gallbladder inflammation often persists despite medical therapy.⁶ In addition, cholecystectomy will prevent further biliary attacks and reduce the risk of developing gall bladder perforation, which can lead to mortality in 30% of cases, and other well-recognized complications such as pancreatitis.⁷ A laparoscopic approach is the preferred surgical method for cholecystectomy, as early laparoscopic cholecystectomy (ELC, within 72 h of onset) resulted in a reduced hospital stay and conversion rate to open cholecystectomy. Moreover, early ELC is also associated with reduced hospital costs and earlier recovery.^{8–13} Early surgery, even when performed in patients >72 h from onset of symptoms, is safe and associated with less overall morbidity, shorter total hospital stay and duration of antibiotic therapy, and reduced cost compared with delayed cholecystectomy (performed ≥ 6 wk after the onset of symptoms).¹⁴

During the first wave of increased hospital admissions associated with COVID-19, the guidelines changed in order to limit the admission rates to free up spaces for possible COVID-19-infected patients. The Association of

Upper Gastrointestinal Surgeons (AUGIS) Guidelines for biliary disease during the crisis period stated that acute cholecystitis and biliary pancreatitis should be treated conservatively, with pain relief plus antibiotics if needed. In case of sepsis and ultrasound confirmation of gall bladder empyema, then cholecystostomy should be considered, if radiology services are available.¹⁵ The same concept was applied in all university hospitals and surgical units in Egypt (the crisis approach). However, reviews of this approach have not been widely published to assess the results and, in turn, planning our future management approach during future crises of whatever cause, including further waves of COVID-19 admissions. Therefore, our prospective study aimed at comparing both approaches for the management of acute cholecystitis before and during the COVID-19 era, regarding delayed clinical presentation, operative difficulty, intraoperative findings, postoperative complications, and length of hospital stay.

2 | METHODS

Our cohort study originated from the Cairo University teaching hospital after obtaining approval from the Ethical Committee, Institutional Review Board, and informed written consent for surgery from all the patients. The study included all the patients diagnosed with acute cholecystitis who needed surgical intervention in seven tertiary medical centers that have the feasibility and capability to perform hot gall bladders in Egypt (university teaching hospitals). The elapsed time of the study was divided into two periods: the pre-COVID era from June 15, 2019 to March 15, 2020, then after the rise of COVID-19 and application of the crisis approach from March 16, 2020 to March 16, 2021. We excluded patients who were deemed unfit for surgical intervention due to frailty and/or multiple comorbidities (19 patients) and patients with incomplete data (seven patients).

The diagnosis of acute cholecystitis was based on a combination of clinical, imaging, and perioperative findings. Clinical signs encouraging a preoperative diagnosis of cholecystitis were pain, tenderness, or rebound tenderness in their right upper abdomen and epigastrium. Imaging was usually achieved with ultrasonography but with occasional diagnoses reached with CT. The radiological signs that were sought to confirm "cholecystitis" were increased wall thickness, pericholecystic fluid collection, empyema, gangrene, and/or perforation of the gall bladder. Moreover, all cases of cholecystitis were confirmed histologically after specimen retrieval.

During the pre-COVID-19 era, all patients who were deemed fit for surgery were managed by early

laparoscopic cholecystectomy, while, after the pandemic started patients were managed initially by antibiotics for 14 d with strict follow-up to detect the patients' response (Figure 1). Meanwhile, attempted ultrasound-guided cholecystostomy was tried in order to drain the gall bladder in selected patients. Failure of conservative management was defined as persistent fever, right upper quadrant pain not responding to strong pain killers, persistent Murphy sign, impaired kidney function, further elevation of inflammatory markers (white cell count and CRP), signs of sepsis, and/or septic shock.

All patients were operated on under general anesthesia and all surgeries were performed with experienced consultant biliary surgeons as the principal operator. The preoperative clinical status of each group was examined by age, sex, weight, American Society of Anesthesiologists (ASA) classification, white blood cell (WBC) count, and C-reactive protein (CRP) value upon the patient's admission.

