DSEN ABSTRACT

Prescription patterns of ranitidine, nizatidine, famotidine, and cimetidine in Canada

Summary

- In 2019, some batches of ranitidine, a readily available histamine H-2 receptor antagonist that counteracts stomach acid, contained an impurity called N-nitrosodimethylamine (NDMA), which may increase cancer risk
- Knowing how many Canadians use H2 blockers and who these people are can help researchers/policymakers understand this source of NDMA exposure
- CanPath is a Canadian prospective cohort study that provides a snapshot of participants' health, lifestyle and environmental data to address questions on risk factors for cancer and other diseases
- We studied H2 blocker use in three CanPath cohorts, CaG (Quebec), OHS (Ontario), BCGP (British Columbia)
- Ranitidine was responsible for almost 95% of all H2 blockers
- Overall, people were intermittent users of H2-blockers
- Doses were mostly not above recommended use

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What is the current situation?

Histamine H-2 (H2) blockers, including ranitidine, are used to treat gastric problems (such as reflux) and are available over the counter (OTC) and by prescription. There are 28 prescription ranitidine products available and 10 OTC. In 2019, new safety concerns about ranitidine emerged following the detection of NDMA, a potential carcinogen, in some batches of the drug. Knowing the extent and patterns of ranitidine use in Canada can help regulators estimate the risk of NDMA exposure related to this drug.

What was the aim of the study?

1. To describe exposure to ranitidine, nizatidine, famotidine and cimetidine in Canada
2. To identify patient characteristics associated with the prescription of ranitidine, nizatidine, famotidine and cimetidine in Canada.

How was the study conducted?

- We used data from three Canadian Partnership for Tomorrow's Health (CanPath) prospective cohorts: the Ontario Health Study (OHS), Quebec's CARTaGENE (CaG) cohort and British Columbia's Generations Project (BCGP).
- All were linked with electronic provincial administrative data to obtain information about medication prescribed. For OHS, only seniors could be evaluated in this way.
- Using these cohorts, we evaluated subjects exposed between 2009 and 2018 to one of the four histamine H2 blockers: ranitidine, nizatidine, famotidine, and cimetidine.

What did the study find?

- During our study interval, 6,920 people (7.1% of eligible participants), followed for an average of 3.4 years, filled an H2 blocker prescription.
- Ranitidine was responsible for almost 95% of all H2 blockers dispensed in all cohorts
- Almost two-thirds of those using H2 blockers were female (62.2%). Subjects tended to be middle-aged and older (mean age of 57.7 years in CaG and BCGP)
- After filling the first prescription for an H2 blocker, the average OHS subject had 3-4 episodes of taking the drug for about 111 days at each time. In CaG and BCGP, subjects had nearly half the exposure of OHS participants (possibly related to the older age in OHS).
- On average, subjects did not exceed recommended daily doses in adults for ranitidine, nizatidine, or cimetidine
- In summary
    - Ranitidine was responsible for almost 95% of all H2 blockers
    - Overall, people were intermittent users of H2-blockers
    - Doses were mostly not above recommended use

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