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Steven-Johnson Syndrome and Toxic Epidermal Necrolysis Following COVID-19 Vaccination: An Analysis of the EMA EudraVigilance Database

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Introduction: Steven-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are rare, potentially life-threatening mucocutaneous disorders arising as drug hypersensitivity reactions, most commonly following treatment with antibiotics or anticonvulsants. However, rare cases developing after vaccination were also described.

Aim: SJS/TEN clinical presentation is impressive and anti-vaxxers' misinformation regarding COVID-19 vaccination campaign was focused on SJS/TEN to increase vaccine hesitancy. We conducted an analysis of the European Medicine Agency's EudraVigilance database of suspected adverse drug reaction reports (SADRR) to provide a more data-based outlook on the potential link between COVID-19 vaccination and SJS/TEN.

Materials and Methods: Data reported up to 9th July 2022, regarding the total number of SADRR, and the number of SADRR reporting on SJS/TEN were retrieved for seven vaccines. This included five COVID-19 vaccines: Moderna and Pfizer-BioNTech (mRNA), AstraZeneca and Janssen (adenovector) and Novavax (protein), as well as two influenza vaccines (control group). The odds ratios (OR) and 95% confidence intervals (CI) for SADRR reporting on SJS/TEN were calculated for each vaccine and compared to the control group, and to every other COVID-19 vaccine.

Results: Our analysis suggests that the odds that a SADRR reports on SJS/TEN are significantly lower for COVID-19 vaccines than for the control group, apart from SJS and the Moderna vaccine (OR=0.47; 95%CI [0.22 -1.00]). Furthermore, the odds that a SADRR reports on SJS are significantly higher for the Moderna vaccine when compared with the Pfizer-BioNTech (OR=2.30; 95%CI [1.57 - 3.38]) or AstraZeneca (OR=2.38; 95%CI [1.43 -3.95]) vaccines.

Conclusion: SJS/TEN after COVID-19 vaccination seems to be a possible, but exceedingly rare adverse drug reaction. The potential signal identified in our short analysis, regarding the Moderna vaccine, deserves further in-depth analysis and could be due to the substantially higher dose used by the Moderna vaccine (100 µg) compared to the Pfizer-BioNTech vaccine (30 µg).

Keywords: COVID-19 Vaccines, Pharmacovigilance, Stevens-Johnson Syndrome, Toxic Epidermal Necrolysis