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EDITORIAL

The role of COVID-19 symptom and exposure screening and SARS-CoV-2 nucleic acid amplification testing in risk stratification before endoscopy

The coronavirus disease 2019 (COVID-19) pandemic upended the world order and disrupted social, medical, and economic life across the globe. It paused a series of time-sensitive challenges for the international medical community, whose members leveraged existing and emerging technology to tackle them head on. Despite the immense suffering and loss of life, this period also witnessed astonishing medical breakthroughs, including the fastest time to vaccine creation in the history of medicine. Intravenous and eventually oral treatments were also discovered and commercialized in the United States. However, with the ability to mutate, successive virus variants continue to evade those treatments, leading to surges in rates of positive test results, hospitalizations, and mortality.

As such, one of the very important questions in healthcare delivery and care access is how to balance the safety of patients and medical providers against the need to perform invasive medical procedures, both emergent and elective. For gastroenterologists, this balance is most apparent in the decision and process of performing outpatient procedures, which were almost brought to a halt in the early days of the pandemic.[1] In the United States, the different GI societies published guidance and position statements to help in this delicate process.[2-4] There is unanimous agreement on the recommendation of symptom screening before outpatient procedures.[2-4] However, conflicting guidance is given regarding nucleic acid testing. Whereas the American Society for Gastrointestinal Endoscopy (ASGE) and the American College of Gastroenterology recommend testing,[2,3] the American Gastroenterological Association recommends against it.[4]

In this issue of *Gastrointestinal Endoscopy*, Gawron et al[5] used of the Veterans Affairs (VA) database and established several important points to help resolve this disagreement. The VA is the largest integrated healthcare system in the United States. It is composed of 170 medical facilities and 1074 outpatient sites. All veterans undergoing outpatient upper endoscopy or colonoscopy from March 18, 2020, through April 30, 2021, were included. The primary outcome was to describe the real-world results from a strategy of pre-endoscopy COVID-19 symptom and exposure screening and severe acute respiratory syndrome—coronavirus-2 (SARS-CoV-2) nucleic acid amplification testing (NAAT). The secondary outcomes were prevalence of asymptomatic infections among patients undergoing endoscopy, the sensitivity and specificity of COVID-19 screening, and the use of pre-endoscopy SARS-CoV-2 NAAT testing across the system and its association with endoscopy procedure volumes. A total of 220,891 completed outpatient endoscopies and 131,894 cancelled appointments were included. Of the completed endoscopies, 52.5% and 69.8% had documented preprocedure COVID-19 screening and preprocedure NAAT results, respectively. Of the cancelled appointments, 20.1% and 21.6% had documented COVID-19 screening and NAAT, respectively. The rate of positive screening results was higher among cancelled procedures than among completed procedures (11.4% vs 1.7%). The same was true for NAAT positivity rates (10.1% vs 0.3%). Taking NAAT as standard, COVID-19 symptom and exposure screening had a sensitivity of 34.6%, a specificity of 96.4%, a positive predictive value of 15.0%, and a negative predictive value of 98.7%. Testing volume reached a peak in March 2021, with 21,136 NAATs performed. The proportion of positive NAAT results per month ranged from 0.5% in June 2020 to a high of 3.7% in January 2021. There was a very weak correlation between monthly testing and monthly endoscopy volume by site (Spearman rank correlation coefficient = 0.09).

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Despite the methodologic limitations that are inherent to administrative database analysis studies, the data provided by Gawron et al[5] help further our understanding of the role of NAAT and COVID-19 symptoms and exposure

