

Letter To Editor

Application of Practice Ambulatory Digestive Endoscopy Protocols During the Covid-19 Pandemic. how we are doing in Real Life.

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Abstract

In Colombia, since March 2020, when the first case of SARS COV-2 was identified, normal functioning of health systems was affected, including gastroenterology and digestive endoscopy units. As majority of countries, mandatory confinement with suspension of outpatient diagnostic procedures was implemented, initially during seven weeks. Outpatient gastroenterology units remained closed and had to adapt physically and logistically to be able to perform endoscopic procedures to patients with relevant symptoms for whom endoscopic procedures could have an impact on the prognosis and outcomes in medium and short term intime-sensitive diseases. Experience shared by countries previously affected from December 2019 to April 2020 and the development of guidelines and recommendations by different scientific societies were invaluable resources for countries just starting with the pandemic. Remote consulting, application of scales to filter, prioritize and ponder cases based on clinical criteria through adequate planning has been the basis of our endoscopy unit for responding to the challenges generated within a complex and unpredictable scenario such as current one. Keywords: sars-cov-2; covid-19; endoscopy; quality; safety; sedation

Introduction

The pandemic declared by the World Health Organization [1] (WHO) on March 11, 2020 by the new coronavirus (SARS-Cov-2) and that causes the Coronavirus Disease 2019 (COVID-19) required the adaptation of health systems worldwide to avoid its collapse. The functioning of gastroenterology and endoscopy units was particularly affected by the possible infection transmission attributed to the aerosols during endoscopic procedures, the detection of viral particles in feces and initially by the suspicion of transmission through endoscopy equipment, which was finally discarded recognizing that the rigorous cleaning and disinfection of the equipment is sufficient to avoid this risk.

In Colombia, the national government decreed mandatory quarantine with successive extensions from March 2020 in seeking to delay the rapid rise of cases. During a first absolute quarantine (7 weeks), only urgent procedures could be performed at the hospital level, causing the holding back of patients requiring outpatient endoscopic procedures. In May, reopening was allowed, without specifying for how long. This situation made it essential for the provision of **outpatient services** to determine how, when and which patients would be treated, in what order, how exposure to risk would be controlled so as not to outweigh the benefit, and how available resources would be used optimally. Delaying diagnosis in **time-sensitive pathology** in a country as Colombia, where colon and gastric cancer are among the top five in prevalence, incidence and mortality [2], along with the impact on clinical outcomes that an early and timely diagnosis could have, were sufficient reasons for our unit - **EMDIAGNOSTICA** - developed a **comprehensive**

action plan that would allow the performance of outpatient urgent and elective and determining their scheduling according to endoscopic procedures. Early in March, remote consulting the behavior of local epidemiological curves of COVID-19. This modality was established, together with the application of scales document was the basis for the establishment of contingency to filter, prioritize and ponder cases based on clinical criteria with measures in EMDIAGNOSTICA. a careful planning of the expenditure was the basis to respond to the challenges generated. On this scenario EMDIAGNOSTICA in Shortly thereafter, ASGE [14,15] published guidelines for Bogota-Colombia, developed an action plan, published in the Colombian Journal of Gastroenterology (Rev Col Gastroenterol. Bogotá.2020; 35(3):287-297) [3] with protocols, processes, and procedures that made it possible to respond to the contingency in patients, room preparation, appropriate use of PPE, reprocessing a planned and orderly manner applicable to all phases of the of equipment, post-procedure follow-up, and classified pandemic. A multidisciplinary group of professionals (gastroenterologists, anesthesiologists, lawyers, nurses, and financial advisors) participated in the plan, which finally wrote a series of recommendations to return to the provision of services In May, the World Endoscopy Organization [18] called attention based on a scheme of logistical and physical infrastructure adaptations, objective prioritization of procedures, adjustments to the importance of recognizing the benefit over the risk in the availability of supplies (including availability of personal protective equipment (PPE)), and a possible shortage of analgesics and sedatives; always maintaining the internationally procedures, differentiating an elective procedure from one that is recommended quality standards for upper endoscopy, not indicated. colonoscopy and sedation.[4,5,6]

Experience shared by affected countries from December 2019 to April 2020 along with national and international guidelines to define whether a procedure is time-sensitive and therefore and recommendations [7,8,9,10,11,12,13,14,15,16,17] were invaluable resources for countries as we began to experience the pandemic. Scientific societies worldwide made great and generous efforts to unify criteria, focusing especially on diagnostic procedures at intrahospital environment, establishing guidelines and protocols to define those who should perform such procedures, giving priority to those classified as urgent. However pandemic lasted beyond any established planning while the emergency services were overwhelmed, patients refused to attend the emergency department and waiting time to reach the "new normal" was prolonged.