Laparoscopic cholecystectomy was performed using the standard four-trocar technique. After the introduction of the laparoscope below the navel trocar (10–12 mm) into the peritoneal cavity, carbon dioxide gas was injected intraperitoneally to maintain a 12–14 mmHg intra-abdominal pressure, and three operating trocars (one 10–12 mm port and two 5 mm ports) were additionally inserted. In most cases a laparoscopic approach was

successful; however, in difficult cases with no progression via the laparoscopic approach, conversion to open surgery occurred. In the case of patients with concurrent COVID-19 infection, routine use of appropriate PPE for all operating theater staff was applied and procedures were carried out by senior, trained laparoscopic surgeons, in order to minimize operating time and potential of aerosolization. A closed circuit smoke evacuation / ultra-low particulate air (ULPA) filtration system were used to minimize possible aerosolization from port sites especially at the end of procedure, prior to specimen and port removal.

With regard to the COVID-19 management strategy, individuals were considered potential COVID-19 patients when they developed new continuous cough, temperature $\geq 37.8^{\circ}\text{C}$, and/or loss of, or change in, normal sense of smell (anosmia) or taste (ageusia). Individuals with any of the above symptoms who were well enough to remain in the community were asked to follow the stay-at-home guidance after confirmation through a PCR test. COVID-19-infected patients were admitted to the hospital in case of acute respiratory compromise, cardiovascular instability, COVID-19-related complications that cannot be managed in the community or secondary to concurrent unrelated medical or surgical emergency. Patients were placed in respiratory isolation or within a specified cohort bay as per the infection prevention and

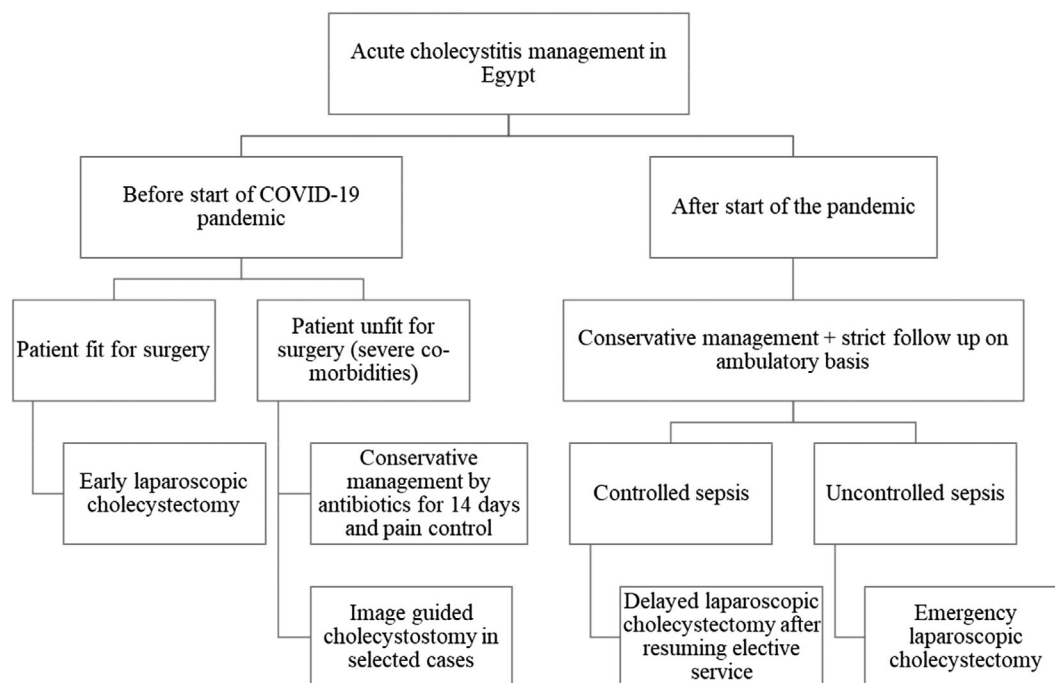


FIGURE 1 The treatment strategies for acute cholecystitis before and after the rise of the COVID-19 pandemic in Egypt. Patients were deemed unfit for surgery after strict cardiopulmonary, anesthetic assessment, and calculation of the surgical risk through NELA, P-possum scores and assessment of the functional capacity of each patient. Uncontrolled sepsis means persistent fever plus right upper quadrant pain and positive Murphy sign despite using antibiotics plus or minus tachycardia and/or hypotension

control guidance. Most of the surgical and medical wards were turned into COVID management bays with limited bed availability for other emergencies (green/clean areas). Patients were discharged after appropriate clinical assessment and provision of self-isolation advice until at least 14 d from their first positive test. If patients were febrile on discharge, they should extend their self-isolation until their fever had resolved for a consecutive 48-h period without any medication to reduce their fever.

