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Research Article

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COVID-19 Infection Relative Risk Reduction Versus Absolute Risk Reduction Since 2020-2022 to 2023 and 2023 to 2024 in A General Medicine Office in Toledo (Spain)

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ABSTRACT

Background: The expression of the true impact of COVID-19 prevention measures in daily practice on the population can be confusing when presented as relative risk reduction (RRR) or absolute risk reduction (ARR).

Objective: To compare RRR with ARR of SARS-CoV-2 infections since 2020-2022 period to 2023 and since 2023 to 2024.

Methodology: Comparison of secondary data among COVID-19 infection cases in from 2020-2024 years of previous studies, all of them carried out in the same population of patients treated in a general medicine office in Toledo, Spain. 2020-2022 period was considered a control group compared to 2023 (intervention group; hybrid immunity: vaccination and/or infection); and 2023 was considered a control group for 2024.

Results: For all COVID-19 cases (>=14 years) from the period 2020-2022 [1, 2 or 3 doses vaccine (first booster) in fall-winter 2021-2022] to 2023, an RRR of 67% versus an RRA of 8% was found, and from 2023 to 2024 [Fourth dose (second booster) was inoculated in fall-winter 2022-2023, and Fifth dose (third booster) in fall-winter 2023-2024] an RRR of 25% and an RRA of 1%. For all the selected variables studied, the ARRs were always lower or at times equal to the RRRs both from the period 2020-2022 to 2023, and from 2023 to 2024, except for Socio-health workers and Presence of chronic diseases from 2020-2022 to 2023. The downward differences in the ARR versus the RRR were more striking from 2020-2022 to 2023 than from 2023 to 2024.

Conclusion: Expressing the risk reduction as RRR shows an exceptionally striking appearance of risk reduction that does not exist in its expression as ARR, especially in the first period of the COVID-19 pandemic. However, the evolution of the decrease in incidence that decreases the ARR, and the possible underreporting of cases must be taken into account. This underlines the importance of considering both the ARR and the RRR.

Keywords: COVID-19, Sars-CoV-2, Risk and Benefit Data, Population Surveillance/Methods, Epidemiological Characteristic, Public Health Practice, General Practice

Introduction

Presenting results as risk differences makes the benefits and adverse effects of the treatment or intervention easier to compare. There are different indices to express the effect of a treatment or preventive intervention, all of which are correct and legitimate. The effect of the treatment as perceived by physicians depends on the index with which it is expressed. Therefore, it is necessary to become familiar with the different indices and their relationships. One way to do this is to calculate all of them for the data of the studies being carried out [1].

Although scientific papers often provide results indicating their statistical significance, they are less likely to provide data on their clinical importance. The Absolute Risk Reduction (ARR) calculation is probably one of the most useful and intuitive data in this regard. The ARR is most useful for understanding the individual benefit of an intervention. The Relative Risk Reduction (RRR) is often used in marketing or the media because it tends to

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produce a larger, more eye-catching number. However, the ARR can provide guidance on the benefit that an individual patient can expect. And not only is this RRR biased impact perceived by the public, but a similar effect has been reported in the interpretation of risk data by primary care physicians [2-8].

The ARR is the simplest way of expressing the difference in efficacy between the groups studied. It is the difference in proportions of an event between the control group and the intervention group. The basic data on the proportion or incidence of the event in each group studied and its difference or ARR inform us in a simple way of the magnitude of the difference in efficacy. The ARR must be known before making decisions about the advantage of an intervention (a drug, a vaccination, and which patients should be treated) [9].

Thus, in severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection, it may be more intuitive to give the results of the intervention (vaccination and natural immunity from having had the infection) in the form of ARR. Measuring the ARR and the number of people to be treated or vaccinated are more appropriate for prioritizing vaccination of vulnerable populations than relative measures, such as RRR [10].

In this scenario, information on the evolution of community RRR and ARR measures for COVID-19 infection from 2020 to 2024 is not clearly known. We present a comparative study based on previously published data, to evaluate the trend of RRR and ARR of infections COVID-19 since period 2020-2022 until 2023 [with alpha, delta and omicron SARS-CoV-2 variants; and in 2020 without vaccination, in 2021 with 1 or 2 dose vaccination and in 2022 with first booster;] and since 2023 until 2024 [in 2023 omicron variant and with second booster -4th dose-, and in 2024 omicron variant with third booster -5th doses- of vaccine], from the same population attended in a general medicine consultation in these time periods.