Repici and cols [16] at the beginning of 2020 published recommendations for hospital safe operation of endoscopy units, with emphasis on personal protection elements, individual COVID-19 risk of patients and prevention of spread of infection. In March 2020, the Canadian Gastroenterological Association drafted guidelines [7].to reduce and delay the transmission of COVID-19. These guidelines classified all high endoscopic procedures as high risk for the spread of the virus regardless of the patient's individual risk, insisting on the need to classify the protective measures are routinely applied in all cases. procedure to be performed as essential or not.

GI Society Message [8] setting for recommendations to adjusted according to the recommendations of Cennamo et al [17]. scheduling non-urgent elective procedures, taking into account ensuring adequate ventilation, availability of negative pressure, priority, such as screening for suspected cancer, need for HEPA filters and sufficient air changes (15 per hour). Common prosthesis removal, and assessment of relevant symptoms. areas and work cubicles were demarcated with warning lines Thompson [9] described strategies for an orderly step-by-step according to the degree of exposure to drops and aerosols and safe approach and classified non-urgent procedures into those to areas were established for posture and removal of PPE. perform and those to postpone, highlighting the relevance of Since March, the gastroenterology clinic is carried out by telemedicine to the success of these strategies.

APSDE [13] published perhaps one of the most important position statements establishing strategies for pre-selection and filtering of patients, classifying endoscopic procedures as urgent, semi-

reopening endoscopy units after the COVID-19 pandemic aiming to decrease the risk of infection during a gradual reopening. It established strategies for estimating the risk of infection in procedures in urgent, semi-urgent, and elective, considering comorbidities and establishing activities in every step of the process.

to the potential danger of delaying diagnosis in some patients and performing endoscopic procedures. Additionally, it highlighted the importance of strict follow-up for patients with deferred

The AGA[19] issued recommendations for gastrointestinal procedures during the pandemic in August, emphasizing the need whether its cancellation could significantly affect the prognosis or progression of the disease; it also established an 8-week maximum period in which such procedures should be performed.

The action plan in force in EMDIAGNÓSTICA since April 2020, considered first a risk estimation for the assistance and administrative personnel of the unit, which allowed to divide the work group in two, one for face-to-face activity in the physical plant and another for assistance in teleworking. Additionally, in order to limit the exposure of the members of the on-site group, this group was divided into two subgroups for the rotating provision of services. Multiple virtual meetings were held for education on posture and withdrawal of PPE and the continuous availability of these elements was guaranteed.

Educational videos and guides for patients are available on our website www.emdiagnostica.com. All the documents generated or adapted for the contingency are summarized in TABLE 1. Due to the high percentage of asymptomatic patients, it was agreed to consider all of them as suspects of active infection and therefore

In March, AASLD, ACG, AGA, and ASGE published the Joint In order to modulate the risk of infection the physical plant was

telemedicine modality, determining which patients require faceto-face attention and establishing the relevance of performing diagnostic endoscopic procedures and prioritizing them according to the criteria defined in TABLE 2 and FIGURES 1 and 2. Procedures scheduling is based on the gastroenterologist's

presence of alarm symptoms and the risk/benefit balance during elastomeric masks. The external anti-fluid gown is removed in a the pandemic. In addition, the possibility of reducing hospital specific area of the unit and a new gown is always used with each overload by relaxing the criteria for performing endoscopic patient. procedures at the outpatient level for specific situations such as elderly patients with controlled comorbidity, hemodynamic In all procedures, the plastic barrier described by Dr. Luis Carlos stability, and the presence of melena in the context of overuse Sabbagh [21] is used to isolate the patient from the care staff. The hospitals has been taken into consideration.