3 | CLINICAL DATA

Clinical details at the time of surgery were collected from medical records and included: the surgical approach and intraoperative details, complications, and duration of hospital stay. Medical records were reviewed according to a predefined study protocol to ensure consistency and uniformity of data collection. The quality of the review was controlled with random validation by two independent researchers to avoid any bias from the authors regarding data collection or patient selection..

4 | OUTCOMES

The primary outcome was to compare and perform analysis of the two distinctive periods regarding: delayed presentation (time between the onset of symptoms till having the operation); the degree of operative difficulty, which was quantified by analyzing the operative time (knife to skin time till the last suture applied); blood loss; rate of drain insertion; and rate of conversion into open surgery. Furthermore, a detailed review of intraoperative findings was undertaken. Intraoperative findings deemed to be unfavorable included cases where inflammation of the gall bladder was subjectively judged to exceed the typical challenges where wall thickness ≥ 4 mm with extensive adhesion to surrounding organs was described to be challenging: cases of hydrops, empyema, gangrene, and/or perforation. The postoperative results were also analyzed, according to the length of hospital stay, and the occurrence of postoperative complications. All these complications were classified as per the Clavien–Dindo classification for postoperative complications.¹⁶

Surgical complications that occurred in the immediate postoperative period (14 d) included bile leak, organ injury (confirmed by CT scan), and missed stones (confirmed by postoperative rise of bilirubin and magnetic resonance cholangiopancreatography [MRCP] scan). Postoperative nonsurgical complications (secondary outcome) including sepsis based on a confirmed source: body temperature above 38.3°C or below 36.0°C and/or a

positive blood culture; lung atelectasis; and infections diagnosed by fever, cough, or pathological findings on chest X-ray; pulmonary embolism diagnosed by CT pulmonary angiography (CTPA), and requiring treatment; and finally, cardiac events such as arrhythmias and/or ischemic heart attack diagnosed by ECG .

5 | DATA ANALYSIS

Data of the patients were collected by a project coordinator who was responsible for contacting the surgical departments in all hospitals and filling the study proforma for each patient. All analyses were based on an a priori protocol and conducted by an expert biostatistician specialized in data analysis. Statistical analyses were performed using SPSS v. 25.0 (IBM, Armonk, NY) through independent sample *t*-tests. The statistical results were considered significant when $P < 0.05$. Variables that could be associated with both nonsurgical postoperative complications (secondary outcome), which are potential confounding factors, were prespecified and included in multivariable adjusted models: age (continuous variable), sex, and Charlson Co-morbidity Index score (0, 1, or at least 2). An additional model was created with the addition of Clavien–Dindo grade of complications. χ^2 and Fisher's exact test were used to assess the distribution of complications across surgical techniques with a 5% level of significance.

6 | RESULTS

The total number of patients included in the study was 458 before the COVID-19 era (Group I) and 311 after the start of the pandemic (Group II). Patient demographics are shown in Table 1. There was no significant difference in the Charlson Co-morbidity Index scores between the two groups. After the start of the pandemic, 389 patients presented to the Emergency Department with a confirmed diagnosis of acute cholecystitis. Intravenous antibiotics followed by oral switch was given as per the crisis approach and ultrasound-guided cholecystostomy was attempted afterwards in unresponsive patients. The radiologist failed to insert the drain in 59.8% due to unfavorable conditions such as extensive adhesions, contracted gall bladder, perforated and/or gangrenous gall bladder, and was able to safely insert the intracholecystic drain in the rest of the group. However, these measures failed to control the condition in 79.94% (311 patients/Group II). The average time of clinical presentation till operation was 2.21 d in Group I and 16.74 d in Group II ($P < 0.01$). Of the 311 patients (Group II), 13 patients (4.18%) had

TABLE 1 Patient characteristics, operative findings, and difficulty stratified by the two periods before and after the pandemic

