Twenty day-long increased COVID-19 infection risks after initiating the vaccination process and inadequate design of the vaccinated group from Dagan et al 2021

1st draft

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Summary

Reanalyses of data released by the Israel Ministry of Health and published in a recent Ynet article indicate increased risks due to COVID-19 during the 35-d long vaccination process. Reanalyses of detailed data from Dagan et al 2021 confirm increased COVID-19 incidences during the first 20 vaccination days. Significant differences on 1st vaccination day between vaccinated and control groups invalidates their conclusions which require comparable groups(Covid-19 incidence:treatment, 172/596618 =2.88/10000 vscontrol, 359/596618 =6.02/10000, P = $1.72x10^{-16}$; symptomatic case incidence: treatment, 90/172,52.33% vs control, 227/359, 63.23%, P =0.0165).**The control group resembles the total population on February 1st in incidences of COVID-19, severe and death case incidences. Hence, treatment group design is biased.** Vaccination reduces hospitalizations cumulated over 44 days(vaccinated, 1.76%vs control, 65.8, P = 0), but increases rates of cumulated severe and deadly cases among hospitalized (vaccinated, 33/42, 78.57% vs control, 142/259, 54.83%, P =0.00381). Despite biases, results show that **vaccination protects the majority that would develop mild cases and fragilizes the minority likely to develop more severe cases**. Note that 1. data exclude potential short- and long-term adverse vaccine effects unrelated to COVID-19, and 2.eight among ten authors of Dagan et al 2021 disclose funding by relevant pharmacological companies.

Introduction

A recent Ynet article published data on hospitalizations, severe and death cases for COVID-19 among different age groups during the 5-week vaccination process, which includes 3 weeks between the first and the second vaccine doses, and 2weeks after the second dose. For both age groups, COVID-19-associated risks were increased as compared to unvaccinated individuals, according to rates provided in the same Ynet article.

This point, that vaccination increases risks during the vaccination process despite decreasing risks of developing COVID-19 after the 5-w vaccination process, requires confirmation. The data from Dagan et al 2021 include 596618 control and 596618 vaccinated individuals, and COVID-19 infection rates are given for days 1 to 44 postvaccination for both control and vaccinated groups. These data are therefore adequate to examine the working hypothesis that vaccination increases COVID-19-associated risks during the vaccination period.

Such **analyses comparing control and vaccinated groups imply that Initial infection rates are identical for both control and vaccinated groups. This is *a sine que none* condition for proper experimental design. Their experiment assumes that the comparison between vaccinated and untreated individuals is adequate, because these are drawn randomly from the same population. The negation of this proposition proves that comparing these two groups is inadequate and conclusions flawed**.

Results

Unvaccinated and vaccinated groups differ on 1st vaccination day

On the first day of vaccination, when the vaccine could not yet have any effects, there are 359 (6.02/10000)COVID-19-infected individuals in the control group, and 172COVID-19 cases(2.88/10000)in the equal sized treated (vaccinated) group. Randomized assignments of

individuals to these two groups should have resulted in approximately half the COVID-19 cases in each group, however, the vaccinated group includes only 32.39% of positive COVID-19 cases on day 1. This has P =1.72×10^{-16} according to a two-tailed sign test, suggesting inadequate, non-random sample design.

Analyses for rates of symptomatic cases among COVID-19 cases reveal on 1st day 63.23 (controls) vs 52.33%(vaccinated) symptomatic COVID-19 cases (P = 0.0165, non-directional chi-square test). Considering over the whole period hospitalized cases, there are 65.76 vs 1.76% hospitalizations among symptomatic control and vaccinated individuals, respectively (P = 0, non-directional chi-square test).

Cumulated over 44 days, severe cases (deaths included) among those hospitalized were 54.83 (142 among 259, controls) vs 78.57% (33 among 42, vaccinated)(P = 0.00381, non-directional chi-square test).

Incidence rates for COVID-19, severe and death cases match those in the general Israeli population on 1st of February. Hence, biases originate from the design of the vaccination group.

