18 December 2020

BRIEF19

A daily review of covid-19 research and policy

RESEARCH BRIEFING

Tocilizumab not the blockbuster drug for patients with covid-19 pneumonia as hoped.

A new randomized clinical trial published in *The New England Journal of Medicine* looks at the efficacy of tocilizumab for patients hospitalized with covid-19 when given in combination with remdesivir, a now-approved though underwhelming covid-19 treatment. Tocilizumab is a "monoclonal antibody" that targets receptors in our immune system called interleukin 6 (IL-6). IL-6 plays an important part in the body's inflammatory response and suppressing its action was hoped to combat counterproductive immune activity mounted by our own defenses.

In this study of 328 patients hospitalized with covid-19 and evidence of pneumonia, patients were randomized to receive standard of care treatments plus one or two doses of either tocilizumab or a placebo. The primary outcome of the study was a meaningful one: how long it was before mechanical ventilation (i.e. intubation) was necessary or death by day 28.

Patients were less likely to progress to mechanical ventilation *or* death by day 28 in the tocilizumab group (12 percent) compared to the placebo group (19.3 percent). In addition, only 8.6 percent of patients in the placebo group died compared to the 10.4 percent in the tocilizumab group; however, this difference was not statistically significant, meaning that it's impossible to rule out that chance alone accounted for that difference. A slightly higher number of patients in the placebo group received steroids (which have been proven to lower mortality in patients with serious covid-19 illnesses) compared to the tocilizumab group, though it is uncertain whether this contributed to fewer deaths in the placebo group. There are some patients in whom steroids help, and others it may hurt. We don't know enough about the breakdown of the patients in this study to glean that information. Length of stay in the hospital, another important outcome that patients tend to care about, was not statistically significantly different between groups.

Tocilizumab appears safe as serious adverse events were not significantly different between the study groups.

In summary, tocilizumab appears to be safe and *might* prevent patients from progressing to requiring mechanical ventilation, though the total effect appears to be small. Overall, tocilizumab seems slightly less effective than remdesivir, which has been shown in one major study to reduce hospital length of stay. It is unlikely that this randomized clinical trial will significantly change current practice.

—Joshua Niforatos, MD, MTS

POLICY BRIEFING

Safety of consumer-grade face masks.

Not all masks are created equal. Between attachment methods, underlying materials, and filtration features; they all make a difference. Today, there are thousands of options available to consumers. Just as all of these options vary, so does a mask's ability to perform the task for which it was ostensibly created: particulate filtration.

To date there has been no government agency responsible for setting minimum standards or ensuring compliance from manufacturers. But the National Institute for Occupational Safety and Health (NIOSH), a division within the Centers for Disease Control and Prevention (CDC) and the ideal choice for this kind of work, has been working in the background to do exactly this.

Working with a standard-setting industry organization, the goal is to publish guidelines and corresponding labels by next month. While both NIOSH and the US Food and Drug Administration (FDA) have some regulatory oversight of medical-grade masks, many of the options publicly available are essentially pieces of cloth. This renders them immune from such regulatory scrutiny. While the CDC has published general recommendations on appropriate mask practices, a national standard with testing and validation is vital to adequate population protection.

This past year, the mask industry has taken off. In fact, interest in masks fundamentally changed many business models, including Etsy, which helped sell $346 million worth of masks to 4 million users. Meanwhile, an iteration of the XPRIZE has been launched to "reimagine protective face masks used to prevent the spread of COVID-19 by making them more comfortable, functional, accessible, and even stylish." The "Next-Gen Mask Challenge" will give $1 million to the winner. Interestingly, a delay in announcing a winner was recently announced by the organizers because the judges felt that tangible metrics should be used to choose a winner. To that point, perhaps NIOSH and the FDA will soon provide much-needed quantitative guidance that could make such evaluations—whether in competition or the marketplace—more objective.

—Brief19 Policy Team

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