ESGE and ESGENA Position Statement on gastrointestinal endoscopy and the COVID-19 pandemic

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ABSTRACT
We are currently living in the throes of the COVID-19 pandemic that imposes a significant stress on health care providers and facilities. Europe is severely affected with an exponential increase in incident infections and deaths. The clinical manifestations of COVID-19 can be subtle, encom-
passing a broad spectrum from asymptomatic mild disease to severe respiratory illness. Health care professionals in endoscopy units are at increased risk of infection from COVID-19. Infection prevention and control has been shown to be dramatically effective in assuring the safety of both health care professionals and patients. The European Society of Gastrointestinal Endoscopy (www.esge.com) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (www.esgena.org) are joining forces to provide guidance during this pandemic to help assure the highest level of endoscopy care and protection against COVID-19 for both patients and endoscopy unit personnel. This guidance is based upon the best available evidence regarding assessment of risk during the current status of the pandemic and a consensus on which procedures to perform and the priorities on resumption. We appreciate the gaps in knowledge and evidence, especially on the proper strategy (ies) for the resumption of normal endoscopy practice during the upcoming phases and end of the pandemic and therefore a list of potential research questions is presented. New evidence may result in an updated statement.

Introduction

The outbreak of COVID-19 disease has spread from its original cluster in Hubei province, China [1, 2] throughout the world, and has been declared a pandemic by the World Health Organization [3]. Europe is severely affected with an exponential increase in the number of COVID-19 cases and deaths [4]. It has been estimated that approximately 10% of Health Care Professionals (HCP) have become COVID-19 positive in Western countries [5, 6]. The clinical manifestations of COVID-19 are varied, encompassing a broad spectrum from asymptomatic mild disease, to severe critical respiratory illness leading to respiratory failure, multiorgan failure and death [1, 2, 7–9]. Thus, high clinical suspicion and appropriate risk stratification of patients are needed.

HCP in endoscopy units are at increased risk of infection by COVID-19 from inhalation of airborne droplets, conjunctival contact, and potential fecal-oral transmission [2, 10]. Pneumococcal aerosolized infections have been reported, making upper GI endoscopy a high-risk procedure [11–17]. In addition, live virus has been found in patient stool [10, 18–20]. As a mechanism of entry, the angiotensin-converting enzyme II (ACE2) receptor, widely expressed in the intestinal tract [21], is likely used by the virus to enter human cells [2] making lower GI endoscopy procedures of uncertain risk status. Furthermore, infected HCP may transmit the infection to their colleagues, patients, families, and communities as hospital-based epidemics have been reported in European countries [22].

Infection prevention and control (IPC) has been shown to be dramatically effective in assuring the safety of both HCP and patients. This is not limited to the use of personal protective equipment (PPE), but is also based on a transparent and detailed IPC strategy, risk stratification of patients, correct use of PPE and interventions based on testing, separation and isolation of patients at high risk of COVID-19 [22–25].

Given the simultaneous COVID-19 outbreak in all European countries, a rational approach regarding limited resources is important [22, 26]. Shortages do not only apply to PPE, but also to the availability of hospital infrastructure including HCP staff, availability of beds (including ICU beds), and medical equipment such as ventilators. On the other hand, the need to protect the patient population, especially patients at high risk of COVID-19 morbidity, has forced Endoscopy Units to postpone a disproportionate number of procedures, weighing case-by-case the benefit of endoscopy with the risk of COVID-19 infection. A clear and thoughtful policy regarding the timely rescheduling of these postponed endoscopy procedures will be required.

The European Society of Gastrointestinal Endoscopy (www.esge.com) and the European Society of Gastroenterology and Endoscopy Nurses and Associates (www.esgena.com) have joined forces to provide guidance in order to assure the highest level of protection against COVID-19 for both patients and health care personnel. This position statement was first presented as an online statement March 18, 2020 (www.esge.com and www.esgena.com) and is now updated.

