Risks of using pre-event time scale and ordinal scale measurements in COVID-19 clinical trials

M.V. Yashchenko
Pharmaxi LLC, Kyiv, Ukraine
Conflict of interest: none

BACKGROUND. The article shows the results of literature search and analysis of endpoints of interventional clinical trials of phase III-IV of the treatment of hospitalized patients with coronavirus disease (COVID-19) and of its prevention.
MATERIALS AND METHODS. Among 102 trials found, ordinal scales were used in 60 trials, time-to-event outcome measures were used in 54 trials, both scales – in 49 trials. Time-to-event endpoints were related to hospitalization/intensive care unit term, discontinuation of oxygen therapy, and clinical improvement standardized on ordinal scales. At the same time, the early discontinuation of oxygen therapy and the early discharge create risks to the biometric measurement.
RESULTS AND DISCUSSION. Statistical calculations showed the association of the number of new COVID-19 hospital admissions per day with the percentage of free beds, but not only with the number of new coronavirus infection cases in general, the number of deaths and the number of people recovering from COVID-19 per day in different regions of Ukraine. These results may indicate that resource-dependence and organizational aspects affect the hospitalization of patients with COVID-19.
CONCLUSIONS. Therefore, to ensure that the discharge or discontinuation of oxygen therapy was due solely to a positive clinical outcome, data on changes of number of beds, access to oxygen supplies as well as data relevant to determination of the desired clinical outcome (body temperature, oxygen saturation, severity of symptoms, etc.) should be collected. It is recommended to collect biomarker data after discharge, if possible.

KEY WORDS: coronavirus disease, interventional trials, hospitalization, time-to-event, ordinal scale.