COMMENTARY



Real-world practice of the Egyptian Kelleni's protocol amid changing tropism of SARS-CoV-2 omicron BA.5.2.1.7, XBB 1.5 and CH.1.1 subvariants: a multi-purpose protocol

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Abstract

The Egyptian immune-modulatory Kelleni's protocol, including nitazoxanide as an integral component, is being safely and effectively practiced to manage SARS-CoV-2, RSV, influenza infections in pediatric, adult and pregnant patients with negligible requirements for the relatively expensive diagnostic molecular tests. Most recently, Kelleni's protocol is being likewise used to manage potential norovirus infection which is currently confused with SARS-CoV-2 Omicron new enterotropic subvariants and the antihistaminic loratadine has been co-administered in selected patients. Notably, Africa has the least mandates, restrictions and SARS-CoV-2 vaccination rates and yet the least COVID-19 mortality.

Keywords Kelleni's protocol · Nitazoxanide · Loratadine · SARS-CoV-2 · RSV · Influenza · Norovirus

Before SARS-CoV-2 was first reported; most human coronavirus infections displayed a predominant tropism towards the upper respiratory tract epithelial cells causing mainly common cold. Meanwhile, only SARS-CoV-1 and MERS-CoV have epidemically caused a severe and potentially fatal infection of the lower respiratory tract, and very little knowledge was available regarding the epidemiology of human enteric coronavirus infections (Riedel et al. 2019). Moreover, to the best of my knowledge, our current medical literatures do not include human coronaviruses, including SARS-CoV-2, among the causes of viral gastroenteritis (Parashar and Glass 2022).

Interestingly, gastrointestinal (GIT) symptoms, such as abdominal pain, vomiting and diarrhea, were reported among the most common manifestations since the beginning of COVID-19 pandemic, though in a clinically observed substantially lower frequency than the respiratory manifestations such as new or worsening cough. However, the frequency of GIT manifestations has persistently increased with time, and recently up to one in every five COVID patients might only present with them (Lui et al. 2021). This can

Currently, a tripledemic of SARS-CoV-2, RSV and influenza viruses' infections with mutual similar respiratory manifestations has been encountered globally, making great diagnostic challenges that were mostly resolved by relatively expensive microbiological molecular investigations which cannot be afforded by most African patients, and thus the clinical practice evolved through a safe, effective and economic protocol; the Egyptian Kelleni's immune-modulatory protocol (Kelleni 2022; 2023b). Furthermore, the continuous evolution of the immune-evasive SARS-CoV-2 Omicron subvariants including BA.5.2.1.7, XBB 1.5 and CH.1.1 has introduced another clinical diagnostic challenge with enteric viruses' infection, especially infection with noroviruses (the family prototype) as Norwalk virus (norovirus) is considered as the major cause of gastroenteritis epidemics worldwide and a major cause of under 5-year-old children's morbidity and mortality especially in the developing countries (Parashar and Glass 2022; Ryan 2022).

I wish to suggest, from a practical clinical point of view, that though abrupt nausea, vomiting, abdominal cramps, myalgia, fever, chills and headache could be considered as mutual shared manifestations (Parashar and Glass 2022), yet SARS-CoV-2 new evolving subvariants are frequently causing peculiar manifestations, including night sweating,

be considered as an interesting evolutionary shift in SARS-CoV-2 tropism towards the enteric epithelia with still to be fully explored etiology and clinical significance.

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lack of concentration, hypersomnia, lingering or subsequently appearing bouts of troublesome productive cough accompanied by a change of voice. Interestingly, nororvirus coexisting respiratory manifestations were previously seldom reported (Ryan 2022), and though it is least likely, updated microbiological research should exclude a potential concomitant evolutionary change in norovirus tropism.

Importantly, I wish to share that Kelleni's protocol used to manage SARS-CoV-2, RSV and influenza viral infections (Kelleni 2023b), is also being likewise safely and effectively practiced to manage potential norovirus infection with the same negligible prior requirement of any microbiological molecular investigations. Interestingly, nitazoxanide, an integral part of Kelleni's protocol, has been previously reported to be effective in management of human norovirus infection (Morris et al. 2013; Siddiq et al. 2011).

Notably, to manage some pediatric and adult patients who complained of the previously mentioned bouts of productive cough appearing at or shortly after the end of the initial GIT manifestations, a once daily dose of the second generation antihistaminic, loratadine has been co-prescribed, in selected pediatric and adult patients, with a recommendation for twice daily ingestion of locally available herbal expectorant and antitussive preparations in syrup dosage forms and/or ingestion of herbal tea containing the natural antitussive and antispasmodic *Pimpinella anisum* L. (anise), to be noted that loratadine was previously suggested to possess a potential beneficial effect if included in COVID management(Hou et al. 2021). A teaspoon of honey was also recommended to be used once (before bedtime) or twice daily for all patients except those under 12 months of age.

Finally, in Africa, we continue to enjoy a free life without restrictions or mandates, with the least COVID-19 mortality (Kelleni 2023a) and early treatment using Kelleni's protocol is continuing to safely and effectively manage different RNA respiratory and enteric viruses while sparing impoverished patients in Egypt the burden, as we suggest, of the currently westerly adopted very expensive, potentially inconclusive or apparently endless, drugs, investigations and mRNA jabs; respectively.

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Declarations

Conflict of interest The authors have no competing interests to declare.

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