This ESGE-ESGENA Position Statement will provide guidance on 4 main topics:

1. How to perform gastrointestinal (GI) endoscopies during the COVID-19 viral pandemic?
2. Which GI endoscopy procedures should always be done? Which should be postponed?
3. How to protect GI endoscopy unit personnel during the pandemic?
4. What knowledge is currently missing and what is needed in this evolving field?

Methods

A PubMed/MEDLINE search was performed using ‘severe acute respiratory distress syndrome coronavirus 2’, ‘COVID-19’, ‘endoscopy’, ‘digestive system endoscopy’, ‘gastrointestinal endoscopic examination, therapy’ as MeSH terms. As our aim was to provide guidance rather than clinical recommendations, statements by international medical bodies such as the World Health Organization and the European and US Centers’ for Disease Prevention and Control were prioritized. Furthermore, the most recent guidance available to date issued by major gastroenterology societies was reviewed.

Guidance was grouped according to the three main phases of an endoscopic procedure, that is, pre-, intra- and post-procedure.

In order to define the proper timing of endoscopy according to clinical indication, between the 23rd and 25th of March 2020, the ESGE Governing Board addressed the main GI endoscopy
procedures, assigning them to predefined priority stratification groups and thereby differentiating between procedures that can be systematically performed or postponed, and those that must be assessed on a case-by-case basis weighing the trade-offs of the medical indication / necessity with the COVID-19 risks. Endoscopic procedures were assigned to a group if an agreement/consensus of ≥75% was reached. When agreement/consensus was not reached, the endoscopic procedure was recommended to be performed on a case-by-case basis.

All Governing Board members were also asked to vote on the level of priority for rescheduling postponed endoscopic procedures (high or low priority) and to assign every endoscopic procedure a proposed rescheduling time (in weeks).

Part I: How to perform gastrointestinal (GI) endoscopies during the COVID-19 viral pandemic

General comments

1. The entire staff of the endoscopy unit must be appropriately trained and informed on the IPC strategy for COVID-19 [22]. This should include potential sources of contamination, hygiene measures, COVID-19 risk factors, correct use of PPE, and interventions, such as separation, isolation and testing, for high-risk or infected patients.

2. Health Care Professionals (HCP) in endoscopy units should be triaged daily: staff should assess themselves according to potential risk factors, symptoms and signs (daily measurement of temperature). Those considered to be at high-risk of COVID-19 should be isolated and tested.

3. COVID-19 can effectively be inactivated by commonly used disinfectants having virucidal activity (EN 14885). Reprocessing of flexible endoscopes and endoscopic accessories should be performed according to published guidelines [28]. Reuse of any disposable GI endoscopic device is strongly discouraged. During reprocessing, mucosal surfaces must be protected as recommended [28]. Additional precautions should be taken in the reprocessing of equipment, such as FFP2/3 masks, after endoscopy in confirmed COVID-19 cases.

4. Each GI endoscopy unit should have a detailed plan for the cleaning and disinfecting of endoscopy procedure rooms [29]. Cleaning the endoscopy unit with virucidal agents is recommended as infection by contact is possible. This is mandatory after each case in patients at high-risk of or known infection with COVID-19 [29].

5. If feasible, online care should be provided (e.g. telemedicine). If this is to replace an outpatient clinic visit, audio and video transmission is preferred and formal documentation in the patient’s medical record should be performed.