Material and Methods

Design and Emplacement

This study compares data from previous observational, longitudinal and prospective study of COVID-19 infections from October 2023 to October, 2024, already published [11,12]. Both studies were conducted on the same population: patients saw in a general medicine office in Toledo, Spain, which has a list of 2,000 patients > 14 years of age (in Spain, general practitioner (GP) care for people > 14 years of age, except for exceptions). The GPs in Spain work within the National Health System, which is public in nature, and are the gateway for all patients to the system, and each person is assigned a GP. The methodology of all studies has been previously published, but the main elements will be repeated here to facilitate understanding of the current study.

Outcome of Interest

To compare the RRR with ARR of SARS-CoV-2 infections, associated with public health measures (confinement, social distancing, use of masks, acquired immunity by vaccination and/or infection) since 2020-2022 period to 2023 and since 2023 to 2024.

Methodology

Comparison of secondary data among COVID-19 infection cases in 2020-2024 years of previous studies carried out in the same population of patients treated in a general medicine office in Toledo, Spain. The incidence rates from 1) March 2020-October 1, 2022 period was considered control compared to the period October 1, 2022 to October 1, 2023 period (intervention); and 2) October 1, 2022 to October 1, 2023 period was considered as control regarding October 1, 2023 to October 1, 2024 period (intervention).

Calculation of Incidence Rates

Cumulative incidence rates were calculated at the GP's office by dividing the number of infection events during the study period by the individuals that could develop the event at the start of the study (population at risk). That is, the incidence rate was calculated by dividing the number of cases of COVID-19 infections by people on the list of patients dependent on the consultation object of the study (N=2,000 people), from the period 2020-2022, in 2023 and 2024 years [13-15].

Calculation of RRR and ARR

The RRR was calculated as control incidence minus the intervention incidence and divided by the control incidence. ARR was calculated as the arithmetic difference between 2 event rates: the event rate in the control group minus the event rate in the intervention group [13]. As mentioned in the "Methodology" subsection, the following intervention groups were considered: 1) the incidence rates in 2023 (immunity by vaccination and/or infection: omicron SARS-CoV-2 variant and 4th booster doses of vaccine) compared with period 2020-2022; and 2) the incidence rates of 2024 (immunity by vaccination and/or infection: omicron SARS-CoV-2 variant and 5th booster doses of vaccine) compared with 2023. Therefore, the following were considered as control group: 1) the period 2020 -2022 (successively alpha, delta and omicron SARS-CoV-2 variants, and in 2020 without vaccination, in 2021 with 1 or 2 dose vaccination and in 2022 with third dose -first booster) compared with 2023 (omicron SARS-CoV-2 variants and 4th booster dose of vaccine); and 2) the year 2023 as a control compared to 2024 (5th dose -second booster of vaccine).

Diagnosis of COVID-19

The diagnosis was performed with reverse transcriptase polymerase chain reaction oropharyngeal swab tests or antigen testing performed in health services or at home [16].

COVID-19Vaccination

Patients could have received 1, 2 doses of vaccine, first booster for fall-winter 2021, fourth dose (second booster) for fall-winter 2022 and fifth dose (third booster) for fall-winter 2023. In our study, only Pizfer / BioNTech, Moderna, Oxford / AstraZeneca and Janssen (Johnson & Johnson) vaccines were used for the first and second doses. For the first booster, only messenger RNA was used. And only Moderna and Pfizer-BioNTech's bivalent COVID-19 vaccines were used for the second booster. Omicron XBB.1.5 adapted vaccines Pfizer / BioNTech and Moderna were used for the third booster in autumn-winter 2023-2024 [17-21].

Collected Variables
The following variables were collected:

Age and sex
Chronic diseases (defined as "any alteration or deviation from normal that has one or more of the following characteristics: is permanent, leaves residual impairment, is caused by a non-reversible pathological alteration, requires special training of the patient for rehabilitation, and / or can be expected to require a long period of control, observation or treatment [22].

If they were Health Care Workers
Disease severity (classified according to:

- mild cases: clinical symptoms are mild and no manifestation of pneumonia can be found on images;
- 2. moderate cases: with symptoms such as fever and respiratory tract symptoms and the manifestation of pneumonia can be seen on the imaging tests;
- severe cases: respiratory distress, respiratory rate ≥ 30 breaths / min., pulse oxygen saturation ≤ 93% with room air at rest, arterial partial pressure of oxygen / oxygen concentration ≤ 300 mmHg.) To simplify comparison, moderate and severe cases were counted together [23].

