CANDESARTAN INDUCED ERECTILE DYSFUNCTION: MINING AND ANALYSIS OF REAL-WORLD DATA **BASED ON US FDA ADVERSE EVENT REPORTING** SYSTEM DATABASE FROM 1998 TO 2024.

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AM FARUK AHMED and **E.MAHESWARI**

Department of Pharmacy Practice, Faculty of Pharmacy, M.S. Ramaiah University of Applied Sciences, Bangalore-560054

Karnataka, India

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Candesartan, an angiotensin receptor blocker was utilized as an antihypertensive medication. Candesartan works by blocking the angiotensin II receptor type 1, reducing blood pressure and fluid retention. It binds tenthousand times more strongly to angiotensin II receptor type 1 than type 2, leading to vasodilation and decreased blood pressure. Signal detection of candesartan helps in the detection of **unidentified Adverse Drug Reactions (ADRs)** of candesartan.

The authors aimed to explore the novel signals reported for Candesartan in the USFDA Adverse Event Reporting System (FAERS) database.

- In this study, **FAERS data** was analysed to identify a novel signal for Candesartan.
- The data mining algorithms like **Proportional Reporting Ratio (PRR)** and **Reporting Odds Ratio (ROR)** values were obtained from **OpenVigil database**.
- Positive signals were defined as values of **PRR≥2**, **ROR-1.96SE>2**, **chi square >** 4 with more than 2 adverse events.
- The genes and proteins associated with Erectile Dysfunction were found out from various databases such as STITCH, STRING and HuGE Navigator.
- Later these genes were docked with Candesartan using **BIOVIA Discovery** Studio, PyRx, Pymol and Swiss PDB viewer.

RESULTS

A total of **28655483 adverse events** are reported in the database. Of these adverse events, 6551 were







linked to candesartan.

- Candesartan got its **FDA** approval in 1998.
- The OpenVigil data showed **19 events of Erectile** dysfunction for candesartan.
- The PRR value was found to be 3.50 (2.23; 5.48), ullet**ROR was 3.51 (2.23; 5.51)**, **Chi-Squared with** Yates' correction was 31.51 which indicated positive signals.
- The signal was **most prevalent among Europeans** with **11 events** and had a **PRR of 2.525 (1.401**; 4.553) and ROR of 2.537 (1.401; 4.593).
- The genes involved in erectile dysfunction according to the bioinformatics databases are **eNOS** and ACE with the highest binding affinity of -8.7 and -8.6 respectively.





Figure-10



ADMINISTRATION



a pharmacovigilance data analysis tool

Figure-3

BIOVIA

Figure-5

Figure-7

Figure-8

CONCLUSIONS

The binding affinity and the disproportionality results obtained for data mining algorithms confirms erectile dysfunction as adverse reaction of candesartan. However, further pharmacogenetic and prospective pharmacoepidemiologic analysis with extended follow-up are needed to establish the mechanism and prevalence of the reported Adverse Drug Reaction.

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CONTACT INFORMATION

Mail: <u>abdulmannanfarukahmed17@gmail.com</u>

Phone: +91-9482207223