6. Washing of hands with soap and warm water (for at least 20 seconds) or use of alcohol-based hand rub, before and after patient interactions, after contact with potentially infectious sources, and before and after gowning, should be done by all GI endoscopy unit personnel. Mobile phones, pens, computer workstations, and medical equipment should not be shared. Jewelry (watches, rings, bracelets) should not be worn by GI endoscopy unit HCP.
Pre-procedure Risk Management

1. Risk stratification of patients for possible COVID-19 infection should be done 1 day prior to GI endoscopy (by phone preferably) and then again on the day of endoscopy [13, 30, 31] by questioning for symptoms and contacts; or if / when available through tests for virus infection or immunity (► Fig. 1).
   - Please note that:
     • Given the current pandemic status of COVID-19 (April 2020), it may be reasonable according to the local situation, that all patients be considered at high-risk for COVID-19 infection and proper measures should be taken to protect HCP.
     • In the different phases of this pandemia, based on epidemiological factors, testing and potential immunity, patient risk stratification may be possible, converting previously high-risk patients to low-risk.

2. During patient assessment on the day of endoscopy, use of surgical masks is recommended for both the HCP and the patient and a distance of at least 1–2 metres is recommended, as well as the use of a physical barrier, such as glass or face-shield, if possible. Before entering the GI endoscopy unit, temperature measurement should be performed on all patients.

3. Relatives and caregivers should not have access to the GI endoscopy unit. If it is exceptionally required, they should undergo the same risk assessment as the patient.

4. For patients who are considered at high risk for COVID-19, separate pre- and post-GI endoscopy recovery areas (or timeslots) should be arranged.

5. Whenever possible, all patients entering the GI endoscopy unit should wear respiratory protective equipment (facial mask).

Intra-procedure risk management

1. During the current situation in most countries, only essential and fully trained endoscopy personnel should be present in endoscopy cases, all using a full set of PPE. Training programs should be adjusted during this phase, and the use of e-learning is to be encouraged.

2. According to the patient’s risk status, PPE should include gloves, hairnet, protective eyewear (goggles or face shield), waterproof gowns, booties/shoe covers, and respiratory protective equipment. High-filter respiratory masks (FFP2/3) and booties/shoe covers should be used for high-risk or infected cases [13, 22, 25] (► Table 2). Putting on and taking off PPE must be performed as recommended [32] – see also ESGENA-Poster www.esgena.org. In situations of limited availability of masks/respiratory protective equipment, a protective face shield is a useful alternative tool. Prolonged use of face masks/respiratory protective equipment of up to 4 hours is acceptable.

3. Although different GI endoscopic procedures may have different levels of risk, for the sake of simplicity and safety we recommend the same personal protection measures for all procedures, both upper or lower GI endoscopies [25, 33, 34].

4. Whenever possible, in patients who are considered to be at high risk or who are known to be positive for the COVID-19 virus, GI endoscopy should be performed only if medically indicated and if available, in a negative-pressure room by experienced staff [29]. If the only negative-pressure rooms are located outside the endoscopy unit, it must be ensured that these rooms are properly equipped for performing any GI endoscopy procedure. If negative-pressure rooms are not available, endoscopy should be performed in a dedicated room with adequate ventilation. All the other aforementioned protective measures should be taken and the risk of postponing endoscopy versus the risk of COVID-19 infection should be considered.

5. For patients in intensive care units (ICUs), GI endoscopy should be performed bedside.

<table>
<thead>
<tr>
<th>► Table 1</th>
<th>Risk stratification for potential COVID-19 infection in patients requiring gastrointestinal endoscopy.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-risk patient</td>
<td>No symptoms (eg, cough, fever, shortness of breath or diarrhea)</td>
</tr>
<tr>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td>No history of contact with COVID positive individual</td>
</tr>
<tr>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td>No travel or residence in a location reporting community transmission of COVID-19 during previous 14 days</td>
</tr>
<tr>
<td></td>
<td>Negative testing for COVID 19 (with adequate accuracy and proper epidemiological setting)</td>
</tr>
<tr>
<td>High-risk patient</td>
<td>Presence of symptoms with adequate sensitivity (eg, cough, fever, shortness of breath or diarrhea)</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>Travel or residence in a location reporting community transmission of COVID-19 during previous 14 days (eg, most European regions in April 2020)</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
<tr>
<td></td>
<td>Contact with COVID-19 positive (or very likely to be positive) individual</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>► Table 2</th>
<th>Health-professional personal protective equipment stratified by patient risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low-Risk Patient</td>
<td>High-risk or Positive patient</td>
</tr>
<tr>
<td>Surgical mask¹</td>
<td>Respiratory PPE (FFP2/FFP3 mask)²</td>
</tr>
<tr>
<td>Gloves³</td>
<td>Two pairs of gloves³</td>
</tr>
<tr>
<td>Booties/shoe covers</td>
<td>Booties/shoe covers</td>
</tr>
<tr>
<td>Disposable hairnet</td>
<td>Disposable hairnet</td>
</tr>
<tr>
<td>Protective eyewear (goggles or disposable face shield)</td>
<td>Protective eyewear (goggles or disposable face shield)</td>
</tr>
<tr>
<td>Water-proof disposable gowns⁴</td>
<td>Water-proof disposable gowns⁴</td>
</tr>
</tbody>
</table>

