Additional patients were required to be ≥18 years of age at index.

In this study, we examined the risk of adverse GI, CV, and renal events associated with the release form of diclofenac, with particular interest in delayed-release formulation.

In an analysis of US health care claims, increased risks of certain outcomes were associated with increased doses of diclofenac, compared with no current use and with extended/delayed-release formulations, with the exception of nonsteroidal anti-inflammatory diseases.

Gastrointestinal outcomes during follow-up for each of the outcomes were censored when a related event was observed. Risk of outcomes related to diclofenac dose and formulation, using a Cox proportional hazards model, with time-dependent variables for total daily dose and release formulation (available in 25, 50, and 75 mg strengths).

The release form of the drug was defined based on the strength and total daily dose used.

Medical claims include, but are not limited to, diagnoses, procedures, and prescriptions, along with respective dates, and detailed information on hospitalizations, including admission and discharge dates.

Specifi c clinical events of interest in this analysis include the following:

- UGIB
- LGIB
- Gastrointestinal bleeding (with IR/ER)
- Gastrointestinal bleeding (with IR/ER)

In addition to the total daily dose used, NSAID release formulation was controlled for relevant demographic and clinical characteristics of the overall sample.

CONCLUSIONS

The release form of the drug was defined based on the strength and total daily dose used.

The CCAE and MDCR databases provide longitudinal data on medical and pharmacy utilization for over 100 million employer-sponsored private health insurance plans in the US.

While the findings of this study suggest an association between diclofenac daily dose, release formulation, and the risk of outcomes, immediate-release formulation (available only in 100 mg strength) has a differential risk profile compared with the delayed-release formulation (available in 25, 50, and 75 mg strengths).

In addition to the total daily dose used, NSAID release formulation was controlled for relevant demographic and clinical characteristics of the overall sample.

We did not have access to patients’ medical charts or complete medical histories, and the history of events was determined using claims data for a 12-month period before the exposure period.

In an analysis of US health care claims, increased risks of certain outcomes were associated with increased doses of diclofenac, compared with no current use and with extended/delayed-release formulations, with the exception of nonsteroidal anti-inflammatory diseases.

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