	Before the pandemic era (n = 458)/Group I	During the pandemic (n = 311)/Group II	P value
Age (years)*	40.2 (18.7–64.6)	41.1 (17.6–69.1)	0.12
Sex ratio (F:M)	340: 118	208: 103	0.11
Charlson Co-morbidity Index score			
0	46.3%	44.7%	0.064
1	32.3%	31.8%	0.084
≥2	21.4%	23.5%	0.081
Onset of symptoms till operation (d)	2.21	16.74	0.007
Preoperative severity classification			
Mild (Grade I)	68.1%	0%	0.006
Moderate (Grade II)	30.8%	82.6%	0.013
Severe (Grade III)	1.1%	17.4%	0.003
Operative difficulty			
Operative time (min)	71.6	121.0	0.0082
Conversion into open surgery	5.89%	18.97%	0.032
Blood loss (>100 ml)	0%	16.7%	0.014
Drain insertion	8.95%	30.86%	0.008
Unfavorable intraoperative findings			
Extensive adhesions	8.95%	29.9%	0.043
Gangrenous cholecystitis	1.75%	9.0%	0.023
Perforated gall bladder	0.44%	3.5%	0.031
Hydrops of the gall bladder	1.1%	5.5%	0.018
Empyema of the gall bladder	1.53%	6.8%	0.027

Note: Values in parentheses are percentages unless indicated otherwise; values are *mean (range). Grade I (mild) acute cholecystitis does not meet the criteria of “Grade III” or “Grade II” acute cholecystitis. It can also be defined as acute cholecystitis in a healthy patient with no organ dysfunction and mild inflammatory changes in the gallbladder, making cholecystectomy a safe and low-risk operative procedure. Grade II (moderate) acute cholecystitis is associated with any one of the following: elevated WBC count (>18,000/mm³), palpable tender mass in the right upper abdominal quadrant, duration of complaints >72 h, marked local inflammation (gangrenous cholecystitis, pericholecystic abscess, hepatic abscess, biliary peritonitis, emphysematous cholecystitis). Grade III (Severe) acute cholecystitis means the presence of any one of the following criteria: hypotension requiring vasopressors, decreased level of consciousness, PaO₂/FiO₂ ratio < 300, oliguria, creatinine >2.0 mg/dl, PT-INR >1.5, and platelet count <100 000/mm³.

concurrent mild COVID-19 infection. The average number of hospital admissions secondary to COVID-19 was 5093 per month after the start of the pandemic, which was associated with a significant decrease in the number of performed laparoscopic cholecystectomies (Figure 2).

7 | SEVERITY OF ACUTE CHOLECYSTITIS

The preoperative severity was classified into mild, moderate, or severe according to the Tokyo guidelines (Table 1).¹⁷ In Group I, the majority presented with mild (Grade I) acute cholecystitis (312 patients/68.1%) and only five patients (1.1%) had severe (Grade III) acute cholecystitis. In Group II, initially 148 (47.6%) and 163 (52.4%) patients presented with

mild and moderate acute cholecystitis, respectively; however, after the initial conservative management, the inflammatory process progressed and in turn the severity score significantly worsened. The study showed that 257 (82.6%) and 54 patients (17.4%) developed moderate and severe acute cholecystitis, respectively. Of the 54 patients, 53 patients (17.04%) developed acute kidney injury (creatinine >2.0 mg/dl) and one patient (0.3%) developed both acute kidney injury as well as hypotension requiring vasopressors.

8 | OPERATIVE DIFFICULTY

The mean operative time before the pandemic was 71.6 min and it was statistically altered during COVID-19 at 121.0 using iterative statistics for continuous data identified