Epidemiological Analysis
The calculation of ARR and RRR was performed as explained above (subsection "Calculation of RRR and ARR"). The age of 65 years was used as the beginning of old age [24]. Figures with decimals were rounded to facilitate a more intuitive comparison. Similarly, to facilitate understanding of the data, the periods compared were rounded to full years: the period from March 1, 2020 to September 1, 2022 was labeled 2020-2022; from October 1, 2022 to September 30, 2023 was labeled 2023; and from October 1, 2023 to September 30, 2024 was labeled 2024.

Ethical Issues
No personal data of the patients were used, but only group results, which were taken from the clinical history.

Results
For the total number of COVID-19 cases (>=14 years) since the period 2020-2022 [during 2020-2022 SARS-CoV-2 variants were successively alpha, delta and omicron, and the population had received only 1, 2 or 3 doses vaccine (first booster) for fall-winter 2021-2022] to 2023: a RRR of 67% was found versus RRA of 8%, and from 2023 to 2024 [In 2023-2024 omicron subvariants were dominant; Fourth dose (second booster) was inoculated in fall-winter 2022-2023; Fifth dose (third booster) was administered in fall-winter 2023-2024]: an RRR of 25% was found and an ARR of 1%. For all the selected variables studied, the RRAs were always lower or at times equal to the RRR both from the period 2020-2022 to 2023, and from 2023 to 2024, except for Socio-health workers and Presence of chronic diseases from 2020-2022 to 2023. The differences in decline of figures in RRA versus RRR was more striking from 2020-2022 to 2023 than from 2023 to 2024 (TABLE 1, FIGURE 1, FIGURE 2).

Table 1: COVID-19 Infection Relative Risk Reduction Versus Absolute Risk Reduction Since 2020-2022 To 2023 And Since 2023 To 2024

VARIABLES	COVID-19 INCIDENCE RATES IN THE PERIOD OF 2020-2022 (CONTROL)	COVID-19 INCIDENCE RATES IN 2023 (intervention group for 2020-2022 period, and control group for 2024)	RELATIVE RISK REDUCTION (control incidence minus the intervention incidence and divides by the control incidence) (intervention group for 2020-2022 period, and control group for 2024)	ABSOLUTE RISK REDUCTION (incidence in 2020-2022 minus incidence in 2023)	COVID-19 INCIDENCE RATES IN 2024 (intervention group regarding 2023)	RELATIVE RISK REDUCTION (control incidence minus the intervention incidence and divides by the control incidence) (intervention group regarding 2023)	ABSOLUTE RISK REDUCTION (incidence in 2023 minus incidence in 2024)
Total (>=14 years)	36% x 3 years [12% average x 1 year]	4% x 1 year	67%	8%	3% x 1 year	25%	1%
> 65 years	19% x 3 years [6% average x 1 year]	6% x 1 year	0%	0%	5% x 1 year	17%	1%
14-65 years	39% x 3 years [13% average x 1 year]	3% x 1 year	77%	10%	2% x 1 year	33%	1%
Women	33% x 3 years [11% average x 1 year]	5% x 1 year	54%	6%	3% x 1 year	40%	2%

Men	38% x 3 years [13% average x 1 year]	3% x 1 year	77%	10%	2% x 1 year	33%	1%
Socio-health workers	16% x 3 years [5% average x 1 year]	54% x 1 year	-98%	-49%	25% x 1 year	54%	29%
Moderate severe severity	4% x 3 years [1% average x 1 year]	0.1% x 1 year	90%	0.9%	0.1% x 1 year	0%	0%
Exitus	0.5% x 3 years [0.2% average x 1 year]	0 % x 1 year	100%	0.2%	0 % x 1 year	0%	0%
Presence of chronic diseases	7% x 3 years [2% average x 1 year]	3% x 1 year	-50%	-1%	3 % x 1 year	0%	0%