During rising phase in the epidemiological curve, three priority " P" groups were established; Priority-1, those that in the opinion their characteristics, the local occupation of ICU and individual of the gastroenterologist needed to be done in the two weeks following the consultation, **Priority-2**, to be done between weeks 3 and 4, and Priority-3, to be done between weeks 5 and 8, Endoscopic procedures in the unit are performed under sedation according to the criteria listed in FIGURE 1. It was established administered by anesthesiologists. Before the pandemic it was that during curve fall, "D", necessary diagnostic procedures usual to keep patients in a level II sedation according to the would be performed in symptomatic patients with risk factors, Practice Guidelines for Sedation and Analgesia by nonpreviously postponed high-risk screening and cancer follow-up Anesthesiologist classification [22], but considering the need to for whom the risk of delaying the procedure was unacceptable. decrease the risk of droplet and aerosol emission (cough reflex) Also included were patients in whom the procedure was during the crycopharyngeal pass, it was decided to administer the indispensable for taking on actions by other specialties. In the conventionally used drugs until a higher degree of sedation was normalization stage, "N", the diagnostic procedures considered achieved by adjusting the doses accordingly: Remifentanil (0.4 necessary in patients without risk factors, the follow-up of low- 0.5 mcg/kg) and Propofol (1.5 - 2.5 mg/Kg). To mitigate the effect risk lesions or those that allow wide follow-up margins in time, of apnea on desaturation and hypoxemia, the routine and the procedures for average risk screening were added. administration of oxygen by nasal cannula at 2 - 3 L/min oxygen (TABLE 2, FIGURES 1 and 2). With regard to colonoscopies for 3 minutes (below the isolation barrier) was protocolized. The performed by fecal positive occult blood, the AGA patient is always motivated to breathe his vital capacity in each recommendation was followed: however, after the recommended 6 months, it was considered that the colonoscopy should be by desaturation (SpO2 less than 90%) it was established as a plan performed from within group D after a discussion and of action to increase the oxygen flow to 5 L/min and perform individualization of the risk with the patient.

the case for endoscopy or colonoscopy) each patient is contacted by telephone to re-classify his or her risk and define the execution or postponement of the procedure. In case there is any doubt about care staff. the scheduling of the procedure or when it is postponed, the patient is scheduled for a remote consultation. By means of virtual care, in addition to defining the indication and timing of the procedure, the level of care during the pandemic is established using an adaptation of the **MENTS** scale published by Prachand et al.[20] to be applied in the scenario of ambulatory endoscopic procedures, named by us as MENTS-ENDOGI (FIGURE 3), of up to 45 points. For higher values, the recommendation was to refer the patient to an in-hospital level.

and disinfection of the area before each patient's admission. Progressively, during the curve's descent phase and when government guidelines allowed it, the use of the installed capacity ascent was resumed.

The healthcare and administrative personnel involved in patient care always use a complete PPE endorsed and provided by the

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criteria according to the diagnostic probability of cancer, the institution without allowing the use of external items, including

registration of quality indicators for the endoscopic procedure in the roadmap and verification of processes is always diligent and the resection of lesions (polyps) found is performed depending on risk

ventilatory cycle. In cases where the apnea could be accompanied airway permeability maneuvers. To date, only 0.04% of the cases have required oxygen administration by face mask with a four-Between 24 and 48 hours prior to the procedure (depending on handed airtight seal technique. No patient has required endotracheal intubation and 100% of the procedures have been successfully performed without compromising the safety of the

Since September 2020 and as a consequence of a substantial increase in the number of active cases of COVID-19 associated with a high occupation of ICUs, Colombia has experienced a relative lack of analgesic and sedative medicines. This forced the application of new pharmacological strategies for sedation. Currently, the unit uses a sedation scheme with Fentanyl (0.2 - 0.3 establishing the safety of the ambulatory environment for a value mcg/Kg + Ketamine (0.1 - 0.2 mg/Kg) + Propofol (0.5 - 1 mg/Kg), which has maintained the quality of the sedation, the safety of the care staff and incidentally a shorter recovery time, less incidence of desaturation and less hemodynamic impact with During the rising phase of the COVID-19 curve, we program changes in heart rate and blood pressure parameters not exceeding alternately in each of the three available rooms using a maximum 3% of the baseline data of each patient have been found. These of 30% of the installed capacity, allowing ventilation, cleaning measures allow us to continue offering the sedation service using pharmacological resources in an optimal and responsible way.

