Proposed Study to Evaluate Throat-and-Nose Cleaning as a Preventive Strategy for COVID-19

Background

An article published in *Nature,* https://www.nature.com/articles/s41598-018-37703-3, found that hypertonic saline nasal irrigation and gargling significantly reduced the duration of the common cold, including colds caused by coronavirus, if begun within 48 hours after symptom onset.

Scientists at the University of North Carolina have discovered how the novel coronavirus moves through our respiratory system to ultimately do its damage to our lungs: https://www.unc.edu/posts/2020/06/08/researchers-map-how-coronavirus-infection-travels-through-cells-of-nasal-cavity-and-respiratory-tract/. UNC determined that *"SARS-CoV-2 — the coronavirus that causes COVID-19 — infects the nasal cavity to a great degree by replicating specific cell types, and infects and replicates progressively less well in cells lower down the respiratory tract, including in the lungs. The findings suggest the virus tends to become firmly established first in the nasal cavity. Then, in some cases, the virus is aspirated into the lungs where it may cause more serious disease, including potentially fatal pneumonia."*

Researchers at Penn State College of Medicine, in an article published in the *Journal of Medical Virology* *https://onlinelibrary.wiley.com/doi/10.1002/jmv.26514*, determined that some substances substantially reduced the amount of an infectious coronavirus (HCoV-229e) used as a surrogate for SARS-CoV-2. For example: *"With contact times of 1 and 2 min, the 1% baby shampoo solution was able to inactivate more than 99% and more than 99.9% or more of the virus, respectively."* Also: *"Even at the lowest contact time of 30 s [Listerine Antiseptic Mouthwash] inactivated greater than 99.99% of HCoV."*

Purpose of the Proposed Study

Given the demonstrated virucidal effect of some substances in vitro – along with the UNC's determination of where SARS-CoV-2 establishes its beachhead, *and* how the duration of the common cold was diminished even if cleaning was performed only after symptoms appeared – it seems prudent to assess what the effect of viral-inactivating substances would be in vivo. Thus, we propose to determine whether throat-and-nose cleaning (TANC) would reduce the viral load of humans who have been infected with SARS-CoV-2…and if it will be by enough to be detectable.

Outline of the Protocol

There are a number of study designs that could produce a rigorous assessment of TANC virucidal action in vivo. However, most of these studies would take an extended period of time to launch and to conduct. Given the urgency of mitigating the pandemic, we are suggesting an approach that will be relatively fast and easy for attaining at least some indicative and potentially compelling results.

Rapid antigen tests do not require a lab; results are available in less than 15 minutes. The sensitivity of these tests is not as high as the gold-standard RT-PCR tests. But specificity is close to 100%. So, while there will be some false negatives, there are only very rarely false positives. When people test positive, they almost certainly have COVID-19.

We will administer the antigen test with the sample coming from an anterior nasal swab, not the deep nasopharyngeal swab. Thus, the test specimen will be acquired from the same area where we would be performing the nasal-cavity cleaning.

For our study, we would need to partner with an organization that is performing rapid antigen testing, using a test like Siemens Clinitest. Below is just an outline of the general approach we propose; this will be modified/enhanced in concert with our partners as we work out the details.

Anyone who tests positive on Clinitest would be offered the option of cleaning their nasal cavity with a large-headed swab dipped in J&J Baby Shampoo diluted to 1% in PBS, which was so successful inactivating the virus in vitro. If they accept, they are guided on how to perform that cleaning for optimal virus contact and removal. Then, after waiting enough time for the shampoo solution to have its virucidal action, perhaps just a few minutes, the test would be repeated. If negative, that is an indication that the in vitro results transfer, at least in part, to in vivo. Note that we might deploy an alternative solution, which we believe will be more effective in virucidal action and would be at least equally safe, or we could incorporate additional substances with the shampoo to heighten the efficacy of the solution.

We would perform a repeat test, perhaps a half hour after the initial test, to see if the results are reproduced and maintained. The subjects would also be requested to return the next day for one more test, to determine if the protection continues over an extended time. We would also like to explore whether wiping the nose with plain water after the cleaning has any effect on results. And we will, of course, track clinical outcomes to see if doing TANC has a correlation to disease incidence and severity.

Since the rapid antigen test is qualitative, we plan to also send a portion of each of the antigen-positive samples for quantitative RT-PCR testing. This will provide a measurement of viral load, which will be useful as we interpret the data on which subjects had success and which had failure with TANC.

Note that Siemens Clinitest has not yet been authorized for self-administered nasal swabbing. This FDA authorization is expected in a matter of weeks. However, we will be using the nasal swab for investigational use. If the nasopharyngeal sample tests positive, the nasal swab will be taken. Only those subjects who test positive on both will be accepted into the study.

The sample size will need to be determined, along with many other details. But if the vast majority of positive-testing subjects retest negative after the nose cleaning, even with a small sample, that is a pretty clear indication that TANC should be evaluated more intensively, extensively, and rapidly.

We would also like to evaluate how TANC works on coronavirus in the throat, presumably via mouth-swishing and gargling with Listerine Antiseptic Mouthwash as the cleaner. However, we are unaware of any rapid antigen test that uses saliva or throat swabs. Nonetheless, it is possible that we could conduct this portion of the study on the throat for research purposes, via investigational use, unrelated clinical diagnosis.

If the results of our simple study are promising, that should drive additional research to determine what substances, process, and timing for TANC will be most effective in preventing or at least mitigating COVID-19.

Why It Is Imperative to Evaluate TANC

Our nation currently has two strategic approaches to combat COVID-19: (1) We encourage behaviors that will keep the virus from ever reaching our susceptible orifices, and (2) We endeavor to manage the disease if and when it becomes established within its host. The former has run into compliance problems. The latter suffers from suboptimal treatment options. We now have extremely promising early results from vaccine trials. But it will be challenging to vaccinate our nation's entire population before well into 2021. We need to mitigate the disastrous impact of this disease *now*.

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