5PSQ-002

ADVERSE EVENTS REPORTED AFTER ADMINISTRATION OF BNT162B2 AND MRNA-1273 COVID-19 VACCINES AMONG HEALTHCARE-WORKERS

M. Valera Rubio[1], MI. Sierra Torres[2], R. Castillejo García[1], J. Cordero Ramos[1], JF Álvarez Zarallo[3], MA. Calleja Hernández[1]
[1]Hospital Universitario Virgen Macarena. Hospital Pharmacy. Seville, Spain.
[2]Hospital Universitario Reina Sofía. Hospital Pharmacy. Cordoba, Spain.
[3]Hospital Universitario Virgen Macarena. Health surveillance department, Seville, Spain

BACKGROUND AND IMPORTANCE

Since December 2019, the world has faced a new disease known as COVID-19. On March 11, 2020, the World Health Organisation officially declared the COVID-19 pandemic. Given the **health emergency, vaccine development progressed rapidly, but with limited safety data under real-world conditions.**

AIM AND OBJECTIVES

To describe and compare the incidence of **adverse events with the BNT162b2 and mRNA-1273 COVID-19 vaccines**, taking into account the **number of doses and subjects previously positive** for **SARS-CoV-2** infection.

MATERIALS AND METHODS

- A retrospective observational study was conducted in a **tertiary hospital** between **March-April 2021.**
- Data were collected through a **questionnaire** sent by email to **hospital staff.**
- Demographics and data regarding the occurrence of **adverse events were collected, indicating which vaccine was administered.**
- **Statistical analysis** was performed using **SPSS software.** Groups were compared using the **chi-square test and Fischer's exact test** when necessary.

RESULTS

- **1249 respondents completed the survey** (25% of all hospital staff). **52%(650) received BNT162b2 vaccine and 48%(599) mRNA-1273.**

- **14402 adverse reactions** were recorded. **6896** were **local: 3939** were with **mRNA-1273** and **2957** with **BNT162b2** (6.6 vs 4.4 reactions per patient); and **7506 systemic: 4460** with **mRNA-1273** and **3046** with **BNT162b2** (7.4 vs 4.7 per patient).

- The occurrence of **local reactions** was **95.8%** after the **first dose/89.1%** after the **second dose** with **mRNA-1273 vs 89.7%/82.5%** with **BNT162b2**. For **systemic reactions**, this proportion was **64.3%/93.3% vs. 46.8%/73.2% (p-value<0.05).**

- In terms of severity, **379 patients (63.3%)** with **mRNA-1273** confirmed a **severe reaction vs 222(34.2%**) with **BNT162b2** and **60 patients (10%)** with **mRNA-1273** confirmed an **urgent reaction vs 33(5.1%)** with **BNT162b2 (p-value<0.001).**

- For both vaccines, there was **no difference in the occurrence of local or systemic reactions between patients seropositive and seronegative for SARS-CoV-2.**

CONCLUSIONS

- The results are consistent with the limited data available so far, confirming that although **these are not particularly serious adverse effects**, they do **occur in a large majority of vaccinated persons** and in greater numbers after administration of the **mRNA-1273 vaccine**.

- The **Hospital Pharmacy Service is a key agent in pharmacovigilance** within the healthcare system and must be aware of the safety profile of new drugs.

- **This study is an essential tool to detect and prevent adverse events**.

eahp european association of hospital pharmacists

Hospital Universitario Virgen Macarena