All patients have been **followed** by telephone after the procedure was increased to 60% and now, since a new ascent phase was to evaluate the appearance of symptoms or diagnosis of COVIDpresented towards a new peak of the COVID-19 curve with an 19 at 7 to 14 days and complications after polypectomy between ICU occupation higher than 85%, the strategy for the curve's 12 - 48 hours. A survey on the degree of satisfaction and the perception of security during their stay in the unit is routinely applied to all telephone contacts with the patient.

Patients whose endoscopic procedures have been postponed have

been monitored by remote assistance, establishing the best time current one. for their performance by reclassifying them to P1, P2 or P3 due to the appearance of alarm symptoms or persistent symptoms despite treatment. Our staff meets on average every 2 weeks to evaluate and socialize results.

From May 11 to December 31, 2020, 3628 endoscopic procedures had been performed at EMDIAGNOSTICA. Eleven patients (0.30%) during follow-up reported symptoms that required ruling out COVID-19, confirming 5 positive cases (0.14%) that required only outpatient treatment; in 3 of these cases there was previous contact with positive cases for COVID-19 not reported by the patient, 1 worked as a pharmacy staff and the other had no known epidemiological risk factor. In none of the cases there was an associated outbreak among EMDIAGNOSTICA care or administrative personnel.

We are currently in the tenth month of the evolution of the COVID-19 pandemic in Colombia, in a new reality that deeply impacted the practice of ambulatory digestive endoscopy. The follow-up of the regulations and guidelines of the different scientific societies allowed us to restart and continue the assistance activity. Continuing with the provision of outpatient services, prioritizing non-urgent but time-sensitive procedures, is indispensable since early and timely diagnosis, clinical intervention on the diagnoses made, resolution of pathologies with therapeutic procedures by endoscopic or surgical means, and risk stratification have a significant impact on the prognosis of the disease and on the medium and long-term outcomes with benefits on the quality of life of patients, being able to access these services in a timely and safe manner, reducing anxiety and uncertainty. In addition, outpatient digestive endoscopy units contribute to decrease the demand for hospital care by maintaining timely coverage and access for patients who feel less exposed in the outpatient units. Follow-up surveys have shown a high degree of satisfaction and biosafety protocols have guaranteed the safety of care especially in the prevention of COVID-19 infection during digestive endoscopy procedures.

The prioritization scales and the application of the MENTS scale adapted to endoscopy (MENTS-ENDOGI) have been important to define which patients to schedule, when and where. Systematic records, patient follow-up, measures to reduce infection, diagnoses achieved, and new aspects related to medical legal liability are issues to be considered in future adjustments.

The shortage of medicines, especially those for sedation, resulting from their high demand in intensive care units worldwide was another challenge for the practice of digestive endoscopy requiring the adaptation of new sedation protocols. The results of the application of our new sedation protocol and the diagnostic data obtained according to the prioritization have been collected and will be socialized in future EMDIAGNOSTICA publications that will be presented as original paper.

The economic aspects (higher costs with fewer procedures) could come to threaten the stability of the institutions so objective strategies to filter, prioritize and balance the cases based on clinical criteria with a fair planning of expenditure have never been so important in a complex and unpredictable scenario as the

Pandemic Long duration, requirement of safety measures that can be exhausting, use of personal protection elements that require specific protocols for their adequate use, fear of getting sick, among other factors, increase possibility of development of burnout syndrome in health personnel, which has serious consequences as worker as patients. Dimitriuet [23] al found an average of 76% burnout in residents, particularly those under 35 years of age. Adequate organization of endoscopy units and good communication of the entire work team are necessary strategies to improve the perception of safety of health care workers and decrease the risk of burnout syndrome.

The COVID 19 pandemic has been a challenge to optimize the maximum available resources in all areas of health. Leadership, teamwork and the generosity of the global scientific community are fundamental elements in the search for solutions applicable to an unpredictable and variable scenario. It remains to be hoped that the initiation of vaccination will progressively return to normal care as the COVID 19 pandemic is brought under control.