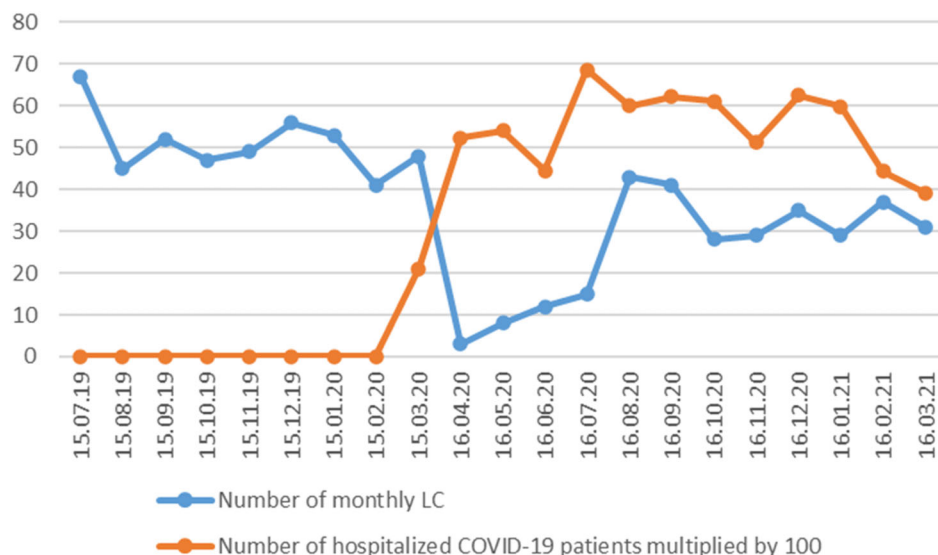


FIGURE 2 Changes in the numbers of monthly performed laparoscopic cholecystectomy (LC) in relation to rise in of COVID-related hospital admissions. As shown in the figure, after the start of the pandemic in the middle of March, the monthly number of performed laparoscopic cholecystectomy plummeted as a result of the crisis protocol (average number of monthly performed LC was 51). Failure of conservative management resulted in a rise in the number of emergency laparoscopic cholecystectomies (average number of monthly performed LC was 25). The average number of hospitalized COVID-19 patients secondary to COVID-related complication was 5093 patients monthly. Note that the number of hospitalized COVID-19 patients on chart is multiplied by 100

TABLE 2 Postoperative complications stratified by the two periods before and after the pandemic

	Before the pandemic era(n = 458)/ Group I	During the pandemic(n = 311)/ Group II	P value*
Clavien–Dindo grade			
I	1.3%	11.6%	—
II	6.3%	28.9%	—
IIIa	0%	6.4%	—
IIIb	0.21%	7.1%	—
IVa	0.44%	2.6%	—
IVb	0%	0%	—
Length of hospital stay (d)	2.6	13.5	0.013
Surgical complications			
Bile leak	0.32%	8.03%	0.006
Missed stones	0%	5.14%	0.004
Organ (Duodenal) injury	0%	0.96%	0.008
Nonsurgical complications			
Sepsis	1.1%	5.1%	0.033
Atelectasis	2.4%	10.3%	0.024
Pneumonia	1.5%	9.3%	0.031
Pulmonary embolism	0.4%	3.2%	0.024
Respiratory failure	0.4%	1.9%	0.05
Arrhythmia	1.3%	2.3%	0.72

Note: Values in parentheses are percentages. * χ^2 or Fisher's exact test.

(Table 1) ($P < 0.01$). In terms of conversion to open, while the figure was 5.89% before the pandemic era, the rate reached 18.97% during the pandemic ($P < 0.05$). Moreover, intraperitoneal drains were used in 8.95% before the pandemic, which almost tripled (30.86%) during the pandemic ($P < 0.01$). With respect to blood loss, considerable blood loss (attributed to a measured blood loss of >100 ml) occurred in 16.7%, with 1.28% needing further second-look laparotomy after 24 h during the pandemic, while no blood loss >100 ml was encountered in Group I ($P < 0.05$).

9 | UNFAVOURABLE INTRAOPERATIVE FINDINGS

Regarding intraoperative pathological findings, 8.95% and 29.9% exhibited extensive adhesions between the gall bladder and surrounding structures, such as: duodenum and/or transverse colon in addition to the dependent part of greater omentum in Groups I and II, respectively ($P < 0.05$). As regards complicated acute cholecystitis pathology, gangrenous (Figure 1), perforated gall bladder, hydrops, or empyema, they were 4.8% and 24.75% in Groups I and II, respectively ($P < 0.05$) (Table 1).

10 | POSTOPERATIVE OUTCOMES

As shown in Table 2, there was a significant difference in the length of hospital stay (LOS) between the two periods of the study, with longer hospital stay in Group II (average 13.5 d) ($P < 0.05$). The COVID-19 era depicted the highest rate of postoperative complications, with 8.03% developing bile leakage, 5.14% had missed duct stones that needed further intervention with endoscopic retrograde cholangiopancreatography (ERCP), and 0.96% developed duodenal injury (Figure 2). On the other hand, only 0.32% had a postoperative bile leak in Group I that needed further ERCP and ultrasound-guided drainage ($P < 0.01$). Nonsurgical postoperative complications again were higher in Group II and were more prevalent in cases with conversion to open surgery. Pulmonary complication rates were 6.11% and 19.6% in Groups I and II, respectively ($P < 0.05$). In Group II, 16.1% of patients had a complication with a Clavien–Dindo grade of IIIa or higher, compared with 0.6% in Group I (Table 2).

