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Research Letter

Gender difference in burden of diclofenac-induced peptic ulcer disease using days lost due to disability

In this cohort study we aim to assess the influence of gender in the burden of diclofenac-induced Peptic Ulcer Disease (PUD). It will be important to have a discussion in the beginning about the tool used to calculate the burden of PUD, i.e., Days Lost due to Disability (DLD). DLD is a new term which was originally developed from the World Health Organization indicator to calculate the burden of disease or illness, popularly known as Disability Adjusted Life Years (DALY). DALY has two arms in its calculation, Years of Life Lost (YLL) and Years Lost due to Disability (YLD). YLL is a good measure to calculate the burden of a disease or illness to a large sample especially in nationwide or worldwide studies.[1,2] Disability Weight (DW) in the calculation of YLD makes it tough to calculate, but it makes more sensible in small sample size studies. DW is the Quality of Life (QoL) component in the calculation of DLD. If we find the QoL in score of one, 1-QoL will give the DW. Individual incidences need to be studied in detail to find out the DW.

METHODS

We had selected YLD as it was a single-center study (community pharmacy in Kasaragod, Kerala, India) and we had calculated the burden in days instead of years as the duration of PUD incidences were short.[1,3] We had sampled only those patients who were clinically recovered of the PUD incidence, so as to measure the duration of PUD as part of DLD calculation. The study was done in patients with the age between 18 and 64 (both inclusive). Diclofenac was the most used Nonsteroidal Anti-Inflammatory Drug (NSAID) in 2009 at study site.[4] The sample size was 1000 prescriptions of diclofenac tablets, 500 each in male and female genders. Naranjo Algorithm was used along with clinical diagnosis of PUD by the physicians, to do the causality assessment and possible, probable or definite ADR. Patients were on concomitant medications which scored a possible or above causal relationship with the PUD were excluded from the study. Some of the literature suggests there were higher incidences of NSAID induced or other PUDs in males.[1]

FINDINGS

We found that the differences do not exist (males had only two incidences higher than females). Smoking (on average, more than 10 cigarettes per day) and alcoholic consumption (on average, more than 2 drinks per day) were considered as exclusion criteria. Thus the incidence of diclofenac induced PUD was in a ratio of 1:1 in males and females. The Relative Risk (RR) was 1.1. Further in our study we had found that the burden of diclofenac-induced PUD was slightly higher in female even though males had a little higher incidence. Both were not statistically significant with confidence interval 95%. The reason for 03 DLD higher in females was because of longer duration of PUD and higher DW. When we calculate the DLD of PUD in males it was 18 incidences multiplied by 6.9 days as duration and 0.3 DW resulting in 37 DLD. For females it was 16 incidences multiplied by 7.8 days as duration and 0.32 DW to get 40 DLD.

COMMENTS

We conclude that there is no statistically significant difference exists between males and females in the burden of diclofenac-induced PUD when heavy smoking and alcoholic consumption are excluded. The limitations of the study include underreporting of diclofenac-induced PUDs and patient dropouts from the pharmacy.

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