Documents adapted, modified, or created for start-up in a pandemic era.
COVID-19 Patient Training Booklet
Informed consent for endoscopic procedures (Endoscopy, Colonoscopy, Polypectomy)
Informed consent for face-to-face consultation.
Informed consent for remote consulting
Informed Consent to Sedation.
Informed consent for escort.
COVID-19 Health and Risk Statement for Patients, Escorts, Providers, Clients, Administrative and Care Staff
Management system and safety at work.
Route map and process verification.
COVID-19 Biosafety Manual, checklist and contingency measures
COVID-19 Sedation Note
Note for face-to-face consultation and procedures
Procedure and checklist for scheduling endoscopic procedures in patients with semi-urgent and priority indications.
Procedure and checklist for scheduling a face-to-face visit during a pandemic
COVID-19 Sedation Procedure

Table 1: Documents adapted, modified, or created for start-up in a pandemic era.

* List of EMDIAGNÓSTICA institutional documents that were adapted, modified and/or edited to fit the COVID-19 scenario. It details the information provided to patients, the informed consent forms, the organizational documents of safety and health at work, the protocols created to guide medical care, the format of minimum information recorded in the clinical notes of gastroenterology and anesthesiology, checklists and roadmaps.

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Pandemic COVID-19 Endoscopy Scheduling with PPE Complete Availability			
Behavior of COVID-19 in the community	Endoscopy service offering	Strategy	Average time per room
Exponential increase of new cases	None		
Rapid (non- exponential) increase in new cases	_ Performing time- sensitive procedures - Postpone elective endoscopies	- Prioritization 1, 2 and 3	- 1 hour
Declining trend in new cases	- Perform time- sensitive procedures -Start elective procedures	-Priorization 1, 2 and 3 -Diagnosis in patients with risk factors - High risk screening -Cancer follow-up -Necessary to take action for other specialties	40 minutes
No new cases diagnosed in the last 2 weeks	- Normalization	-Adding necessary diagnostic procedures without risk factors. -Follow up low grade lesions - Average risk screening	- 30 minutos

Table 2: Strategy for categorizing and prioritizing endoscopic

 procedures during a SARS-CoV-2 pandemic

* Strategies used to define the scheduling and performance of diagnostic endoscopic procedures during the COVID-19 pandemic with full availability of PPE and considering the behavior of the local epidemiological curve based on the AGA institute rapid recommendations for gastrointestinal procedures during the COVID-19 pandemic 19 and APSDE (Practice of endoscopy during COVID-19 pandemic: Position statements of the Asia Pacific Society for digestive endoscopy (APSDE-COVID statements).



D: Descending. Diagnostic procedures in patients with risk factors. High risk screening. Cancer followup. Necessary to take care of other specialties.

N: Normalization. Necessary diagnostic procedures in patients without risk factors. Average risk screening. Follow-up of low grade or wide range of follow-up injuries.

Figure: Scheduling of diagnostic endoscopic procedures according to covid curve





* Flow chart of processes carried out by EMDIAGNOSTICA to determine the priority with which diagnostic endoscopic studies should be carried out in an outpatient setting during the ascent of the Covid-19 epidemiological curve. The decision to schedule a procedure or not falls on the judicious clinical evaluation and the determination of the relevance of the study during the period of the COVID-19 pandemic. The estimation of the MeNTS-ENDOGI score is also taken into consideration.



A. Format to fill out

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B. Programmable Endoscopic Procedure



C. Non-Programmable Endoscopic Procedure

* Representative diagrams of the MeNTS-ENDOGI scale applied by EMDIAGNOSTICA SAS This scale is an adaptation of the original MeNTS model by Prachand et al. (Medically Necessary, Time-Sensitive Procedures: Scoring System to Ethically and Efficiently Manage Resource Scarcity and Provider Risk During the COVID-19 Pandemic). Panel A shows the blank format, prior to completion. Panel B shows the result of applying the MeNTS-ENDOGI scale to a patient with low risk of complications and dissemination of COVID-19 who can be scheduled for an outpatient procedure. Finally, panel C corresponds to a patient that due to its risk factors (clinical and dissemination of COVID-19 infection) cannot be scheduled as an outpatient procedure. The two cases described are simulated scenarios and do not represent information from real patients. EMDIAGNOSTICA assumed a 45-point cut-off point to define whether the procedure could be performed in an outpatient or inpatient setting.

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