¹ DIN EN 14683:2019-6
² DIN EN 149:2001-10
³ DIN EN 420/DIN EN 374
⁴ DIN EN 14126:2004-01
Post-procedure risk management

1. Consider tracing and contacting patients at 7 and 14 days to inquire about any new COVID-19 diagnosis, or development of COVID-19 symptoms.
2. Contaminated waste and endoscopic devices from patients at high risk of or with suspected or confirmed COVID-19 should be disposed of using the specific local regulations related to high-risk waste management.

Part II:
Timing of endoscopy during the COVID-19 pandemic according to medical indication

1. GI endoscopy units should strongly consider temporarily postponing elective, non-urgent endoscopy procedures, based upon availability of local human resources and local policies that may depend on regional/national pandemic rules/regulations (Fig.1 and Fig.2)

2. The following list of GI endoscopy procedures should always be performed (Fig.2)
   - Acute upper/lower GI bleeding with hemodynamic instability
   - Capsule/enteroscopy for urgent/emergent bleeding
   - Anemia with hemodynamic instability
   - Foreign body in esophagus and/or high-risk foreign body in the stomach
   - Obstructive jaundice
   - Acute ascending cholangitis

3. During the current COVID-19 pandemic, the following list of GI endoscopy procedures should be postponed with no need to reschedule before 12 weeks (low priority) (Fig.2)
   - Surveillance for:
     - Barrett’s Esophagus without dysplasia or Low-Grade Dysplasia or after endoscopic treatment
     - Gastric atrophy/Intestinal Metaplasia
     - Inflammatory Bowel Disease
     - Primary Sclerosing Cholangitis
   - Post-endoscopic resection (including immediate endoscopy after resection), surgical resection of cancer or post-pyloroplasty surveillance
   - Diagnosis/surveillance of Lynch syndrome and other hereditary syndromes
   - Diagnosis of irritable Bowel Syndrome-like symptoms
   - Diagnosis of reflux disease, dyspepsia (no alarm symptoms)
   - Screening in high risk patients for esophageal cancer, gastric cancer, colon cancer (primary screening endoscopy) or pancreatic cancer
   - Bariatric GI endoscopy procedures (e.g., intra-gastric balloons, endoscopic sleeve gastropasty)

4. Each of the following GI endoscopy procedures warrant a case-by-case evaluation based upon medical necessity (Fig.2). In general, therapeutic endoscopic procedures or those affecting prognosis (and whenever further therapies can be assured), namely those that are cancer-related or severely symptomatic, should be ranked as “high-priority” (either to be performed immediately or postponed within 12 weeks). All others “low priority” may be either performed immediately or postponed to beyond 12 weeks on a case-by-case assessment.