11 | DISCUSSION

In Egypt, the tertiary hospitals have improved the rate of rapid laparoscopic cholecystectomy throughout the pre COVID-19 period and the philosophical approach of cholecystectomy within 1 wk held sway during the

pandemic. Therefore, we aimed to assess the drastic effects of COVID-19 on the management of acute cholecystitis (the crisis approach) during this period. Patients were initially treated conservatively by antibiotics as per the International Hepato-Pancreato-Biliary Association, World Society of Emergency Surgery, British Society of Gastroenterologists, and the general consensus all over the world. However, as many did not respond well to medical treatment they were readmitted to have emergency laparoscopic cholecystectomy on a more delayed basis (average was 16.74 d). The effect of such delay resulted in a significant increase in the difficulties and complications during the intraoperative and postoperative periods. Our observations showed more challenging cholecystectomies in Group II, which can be reflected in the significant increase in the average operative time ($P < 0.01$) during the pandemic era. This can be directly related to the hostile intraoperative surgical field secondary to delayed surgical intervention. Another definitive evidence is the significantly higher rate of both conversion to open surgery and drain insertion ($P < 0.05$) secondary to operative difficulties, such as extensive adhesions, intraoperative blood loss, and/or complicated gall bladder pathologies such as perforated or gangrenous gall bladder (29.9%, 16.7%, and 24.8%, respectively, in Group II in comparison to 8.95%, 0%, and 4.82%, respectively, in Group I). Similar findings were mentioned by Choudhury et al and Sinha et al, as unfavorable pathology and difficult handling of the friable tissues that led to higher intraoperative risk and, in turn, a significant increase in blood loss and drain insertion.^{18,19}

As for postoperative results, the increase in hospital stay during the pandemic (to a mean of 13.5 d) in relation to before its start (2.6 d) depicts the result of an unsuccessful approach for management of acute cholecystitis. As a longer hospital stay would lead to a higher risk of COVID-19 and other nosocomial infection, while inpatient and significant decreases of the hospital capacity to accommodate patients in need of admission.

Dissecting in unfavorable conditions, secondary to delay, with a higher percentage of gangrenous cholecystitis and extensive adhesions, was more challenging. It was no surprise that our complication rate was higher in Group II, with 8.03% of the patients suffering from postoperative bile leakage, 5.14% developed missed bile duct stones, and 0.96% had duodenal injury. Similar results were shown by previous meta-analysis studies comparing the effect of a delayed surgical intervention.^{10,20} Also, the significantly higher incidence of nonsurgical postoperative complications, especially pulmonary complications and sepsis ($P > 0.05$) in Group II, was associated with an increased hospital stay and longer periods of antibiotic coverage in such patients. Furthermore, the Clavien–Dindo model showed a significant rise in the overall rate

of complications during the pandemic, leading to a significant burden to the patient and the healthcare system. These outcomes were directly related to the different management approaches after eliminating the effect of associated comorbidities (no significant difference between the two groups). Finally, as shown in similar recent studies, emergency cholecystectomy within a week would eliminate patients' readmissions with the same diagnosis, complications such as ascending cholangitis and/or pancreatitis, and decreases in the overall length of hospital stay. Moreover, emergency procedures were associated with overall fewer work-days lost, greater patient satisfaction, and better quality of life.^{17,21} During crisis periods, tough measures and decisions are made to deal with the situation; however, these decisions can lead to grave consequences on the medical staff and, most importantly, on patients. As shown in this study, and supported by the previous studies, conservative management of acute cholecystitis led to serious complications, as many patients were readmitted for emergency surgery as a result of failure of the nonsurgical approach. Moreover, delayed emergency surgery was associated with increased operative difficulties and a higher percentage of serious intra- and postoperative complications. All this led to longer hospital stays, which can prove the failure of this approach. The main purpose of the crisis approach was to avoid hospital admissions and increase the hospital capacity for COVID-19 patients and other patients in dire need of a hospital bed. Unfortunately, while closely studying acute gall bladder disease, we found that the crisis approach appears to have backfired and did the exact opposite. Looking into the future, there may be a need to a further cessation of services for a whole variety of reasons (including further waves of infectious disease) in our publicly funded health service. We believe that there is nothing to support conservative treatment of acute cholecystitis in our unit. We believe that the evidence as displayed suggests that rapid surgery provides the best outcome for individual patients and our system, perhaps especially when under strain for other reasons.

CONFLICT OF INTEREST

The authors do not have conflicts of interest.

ETHICS APPROVAL

Approval by the Ethical Committee and Institutional Review Board were obtained.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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