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screening in the risk stratification of pre-endoscopic patient. Several findings deserve attention and deeper analysis. First, the very high COVID-19 screening specificity and negative predictive value make it a very good readily implementable and cheap tool to exclude the presence of COVID-19 infection. It also minimizes the incremental benefit of NAAT in this setting. However, the low sensitivity and positive predictive value necessitate that any positive result be confirmed with NAAT to avoid unnecessary procedure cancellations. Given that the NAAT results can take ≤72 hours to be available, rapid tests can be used instead. Alternatively, screening can take place 3 days before endoscopy instead of on the day of endoscopy. Both approaches have limitations, namely, lower sensitivity for the former and change in exposure status for the latter. Second, it is good to know that NAAT and COVID-19 screening do not affect the monthly procedure volume. Simulation studies assessing the impact of implementing the recommended pre-endoscopy risk stratification in outpatient facilities revealed a significant and negative effect on their performance indicators, with adverse financial consequences: decrease in staff utilization, increase in total facility time, increase in waiting time for patients, and increased cost per case.[6] Third, 3.5% of all patients had positive screening results for COVID-19. COVID-19 screening was performed on the day of the procedure in the majority of cases. Although low, this number does highlight the tendency of patients to keep the endoscopy appointment even when they are symptomatic. Taking a day off work, arranging for transportation, and, for colonoscopies, drinking the bowel preparation can be some of the incentives in this setting. On the other hand, only 0.3% of patients who had negative screening results for COVID-19 had positive NAAT results. Thus, the majority of symptomatic patients report their symptoms, which in turn increases the validity and utility of COVID-19 screening. Fourth, considering the amount of human and material resources needed for risk stratification, it is critical to have built-in mechanisms to allow timely reporting of results in such a manner as to make them actionable. A useful metric in this setting is the percentage of NAAT-positive patients who underwent endoscopy. This rate was low (0.3%) in the current study. This rate might be even lower, assuming that for at least some of those COVID-19-positive patients the benefit of performing the endoscopy anyway was deemed to outweigh the risks to the patient and staff.

However, in my opinion the findings of this study and other studies should be carefully interpreted in the context of the study limitations. First, the procedure cancellation rate at the VA facilities in the prepandemic period was 30% as reported by the authors. This percentage is orders of magnitude higher than the national endoscopy cancellation rate of 5.5% to 8.5% reported from the ASGE databook.[7] As such, the true impact of COVID-19 testing or screening on procedure volume inside, but especially outside, the VA system is difficult to isolate. This task is made more difficult by the fact that the reasons for cancellation of visits were not available because of database limitations. The authors remedy this limitation by restricting the analysis to endoscopies cancelled within 7 days of the procedure date and by performing a sensitivity analysis that includes only facilities in the top 50% of lowest screening and NAAT results-missing rates. Despite that, only 20% of all cancelled procedures had screening and/or testing data, and only 4% of procedure cancellations could clearly be attributed to COVID-19. Data from centers where procedure cancellation rates are closer to the national average and where the reasons for the cancellation are known will help validate the current study results. Along the same lines, it would be useful to know the study population demographics and basic characteristics. This information will help determine how similar the study population is to that of the individual gastroenterologist's practice, and thus how applicable the study findings are to the non-VA patient population. Second, inasmuch as the study ended in April 2021, it predated the Omicron and Omicron subvariants as well as the increase in SARS-CoV-2 immunity in the United States, either through vaccination or through previous infection. Those factors are believed to have contributed to the increase in asymptomatic infection rates, which have been reported at 40% of SARS-CoV-2–positive patients.[8] Therefore, it would be useful to reassess the performance of COVID-19 symptom and exposure screening tests after April 2021. Such a high asymptomatic infection rate is expected to significantly decrease COVID-19 screening sensitivity and negative predictive value, and thus its appeal.

As SARS-CoV-2 virus continues to mutate and evolve, so will our understanding of it and the preventive, mitigating, and treatment measures we adopt to limit the resulting mortality, morbidity, and disruption to the normal societal and economic life. Studies based on national databases or large integrated health systems similar to the current one are instrumental in this critical task. I, for one, will very much be on the lookout for them.

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Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; COVID-19, coronavirus disease 2019; NAAT, nucleic acid amplification

testing; SARS-CoV-2, severe acute respiratory syndrome—coronavirus-2; VA, Veterans Affairs.

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