COVID-19 incidences are stable among the unvaccinated

Rates of positive COVID-19 tests among controls during the first 10 days are stable (days 1-10, per 10000): 6.02, 6.59, 6.61, 7.18, 7.07, 6.76, 7.38, 7.22, 6.04 and 6.84, mean = 6.77, s.d.= 0.47. For controls, we found a significant difference in infection rates only for one pair of consecutive days, days 8 and 9 (P = 0.039) among 43 comparisons between consecutive days. This implies that overall, for unvaccinated individuals, infection rates remain approximately constant during the study period.

COVID-19 incidences increase among the vaccinated

The unvaccinated group is an inadequate external control for the vaccinated because COVID-19 infection rates on the first vaccination day differ widely. However, incidence rates on that day for the vaccinated can be considered as a fair internal baseline towards which to compare infection rates on following days.

On the 2nd day after initiating the vaccination process, there are 235 COVID-19 cases among the 557172 individuals considered that day in the vaccinated sample, 4.22/10000, vs 2.88/10000 for the first day, which is a statistically significant increase (P = 0.000136, non-directional chi-square test). This tendency for increased post-vaccination infection rates is confirmed when comparing days 2 and 3: on day 3, there are 313 COVID-19 cases among the vaccinated (5.97/10000), a statistically significant increase as compared to the previous day (P = 0.00005137, non-directional chi-square test), and as compared to the base-line on the first day (P = 4.36×10^{-15}, non-directional chi-square test). The difference between consecutive days is statistically significant for days 6 and 7 (6.63 vs 8.44/10000, P = 0.002342, non-directional chi-square test). The first pair of consecutive days for which we observe a statistically significant decrease in COVID-19 infection rates are days 9 and 10 (8.12 vs 6.80/10000, P = 0.045, non-directional chi-square test), and days 14 and 15 (6.52 vs 4.44/10000, P = 0.001281, non-directional chi-square test). Up to day 33, there are three more such pairs, days 17 and 18 (4.58 vs 3.34/10000, P = 0.045, non-directional chi-square test), days 28 and 29 (3.22 vs 1.65%, P = 0.024, non-directional chi-square test) and days 32 and 33 (1.71 vs 0.34/10000, P = 0.0202, non-directional chi-square test).

As compared to the baseline at day 1 after initiating the vaccination process, daily infection rates are greater than the baseline from day 2 to day 20 of the vaccination process. These incidence rates are statistically significantly greater than the baseline at P < 0.015 for all but days 18 and 20. From day 21 to 43, COVID-19 incidences are lower than the day-1 baseline for all days but day 28. The decrease as

compared to day 1 is statistically significant (P < 0.05) for days 29 to 37. Figure 1 describes COVID-19 incidence rates over time for those vaccinated.

