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Editorial Letter

Overview on the COVID-19 Vaccine Effectiveness

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Why do we study COVID-19 vaccine effectiveness?

The lack of standardized assays to compare different vaccine platforms, the unknown duration of protection, tolerability, few clinical trials, efficacy in the elderly, and the newly launched platforms are all reasons for studying COVID-19 vaccine efficacy. Most COVID-19 vaccines are given intramuscular and induce a high IgG response to protect against lower respiratory infections. They protect against symptoms and reduce the duration and amount of virus shedding but cannot stop viral transmission [1]. There are few standardized assays to compare vaccines, such as measuring the level of neutralizing antibodies (nAbs) [2]. It is known that spontaneous infection produces low antibody titers. However, little is known about how long vaccine immunity sustains, and if it lasts longer or shorter than active infection. Booster doses, as with other immunizations, may help [1]. The risk of illness enhancement due to different vaccine platforms is still unknown [2]. Tolerability is critical in children since they react more strongly than adults. Therefore, considering a lower dose is crucial, especially for the adenovirus and mRNA vaccines [1]. The raised concerns include the lack of data from clinical trials on how COVID-19 vaccines will perform in older subjects more susceptible to COVID-19. Multiple variables may contribute to vaccination ineffectiveness in the elderly, justifying VE research on this group. Based on the available data, the elderly group responds less than younger subjects, and a booster dose might be needed [1]. There is a loss of T-cell receptors in both CD8 and CD4 cells and a drop in T-cell survival as people age. However, less functional antibodies are generated, while T-helper cells respond less well to immunization. Thus, monitoring COVID-19 vaccine effectiveness in the elderly is critical [3]. There are concerns about new vaccination platforms (mRNA vaccines) and vaccine manufacture by pharmaceutical companies with no prior experience [1].

Vaccine efficacy *vs.* effectiveness

Vaccine effectiveness quantifies a vaccine's performance in a clinical study [4]. Experiments with controlled circumstances for participants, environment, and vaccine type are the most accurate to determine efficacy. This step is required for licensing globally. Less than 50% reduction in disease attack rate (AR) between unprotected and vaccinated trial cohorts is considered efficacious. The relative risk (RR) in the vaccinated community can be calculated using the following equation [5]:

Efficacy=(ARU-ARV/ARU)*100 and

Efficacy=(1-RR)*100

Vaccine efficacy is a measure of how a vaccine works in the real world. The most well-known VE study design is the retrospective case-control study, which compares VEs between infected patients and healthy controls. The odds ratio (OR for developing infection despite vaccination) is used to describe VE [Effectiveness= (1-OR) 100] [5].

Types of effectiveness studies

Vaccine effectiveness can be studied using cohort, case-control, quasi-cohort, and ecological study methods. Uncertainty about the premarketing stage can be addressed by observational studies in post-marketing. Two typical VE evaluation methodologies are cohort studies and case-control studies [6]. Age, comorbidities, socioeconomic position, and other characteristics, such as various AEFI, are all confounding factors that can alter the findings and lead to bias [7]. The "indirect cohort" or "quasi-cohort" study design evaluates diverse responses in the same vaccinated group. Ecological or observational VE evaluates the changes in disease burden throughout time (e.g., before and after the introduction of routine vaccination). This strategy can utilize laboratory-based diagnostics or large-scale databases with billing codes or ICD-10 discharge codes [5]. The post-marketing research was influenced by many factors such as clinical trial efficacy, immunization program performance, disease risk factors, and seasonality [7].

COVID-19 vaccine effectiveness studies

COVID-19 VE investigations are ongoing. Worldwide, most health authorities have chosen two categories for early vaccination: healthcare professionals and the elderly, mostly in nursing homes (LTCF). So far, most COVID-19 vaccination efficacy trials have focused on these two populations. All vaccines investigated showed promising efficacy following the second dose, according to the available data. On average, 296,093 (99.0%) of those who received one vaccine dose obtained a second dose in a median of 21 days, according to a study on the direct and indirect effects of mRNA vaccine against SARS-CoV-2. The average age was 85.9 years, with 70.9% females. VE was 57.2% (95% CI: 56.1-58.3) following two vaccination doses, while it was 81.8% (95% CI: 81.0-82.7) for residents who were fully vaccinated and had never had SARS-CoV-2 infection, but declined to 56.8% (95% CI: 47.1-67.7) for those who had. Indirect protection was calculated at 57.3% (95% CI: 48-66.3) [8]. In a retrospective registry, 95.2% of LTCF residents and 86.0% of frontline HCWs received the first and second vaccine doses of BNT162b2 mRNA (BioNTech, Pfizer) vaccines. The first dose had no protective impact on LTCF residents. VE was 17% (95: CI: 4-28) in the HCWs 14 days after the first dose (before the second dose). After seven days, LTCF VE increased to 64% (95% CI: 14-84) and in HCWs, VE increased to 90% (95% CI: 82-95) [9]. A prospective cohort study in Denmark indicated that a single dose of BNT162b2 vaccine had a 21-day efficacy of 72% (95% CI: 58-86) and 7-day effectiveness of 86% (95% CI: 76-97) in the antibody-negative cohorts [10]. A cohort study evaluates the BNT162b2 Covid-19 VE with various variants and compares infection rates in vaccinated people 14 days following their second dose with the national infection incidence. Effectivity was estimated to be 87% (81.8-90.7%) against B.1.1.7, 72.1% (66.4-66.6%) against B.1.351, and 69% (63.1-74.1%) against unknown variants [11]. Researchers examined the efficiency of the initial doses of ChAdOx1 nCoV-19 and BNT162b2 vaccinations against SARS-CoV-2 infection in LTCF residents in England. The first dose of BNT162b2 (Pfizer, BioNTech) and ChAdOx1 (Oxford, AstraZeneca) vaccines was linked to a lower risk of SARS-CoV-2 infection, and the VE increased 4-7 weeks after vaccination [12]. Contrary to expectations, HCWs exposed to COVID-19 demonstrate strong secondary antibody responses following immunization, with IgG spike titters continuously rising over seven days, peaking at 10 and 14 days. HCWs with prior COVID-19 infection had greater binding antibody titers at all-time periods (0, 7, 10, and 14 days) [13]. Most COVID-19 VE trials focused on two or three vaccinations (BNT162b2, ChAdOx1, and Moderna), and most were conducted in high-income countries (the USA, UK, and EU). With additional vaccines approved for emergency use, we expect more VE to be accessible shortly since more research is needed on HCWs, the elderly, and other age groups.

Conflicting Interests

The authors declared no conflicts of interest.

Data sharing statement

N/A

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