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.