

Brief Report

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Brief Report

# Repurposing Nitazoxanide to Manage Severe Bronchiolitis in a 9-Month-Old Infant

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**Abstract:** Lower respiratory tract infections caused by viruses are a leading cause of death in children under one year old. This communication describes, for the first time globally, a real-life practice of how nitazoxanide and Kelleni's protocol can safely manage infants over six months old with viral lower respiratory tract infections.

**Keywords:** SARS-CoV-2; XEC; COVID-19; nitazoxanide; Kelleni's protocol

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It's a very alarming statistic that a child dies from pneumonia every 43 seconds, with most victims being younger than 1 year old [1,2]. Viral pneumonia is most common in children younger than 2 years and viral bronchiolitis is considered the most frequent cause of hospitalization for infants with acute lower respiratory tract infection, imposing a heavy economic burden [3,4].

Importantly, though most of these pediatric pneumonia deaths occur in developing countries with 81% in children younger than 2 years old, this condition still results in nearly a million pediatric hospitalizations annually in developed countries, leading to a significant economic burden [5]. The causative viruses include respiratory syncytial virus, adenovirus, human metapneumovirus, human rhinovirus, parainfluenza virus, influenza, and coronaviruses, including SARS-CoV-2 [4,6].

Meanwhile, an optimal antiviral therapy for viral respiratory tract infections especially in high-risk groups such as infants is lacking in terms of both efficacy [7,8] and safety [7,9]. I'd like to present a real-life practice managing a 9-month-old male infant who experienced a severe viral lower respiratory tract infection that followed a viral laryngitis.

Starting in December 2024 or earlier, and consistent with the global progressive dominance of highly immune-evasive SARS-CoV-2 XEC subvariant, a new surge of viral upper and lower respiratory tract infections was documented in clinics across Egypt, similar to a previous surge encountered a year earlier [10]. Several peculiar manifestations were noted in adults differed from the described XEC common manifestations, including very severe prolonged cough, described as the worst since COVID-19 was first encountered, high fever exceeding 40° C, severe body ache, change in voice and anosmia more frequently than what was previously encountered. Interestingly, during my clinical practice throughout the COVID-19 pandemic, I've consistently observed the evolution of SARS-CoV-2 clinically with my patients, before the new variants being officially named [10–13].

A 9-month-old male infant, weighing 10 kg, initially presented with mild rhinorrhea and a mild cough. He became infected after both his elder sisters, as many other pediatric patients encountered in the clinic, and his mother have recovered from viral laryngitis after using nitazoxanide and NSAIDs as part of Kelleni's protocol [14], to be noted that his 6-year-old sister had an unusual prolonged persistent mild cough that was only relieved when azithromycin was added to nitazoxanide and ibuprofen (full Kelleni's protocol).

Watchful monitoring of the infant revealed an increase in the severity and frequency of cough and a change in voice, similar to the laryngitis encountered in his sisters. Although no fever was encountered, ibuprofen was administered in a single daily appropriate dose wishing to abort the progression of the viral infection as was practiced with his elder sisters [15]. However, unlike his sisters, he didn't receive nitazoxanide which is permitted for infants 1 year old and older.

However, the troublesome cough persisted and within few days his condition rapidly progressed to include a fever of up to 39° C, decreased appetite, tachypnea, mild wheezing, irritability, and hypoxia (84% oxygen saturation by pulse oximeter at room temperature).

I've promptly administered azithromycin q.d. and ibuprofen t.d.s in the first day and b.i.d in the second day. When the fever subsided, wheezing became more evident along with crackles upon auscultation. Throughout his illness, no increased work of breathing was observed and no areas of decreased air entry were detected upon auscultation. The clinical diagnosis was bronchiolitis.

Azithromycin administration was continued for a total duration of five days and if the clinical condition had not improved, amoxicillin/clavulanate would have been added [10] but it was not required due to clinical improvement. In addition to azithromycin antimicrobial activity, threatened by global resistance, I use it in viral infections mainly due to its immune-modulatory properties [16,17].

Due to the increased wheezing, I made the decision to stop administering ibuprofen and only use paracetamol when fever exceeded 38° C, which was done for one day. Good hydration, mainly through breast feeding, was always maintained throughout the illness.

Meanwhile, concomitant with azithromycin administration, I've decided to add nitazoxanide in a dose of 60 mg (3 ml) b.i.d. for five days instead of the usual 100 mg (5ml) for three days that I've used to prescribe for infants 1 to 3 years old. The boy showed clinical improvement and by the end of this described treatment course, tachypnea was decreasing and oxygen saturation reaching 92% at room temperature. The cough was gradually improving, yet it took nearly two weeks for full clinical recovery and oxygen saturation returned to normal level of 96% at room temperature.

Importantly, I decided to add nitazoxanide after careful evaluation of its metabolism that occurs first by hydrolysis to tizoxanide and then glucuronidation through UGT1A1 [18]. Notably, UGT1A1 is responsible for the metabolism of bilirubin and its expression and activity show substantial development at 6 months of age [19].

Importantly, as the cough was very troublesome, I used levocetirizine drops 1.25 mg at bedtime and a single dose of benproperine syrup (2.5 ml containing 8.3 mg benproperine) at bedtime to aid achieving better sleep. Notably, similar to nitazoxanide, benproperine is not prescribed for infants younger than one year. However, unlike nitazoxanide, this low dose of benproperine is adopted by many expert Egyptian pediatricians for years to alleviate troublesome cough in this age group and I've also checked its metabolism that occurs through hydrolysis and glucuronidation [20].

I've also added alpha amylase syrup 600 U.CEIP (3 ml) twice daily during the daytime to help relieve the pulmonary secretions. Alpha amylase was administered for five days and benproperine for three days, after which the cough and wheezing have significantly improved.

Finally, Since December 2024, I decided to start the full Kelleni's protocol for five days and discontinue the "watchful monitoring" in all high-risk groups. Notably, a year ago, I've adopted a similar early management and post exposure approach for the high risk groups but for three days and not necessarily the full protocol [10]. After that surge passed, I returned to "watchful monitoring" before adding azithromycin that was mainly added for those experiencing high fever and less commonly to manage persistent cough [10] that was not encountered in that frequency except after this new surge appeared. Importantly, when I compare this approach to those patients who presented in the clinic for treatment relatively late, it was highly rewarding regarding morbidity.

Currently, this full Kelleni's approach, when initiated earlier in the course of a respiratory viral illness in a high risk patient, has effectively aborted the progression of this current highly immune-evasive viral infection/ variant resulting in symptoms similar to a mild common cold as it did with

all the previous SARS-CoV-2 variants which mostly responded to only some drugs of Kelleni's protocol for a shorter duration [10,11,14].

To the best of my knowledge, this report is the first to describe administering nitazoxanide to manage SARS-CoV-2/ viral respiratory tract infection in infants younger than one year. I recommend further consideration of nitazoxanide and the full Kelleni's protocol for the management of viral respiratory tract infections in infants aged six months and older. Repurposing nitazoxanide and Kelleni's protocol to manage viral pneumonia and bronchiolitis in infants 6 months old and older could save hundreds of thousands of precious lives that are claimed each year.

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**Conflict of Interest Disclosures:** None.

**I, Mina T. Kelleni, am a sole author.**

I approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

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