

NOVEL ADVERSE EVENTS OF EMPAGLIFLOZIN : A DISPROPORTIONALITY ANALYSIS IN USFDA ADVERSE EVENT REPORTING SYSTEM DATABASE

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Introduction

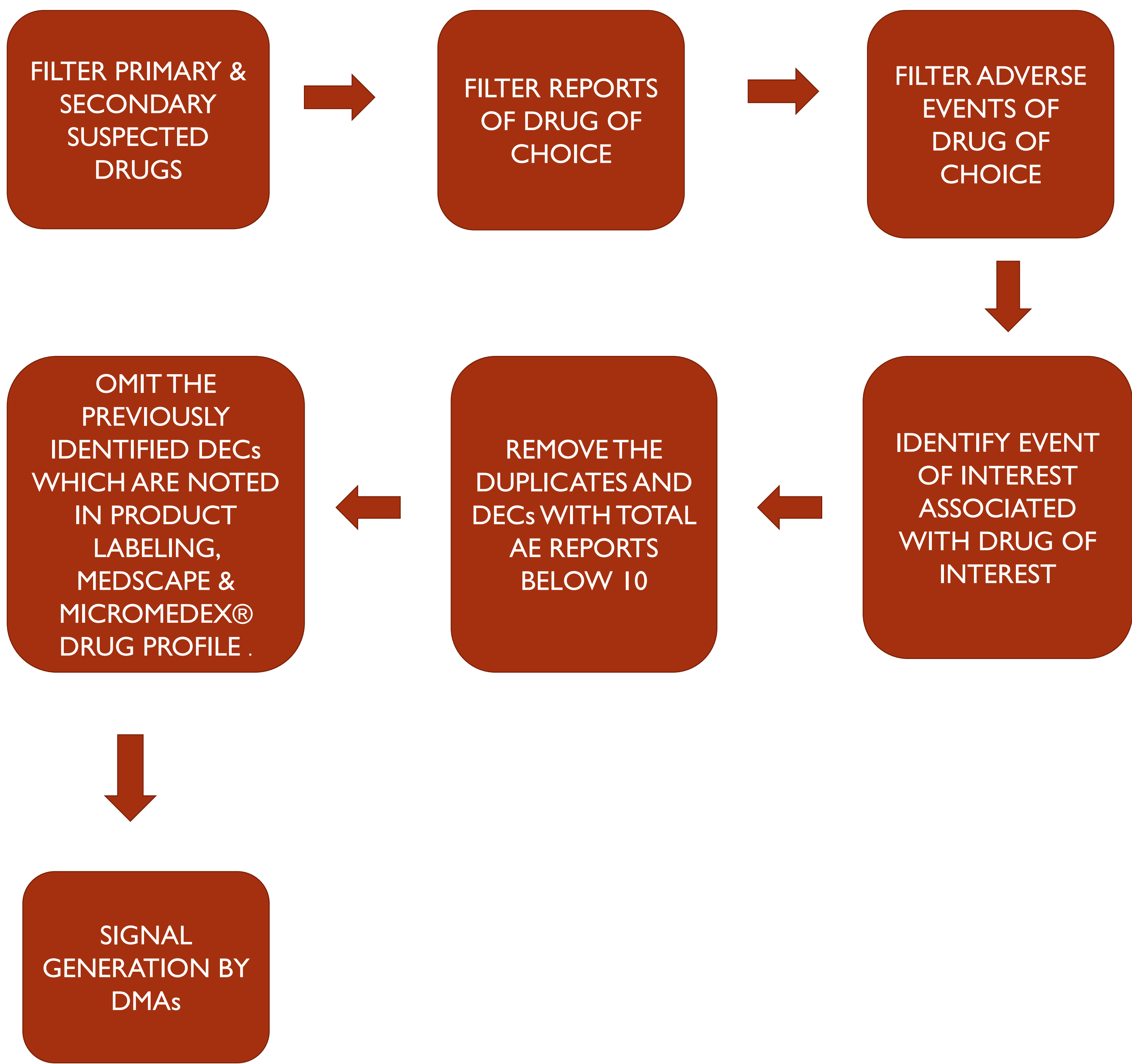
- Signal detection is one of the most advanced and emerging field in pharmacovigilance. It facilitates early adverse drug reaction detection.
- Empagliflozin is a Sodium-Glucose co transporter 2 (SGLT2) inhibitor approved by the US Food and Drug Administration (FDA) in 2014 for the treatment of type-2 Diabetes Mellitus.
- Data mining is defined as the use of statistical techniques, such as disproportionality measures for database or large information sources for extracting an unknown information.
- Data Mining Algorithms (DMAs) are the rapidly emerging computer-assisted technique used to assess the degree of association between the reported adverse drug reaction (ADR) and the suspected drug compared to other drugs in the database.

Objective

- This study aims in the identification of Pancreatitis associated with Empagliflozin using disproportionality analysis of the FDA database of Adverse Event Reporting System (FAERS).

Methodology

- Publicly available FDA AERS database was downloaded from FDA AERS website
- AERS is a spontaneous reporting system that contains data on AEs and medication errors.
- Study Procedure**
- To consider a Drug Event Combination (DEC) to be clinically relevant in this study, a minimum of total ten reports must be present in database for that event.
- Empagliflozin associated adverse events which were detected earlier (in clinical trials) and that have been mentioned in “black-box warning”, “adverse effects”, “post-marketing reports” sections of product labelling, Medscape and Micromedex® drug profiles were excluded from the study.
- The reports were consider for analysis, only if they were reported as primary or secondary suspect for the drug of interest.
- The ROR and PRR as a measure of disproportionality, were used to assess the association between the drug of interest and event of interest.



Results

- A total of 31,070 reports for Pancreatitis have been reported in the FDA database. Among them 148 reports were associated with Empagliflozin.
- Pancreatitis was ranked 27th among 900 Empagliflozin associated Adverse Events (AEs).
- The mean age was 32.29 (95% CI; 27.49- 37.10) and female to male ratio was 1.04:1.
- A positive signal was obtained with ROR: 4.10 and PRR: 4.09.
- Serious reports included hospitalization (76), life-threatening (12), disability (1) and other serious events (107) and one death was reported.
- Linear regression analysis indicated there was no significant correlation between the PRR and time (R=0.491; p=0.400) and ROR and time (R=0.480; p=0.413).
- The Log Likelihood ratio for Pancreatitis with Empagliflozin was found to be 4.81 and the reporting ratio was 4.29 (Critical value- 5.25).

Signal Strength of Clinically Relevant Reactions of Empagliflozin

Pancreatitis	
ROR	4.10
PRR	4.09

Empagliflozin associated Pancreatitis :A total of 148 DEC's associated with Empagliflozin and Pancreatitis were reported. The DMA values for the mentioned DEC was found to be ROR- (4.10), PRR (4.09)

Conclusion

- A positive signal was observed for Empagliflozin associated Pancreatitis, although a causal relation cannot be definitively established.
- Further monitoring of this AE associated with Empagliflozin is necessary in future as the number of cases of pancreatitis are increasing.
- Health care professionals should be cautious about the possibility of encountering serious AEs associated with Empagliflozin.

Reference

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