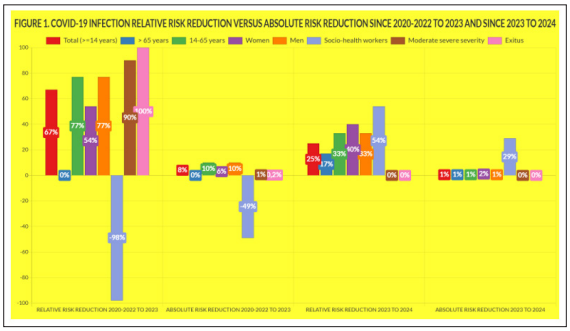

Figure 1: COVID-19 Infection Relative Risk Reduction Versus Absolute Risk Reduction Since 2020-2022 to 2023 and Since 2023 to 2024

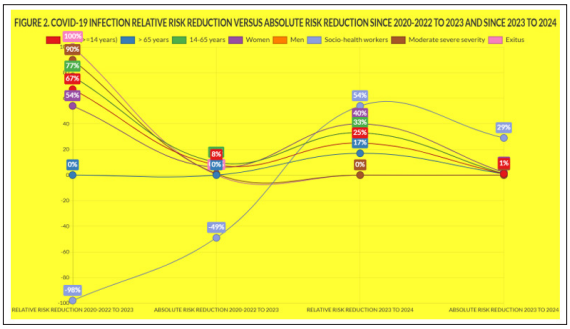

Figure 2: COVID-19 Infection Relative Risk Reduction Versus Absolute Risk Reduction Since 2020-2022 to 2023 and Since 2023 to 2024

Discussion

Main Findings

- For all the selected variables studied, the RRAs were always lower or in a very few equal to the RRRs both from the period 2020-2022 to 2023, and from 2023 to 2024, except for Socio-health workers and Presence of chronic diseases from 2020-2022 to 2023
- The downward differences in the figures for the RRAs versus the RRRs were more striking from 2020-2022 to 2023 than from 2023 to 2024. (TABLE 1, FIGURE 1, FIGURE 2).

In the period 2020-2022 SARS-CoV-2 variants were successively alpha, delta and omicron, and the population had received only 1, 2 or 3 doses of vaccine. In Spain, in April 2022, the population vaccinated with the complete regimen (2 or 3 doses) was 85%. In November 2022, more than 60% of people over 80 years of age, and 37% of people over 60 years of age, already had the second booster dose of the COVID-19 vaccine; this situation was considered in our study as an expression of the baseline rates. The ARR should be interpreted in the context of the baseline risk [25-29].

In 2023, the omicron SARS-CoV-2 variant predominated and the population received the 4th booster dose of the vaccine. By June 2023, the number of people with the 1st booster dose was 56% of the population. In 2024, the omicron SARS-CoV-2 variant predominated and the population received the 5th booster dose of the vaccine. 60% of the population over 80 years of age has received the vaccine adapted against the COVID-19 subvariants of the 2023/2024 campaign [30,31].

Apart from the "peaks" and "valleys" thanks to vaccination and the less severe effect of the current variants, the impact of COVID-19 has been significantly reduced. The course of the disease is in an endemic phase because cases are no longer reported as frequently as in its early years. In Spain, in 2024 vs. 2023 the incidence of COVID-19 and other risk measures are decreasing or it is stable. Population at risk with greater hybrid immunity is better prepared than 2023 to avoid cases of COVID-19 [12]. This lower reported incidence implies lower ARR figures.

In any case, the results must be evaluated with caution. In Spain, since April 28, 2022 there was a new "Surveillance and Control Strategy Against COVID-19" that include the non-performance of diagnostic tests, except on over 60 years of age. This means that positive cases have been counted with tests carried out in health services and with tests carried out at home and later reported to the GP. Thus, there is probably an underreporting. Thus, this lower reported incidence, both real and due to underreporting, implies lower ARR figures [32].

Comparison with Other Studies

Vaccine efficacy is usually expressed as an RRR. The reported efficacy for 2021 was an RRR of 95% for the Pfizer-BioNTech vaccines, 94% for the Moderna vaccines. While the RRR only considers participants who might benefit from the vaccine, the ARR considers the entire population. ARRs tend to be ignored because they give a much less impressive effect size than RRRs:

1.2% for the Moderna vaccines and 0.84% for the Pfizer-BioNTech vaccines. That is, for the Pfizer-BioNTech vaccine, the 2021 ARR data indicated that the vaccine reduces the risk of coronavirus disease of any severity by 94% relative to what occurs in other patients in the control group, and the ARR of 0.84% would mean that out of every 100 vaccinated people, 84 would not develop disease of any severity or that out of every 100 vaccinated people, 16 could develop disease of any severity [33,34].