High-priority endoscopy procedures
   - Endoscopic treatment of high-grade dysplasia (HGD) or early intra-mucosal cancer in the esophagus, stomach, or large colonic polyps at high-risk of submucosal invasion
   - Malignant stricture stenting
   - PEG/PEJ/NJ tube
   - Upper GI fistula/leakage
   - Dysphagia or dyspepsia with alarm symptoms present
   - Upper GI bleeding without hemodynamic instability
   - Rectal bleeding
   - Colonoscopy for melena after negative upper-GI endoscopy
   - Severe anemia with no hemodynamic instability
   - Tissue acquisition needed for the initiation of systemic therapy/surgery
   - Colonoscopy within organized FOBT + CRC screening programme
   - Foreign body in the stomach, low-risk
   - Benign stricture requiring dilation/stenting
   - Radiologic evidence of mass
   - Lymph node EUS sampling
   - Gallstone-related pancreatitis
   - Pancreatic mass/stricture
   - Biliary stricture dilation
   - Pancreatico-biliary stent replacement for non-urgent indication
   - Necrosectomy

Low-priority endoscopy procedures
   - Endoscopic treatment of esophageal or gastric low-grade dysplasia (LGD)
   - Duodenal polyp
   - Ampullectomy
   - Band ligation/non-emergency
   - Iron deficiency anemia
   - Pancreatic cyst (depending on risk features)
   - Biliary stricture/no urgency (no cholangitis, no jaundice, etc.)
   - Submucosal lesion EUS sampling
   - Achalasia (POEM, balloon dilation)
   - gFOBT/FIT + *(outside of an organized regional/national screening program)

Conclusion
The COVID-19 pandemic is having a disruptive effect on the workflow and safety of GI-endoscopy units worldwide. Most GI endoscopy units in Europe are having to manage the current s-
Perform always

- Acute upper/lower GI bleeding with hemodynamic instability
- Capsule/enteroscopy for urgent/emergent bleeding
- Anemia with hemodynamic instability
- Foreign body in esophagus and/or high-risk foreign body in the stomach
- Obstructive jaundice
- Acute ascending cholangitis

Case by case management – high priority

- Endoscopic treatment of high-grade dysplasia (HGD) or early intra-mucosal cancer in the esophagus, stomach, or large colonic polyps at high-risk of submucosal invasion
- Malignant stricture stenting
- PEG/PEJ/NJ tube
- Upper GI fistula/leakage
- Dysphagia or dyspepsia with alarm symptoms present
- Upper GI bleeding without hemodynamic instability
- Rectal bleeding
- Colonoscopy for melena after negative upper-GI endoscopy
- Severe anemia with no hemodynamic instability
- Tissue acquisition needed for the initiation of systemic therapy/surgery
- Colonoscopy within organized FOBT+ CRC screening programme
- Foreign body in the stomach, low-risk
- Benign stricture requiring dilation/stenting
- Radiologic evidence of mass
- Lymph node EUS sampling
- Gallstone-related pancreatitis
- Pancreatic mass/stricture
- Biliary stricture dilation
- Pancreateco-biliary stent replacement for non-urgent indication
- Necrosectomy

Case by case management – low priority

- Endoscopic treatment of esophageal or gastric low-grade dysplasia (LGD)
- Duodenal polyp
- Ampullectomy
- Band ligation/non-emergency
- Iron deficiency anemia
- Pancreatic cyst (depending on risk features)
- Biliary stricture/no urgency (no cholangitis, no jaundice, etc.)
- Submucosal lesion EUS sampling
- Achalasia (POEM, balloon dilation)
- gFOBT/FIT+ (outside of an organized regional/national screening program)

Postpone always

- Surveillance for
  - Barrett’s Esophagus without dysplasia or Low-Grade Dysplasia or after endoscopic treatment
  - Gastric atrophy/Intestinal Metaplasia
  - Inflammatory Bowel Disease
  - Primary Sclerosing Cholangitis
- Post-endoscopic resection (including immediate endoscopy after resection), surgical resection of cancer or post-polypectomy surveillance
- Diagnosis/surveillance of Lynch syndrome and other hereditary syndromes
- Diagnosis of Irritable Bowel Syndrome-like symptoms
- Diagnosis of reflux disease, dyspepsia (no alarm symptoms)
- Screening in high risk patients for esophageal cancer, gastric cancer, colon cancer (primary screening endoscopy) or pancreatic cancer
- Bariatric GI endoscopy procedures (e.g., intra-gastric balloons, endoscopic sleeve gastroplasty)

Fig. 2 List of indications for endoscopic procedures according to rescheduling recommendations and priority.
How to consider the lingering effects of COVID-19 during the coming months/years in our endoscopy practice?

