Janssen Covid-19 Vaccine Safety In A Real-world Setting: A Pharmacovigilance Study

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BACKGROUND:

The development of COVID-19 vaccines is a global priority aiming to mitigate the spread of SARS-CoV-2. Although vaccination has been proved to be effective in reducing the rate and severity of COVID-19, it is also associated with the ocurrence of serious adverse events (AEs).

Jcovden, previously Janssen (Ad26.COV2.S) COVID-19 vaccine, have shown to be safe in phase 3 trials.

We aimed to compare its safety to Pfizer-BioNTech (BNT162b2) and Oxford-AstraZeneca (ChAdOx1) vaccines in a real-world setting.

METHODS:

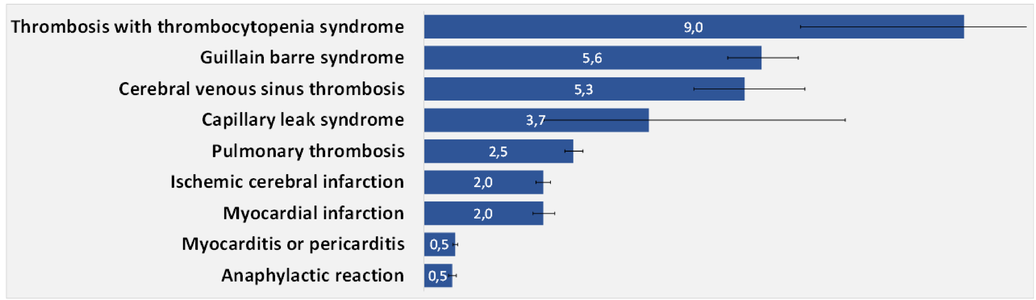
Data about serious adverse events of special interest following vaccination were obtained from EudraVigilance, a large spontaneous-reporting database operated by the European Medicines Agency (EMA).

Analysis included all reports until 22nd August 2022. Vaccines were compared by means of the Proportional Reporting Ratios (PRRs) regarding selected AEs.

PRR was calculated as the ratio between the proportion of spontaneous reports about a specific AE for Jcovden to the same proportion obtaind for the comparators. A PRR >2 indicates a possible association between Jcovden and the AE.

Jcovden is possibly associated with a greater incidence of some serious adverse events compared to other covid-19 vaccines. Monitoring the safety of vaccines is essential to to reduce the risks and increase vaccination benefits.

Jcoviden vs Pfizer-BioNTech (BNT162b2)



Jcoviden vs Oxford-AstraZeneca (ChAdOx1)

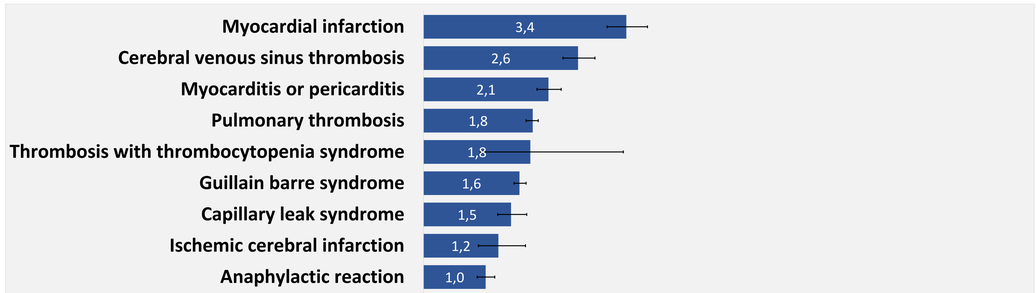


Fig.1 Proportional Reporting Ratios for serious adverse events of special interest following vaccination reported to EudraVigilance until 22nd August 2022.

RESULTS:

We found possible association (PRR>2) between Jcovden vaccine and different AEs of special interest (Fig.1).

The probability of reporting of Thrombosis with thrombocytopenia syndrome, cerebral venus sinus thrombosis, myelitis transverse, Guillain Barret Syndrome, pulmonary embolism and capillary leak syndrome was 3 to 9 times greater (PRR value between 3 and 9) for Jcovden compared to Pfizer-BioNTech vaccine .

Also, reporting probability of myocartidis/pericarditis and Guillain Barret Syndrome was 3 and 2.5 times greater for Jcovden than Oxford-AstraZeneca ChAdOx1, respectively.

CONCLUSION:

Overall, most COVID-19 vaccine-associated AEs occur very rarely. Jcovden is possibly associated with a greater rate of some serious AE compared to other covid-19 vaccines.

The ocurrence of serious AE in the real-word setting that were not previously observed in clinical trials reassure the importance of continuously monitoring of vaccine safety.

REFERFENCES

Evans SJ et al. Use of proportional reporting ratios (PRRs) for signal generation from spontaneous adverse drug reaction reports. Pharmacoepidemiol Drug Saf. 2001 Oct-Nov;10(6):483-6.

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