The potential benefits of the intervention (i.e., the ARR) are greater in patients at high risk than in those at lower risk. It can be seen that the ARR becomes smaller when the event rate is lower, while the RRR, or the "effectiveness" of the treatment, often remains constant. This can influence the design of clinical trials: The drug is studied in very high-risk patients, in whom the ARR is most impressive, but is ultimately marketed to lower-risk patients, in whom its benefit is significantly lower. This highlights the importance of considering both figures when deciding whether to administer a drug [35].

It is important to note that the ARR is highly dependent on the prevalence of a disease, as opposed to the RRR. That is, since the ARR is highly dependent on the prevalence/incidence of a disease, it can vary, especially if the prevalence/incidence of the disease changes frequently, such as in a pandemic. The higher the prevalence of the disease or risk, the higher the ARR compared to a lower prevalence of the disease or risk, where the ARR may be lower. This is despite the RRR remaining the same for both cases. In short, the ARR depends on the baseline risk of the study population or the individual patient.

Because the ARR is a much lower number, it sounds like it is saying that the other number (the RRR) is not true, but this is not accurate, they are both capturing some aspect of reality, just measuring it in a different way. As far as vaccines are concerned, for example the Pfizer studies were done during a low incidence of COVID-19 and one can assume that the ARR in the other vaccine studies done during a high incidence will be higher than in the Pfizer studies due to the higher prevalence of the disease. However, one would expect the RRR to remain constant across the board as far as the intervention is concerned. This is why the ARR is not a good measure of an intervention in a disease that changes prevalence frequently, such as in a pandemic. The ARR is great to use in static diseases such as diabetes, stroke, coronary artery disease, vascular disease, etc. With vaccines, it takes time to become immunized. Vaccines are given to prevent a disease at some point in the future. In a pandemic, you will get absolutely different ARR depending on the prevalence of the disease during that time, i.e. during a surge, you can expect a high ARR, but a lower ARR during times of low prevalence [36].

Despite biases, RRR remains a very useful piece of data: it can be used to estimate the potential impact on people with very different initial risk levels, and it can help people put potential greater benefits and harms into perspective. A pernicious trend is to use ARR figures to try to drastically downplay the value of vaccines [37].

Another aspect to keep in mind is that most people have some degree of protection due to underlying immunity. By the third quarter of 2023, 98% had antibodies against SARS-CoV-2, with 14% due to vaccination alone, 26% due to infection alone, and 58% due to both (hybrid immunity). Seroprevalence surveys suggest that more than a third and possibly more than half of the global population had been infected with SARS-CoV-2 by early 2022. As large numbers of people continue to be infected. Studies have shown a decrease in the immunity provided by the vaccine, but the temporal evolution of natural and hybrid immunity is unknown [38-40].

Based on studies through 2021, it has been reported that participants who received prior infection or placebo had a 92% lower risk of developing COVID-19 in the future compared to participants who did not receive prior infection or placebo. Prior infection, hybrid immunity, and two-dose vaccination provided substantial protection against symptomatic and severe COVID-19 during the early period of the delta variant. Therefore, as a substitute for natural infection, vaccination remains the safest protection strategy [41].

In summary, in general practice setting in Toledo, Spain, the hybrid immunity intervention (natural infection and/or vaccination) in 2024 compared to 2023 shows exceptionally striking RRR figures versus ARR (for the total population seen in the clinic, an RRR of 25% versus an ARR of 1%). In any case, one should be cautious when assessing these figures for 2023 and 2024 as they may have a bias due to reduced incidence and underreporting.

Conclusion

In a general practice setting in Toledo, Spain, the risk reduction by the hybrid immunity (natural infection and/or vaccination) intervention expressed as RRR shows an exceptionally striking appearance that does not exist in its expression as ARR, especially in the early period of the COVID-19 pandemic. The true impact that could be had when applied to patients may not be clearly perceived by the RRR measure, since it illustrates the benefit of the treatment in relative terms. Possibly, in daily practice what would really be desired to determine is the outcome in treated patients, i.e. the ARR. However, the evolution of incidence, baseline risk and, in our study, the possible underreporting of cases must be taken into account. This underlines the importance of considering both the ARR and the RRR.

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