What are the financial consequences of the COVID-19 outbreak for the endoscopy unit?

What is the burden in terms of cancer progression of delaying GI endoscopy unit staff?

What are the financial consequences of the COVID-19 outbreak for the endoscopy unit?

How did COVID-19 affect the endoscopy unit’s workflow?

How to take care of the psychological well-being of the GI endoscopy unit staff?

How did COVID-19 affect fellows?

How did COVID-19 affect the endoscopy unit during and after this pandemic (order to clarify the overall burden of COVID-19 on our GI endoscopy practice)?

Table 3: Suggested Research Agenda

<table>
<thead>
<tr>
<th>Infection and workflow/unit/staff</th>
</tr>
</thead>
<tbody>
<tr>
<td>- How to consider the lingering effects of COVID-19 during the coming months/years in our endoscopy practice?</td>
</tr>
<tr>
<td>- When and how should a patient suspected of having COVID-19 be tested in relation to performance of a GI endoscopy procedure?</td>
</tr>
<tr>
<td>- How often, or if at all, should medical staff/endoscopy staff be tested for COVID-19 and by which methods?</td>
</tr>
<tr>
<td>- How did COVID-19 affect the endoscopy unit’s workflow?</td>
</tr>
<tr>
<td>- How to prioritize postponed GI endoscopy procedures after the pandemic is over?</td>
</tr>
<tr>
<td>- What are the “acceptable” waiting times, stratified by the type of GI endoscopy procedure?</td>
</tr>
</tbody>
</table>

Procedural protection

- Is there any difference in COVID-19 transmission risk between upper and lower GI endoscopy?
- Is oral and/or fecal transmission a true/equal hazard?
- Which are the fundamental PPEs that are required and how to confront their shortages?
- What is the difference in using a FFP2 vs two surgical masks vs one surgical mask on infection risk?

Rescheduling and disease risk

- What is the burden in terms of cancer progression of delaying GI endoscopy procedures due to the COVID-19 pandemic?
- How did you organize the GI endoscopy care for patients?
- How to prioritize postponed GI endoscopy procedures after the pandemic is over?
- What are the “acceptable” waiting times, stratified by the type of GI endoscopy procedure?

We also believe that further research is urgently needed in order to clarify the overall burden of COVID-19 on our GI endoscopy units but also in relation to how to effectively run endoscopic units during and after this pandemic (Table 3).

Competing interests

I. M. Gralnek has received lecture fees from Astra-Zeneca, Taro Pharma, Vifor Pharma and 3D Matrix (ongoing); consultant fees from Boston Scientific, GI view, MotusGI and Symbionix (ongoing); and is DSMB Member by Intec Pharma, MAB member by Motus GI. J. E. van Hooft has received lecture fees from Medtronic (2014–2015) and Cook Medical (2019), and consultancy fees from Boston Scientific (2014–2017); her department has received research grants from Cook Medical (2014–2019) and Abbott (2014–2017). M. Kaminski has received lecture fees from Boston Scientific (2018–ongoing) and consultancy fees from Olympus and Fujifilm (2018–ongoing). P. D. Sierssema has received research grants from Norgine, Pentax, Microtech, Yakult and Motus GI (ongoing) and is on the Advisory Board of Motus GI. C. Antonelli, M. Dénis-Ribeiro have no competing interest.

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Position statement