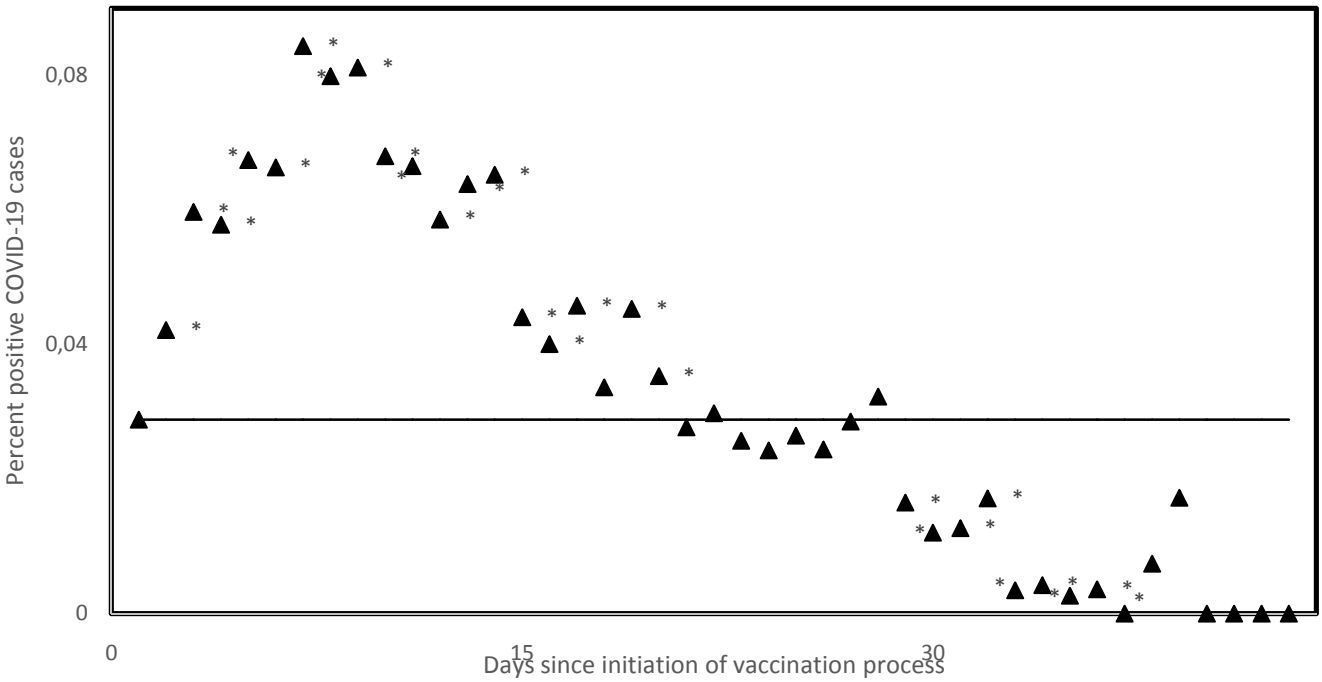

Figure 1. Daily COVID-19 incidence rates among vaccinated, as a function of days since initiation of the vaccination process. The baseline is defined by the COVID-19 incidence on day 1, * indicate P < 0.05 as compared to that baseline.

Discussion

Overall, differences on day 1 between control and vaccinated groups show significant biases in two major metrics, COVID-19 incidences, and incidences of symptomatic cases. These differences probably reveal biases in health levels between the two groups that resulted in fewer hospitalizations among symptomatic cases for the vaccinated. These biases are despite extreme care in the design of matched treatment and control samples as presented in table 1 in Dagan et al 2021, where subpopulation sizes are matched to unbelievable extents for a study matching over half a million controls and treated individuals. For example, the subpopulation of orthodox Jews is perfectly matched between treatment and control samples. However, matching initial infection rates between these two groups is crucial to the experimental design, but was neglected, invalidating the experiment.

Incidences of COVID-19, severe and death cases in the control group resemble those in the wider Israeli population on 1st of February. Hence, biases relate mainly in the design of the treated/vaccinated group.A crucial example relates to deaths rates among the vaccinated, which seem tailored to be minimal. Death data for the period corresponding to the Dagan et al study from the Israel Ministry of Health show that from December 19 2020 until February 1 2021, 1742 Israelis died from COVID-19, meaning 40 per day for an adult population of 6.5 millions. Hence, during that period, 0.61/100000 died per day, hence, 27/100000 cumulated over 44 days.

Considering that the unvaccinated in Dagan et al 2021 had only 5/100000 for that period and considering that this death rate corresponds to the death rate observed before the vaccination started on December 19 2020, we conclude that among the vaccinated there should be 27-5 = 22/100000 deaths. This is in line with observations from in the previously analysed Ynet table on COVID-19 incidences during the vaccination period and from postvaccination reports from VAERS.

These results, together with the disclosure that eight among ten authors of Dagan et al 2021 got funding from relevant pharmacological companies cast shadows on the justification of the ongoing massive vaccination program. Note that analyses do not include data on adverse effects, including deaths, that are not considered as due to COVID-19, but whose incidences might be greater among vaccinated than unvaccinated individuals.