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Poster Abstract

P56-3 Severe drug hypersensitivity of polyethylene glycol (PEG) -containing medicals and drugs before and after the COVID-19 pandemic

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Background : The unprecedented global administration of COVID-19 LNP/mRNA vaccines has delivered billions of PEG-containing doses. While the vaccines themselves are largely safe, the impact of potential PEG sensitization on other PEG-containing medicals and drugs remains unclear. **Methods :** Using the FDA Adverse Event Reporting System (FAERS) database, we analyzed severe drug hypersensitivity for 19 PEG-containing clinical products before and after the pandemic, including Ativan, Cimzia, Definity, Doxil, Krystexxa, Lumason, MiraLAX, Mircera, Moviprep, Neulasta, Oncaspar, Onivyde, Palynziq, Pegasys, Pegintron, Plegridy, Prograf, Somavert, and Taxol. Real-world data were collected for five years before and after 2019 unless otherwise specified. The Wilcoxon Signed-Rank Test (two-tailed) was used to compare pre- and post-pandemic drug events, and the Mann-Whitney U test (two-tailed) analyzed yearly variations for individual drugs. **Results :** Across all 19 PEG-containing products, the median annual cases of anaphylaxis increased from 3.2 before to 5 after COVID-19 ($p=0.54$), while life-threatening and fatal cases rose from 1 to 2.6 ($p=0.04$). Ultrasound-enhancing agents Definity and Lumason were analyzed in detail : median annual anaphylaxis cases for Definity increased from 11 (2015-2019) to 20 (2020-2024 ; $p=0.02$), and for Lumason from 3 to 34 ($p=0.01$). Life-threatening and fatal cases for Definity remained stable (3 vs. 3, $p>0.05$), but for Lumason increased sharply from 1 to 32 ($p=0.01$). **Conclusions :** Severe drug hypersensitivity associated with PEG-containing clinical products appears to have increased following the COVID-19 pandemic.