Abstract

Disability Adjusted Life Years (DALY) is a widely used measure to quantify the burden of diseases or illness. DALYs for a disease is calculated as the sum of the Years of Life Lost (YLL) due to premature mortality in the population and the equivalent healthy Years Lost due to Disability (YLD). The only difference from the YLD and Days Lost due to Disability (DLD) calculation is that instead of considering the duration of Adverse Drug Reaction (ADR) in years, it is calculated in days. Objective: DLD was measured for diclofenac tablets to prepare the ADR profile. Methods: The study was done on the patients (18-65 years old) attending the community pharmacy at Kasaragod district, South India, with prescription of diclofenac tablets. Patients reported ADRs on their next visit to the pharmacy or they had called to the provided phone number and reported it. Disability Weight (DW) was calculated in an analogue scale from 0-1. Zero represent complete health and 1 represent death or equivalent condition. DW was multiplied with occurrence and duration of ADRs in days. Results: About 943 patients received diclofenac tablets in 1000 prescriptions were successfully followed up for possible, probable and definite ADRs. A total of 561 reactions reported in 2010 for diclofenac tablet in the study population. There were 34 different types of ADRs under 12 physiological systems/organs. Most common reactions were on gastrointestinal (GI) system (48%), followed by skin (14%), Central Nervous System (10%), renal (7%), and cardiovascular (7%). Abdominal pain, cramps or flatulence was the highest occurring GI ADR (107), followed by 43 rashes, 42 nausea/vomiting, 37 indigestion, 34 peptic ulcers, 31 edema etc. DLD for peptic ulcer was considerably high (0.078) per 1000 of the study population on diclofenac. The most damaging ADR were peptic ulcer with or without perforation, followed by rash 0.036 DLD and edema 0.027 DLD. There was considerable DLD by acute renal failure (0.012) Steven-Johnson syndrome (0.013) even though few cases were reported. Conclusion: Diclofenac has a complex adverse drug profile. Around 34 types of reactions were reported. Diclofenac was widely prescribed because of the experiential belief of comparative safety with other NSAIDs. The study shows the importance of pharmacovigilance even on the most prescribed medicine. Most disabling ADR for the study population was peptic ulcer with or without perforation. YLD or DLD are useful measures of calculating disability caused by ADRs. Future studies could focus on improving the usefulness & precision of DLD.
Keywords
Diclofenac, Drug Toxicity, Quality-Adjusted Life Years, Disability Evaluation, India.