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Characterization of laboratory and clinical findings of patients diagnosed with Drug-induced liver injury (DILI) as a tool to aid in diagnosis

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Background & Aim: Drug Induced Liver Injury (DILI) is a diagnosis the importance of which has become increasingly clear in recent years as a result of the combination of an increase in the number of reported cases each year and the potential for damage; DILI is the most common cause of Acute Liver Failure in the United States and a major cause of drug termination at various stages of development and marketing. Despite its importance, DILI is often underdiagnosed or suffers from a diagnostic delay, mainly due to a lack of a pathognomonic test, resulting in a Per Exclusionem diagnosis. Various attempts to find a more efficient diagnostic process met with partial success and the diagnostic challenge persists. The main objective of the study is to try to find unique characteristics for patients who have been diagnosed with DILI in order to try to create a basis for dealing with this diagnostic challenge.

Methods: A retrospective observational study was conducted on 50 patients hospitalized at "Shaare Zedek" Medical Center diagnosed with DILI.

Results & Discussion: In accordance with the literature on DILI, we found that the most common injury was hepatocellular (52% of the patients), that most of the cases were women (56% of the patients), that the prevalence increases with age (70% of the cases were over the age of 51) and that there is a relationship between the age and the sex of the patient to the type of injury. In accordance with studies conducted in the United States, the most common drugs described in our study as the cause of DILI are antibiotics (34% of the cases). The hepatocellular enzymes levels in patients with hepatocellular injury ranged from several hundreds to a thousand, and in the majority of the cases were higher than 10 times the upper limit of the norm (AST in 80.8% of the cases and ALT in 53.8% of the cases). These ranges correspond to the ranges described in the literature for toxic liver injury. In our study, we have not been able to verify the worldwide trend of increasing prevalence of DILI. In general, the severity of the cases in our study was relatively mild, as expressed in the absence of mortality, in the absence of liver failure and in relatively low bilirubin levels. Previous studies have found that the most unfavorable outcome was of patients with hepatocellular injury. In contrast to that, in our study, the worst prognosis was of patients presented with mixed injury. In contrast to viral hepatitis, we found that the De Ritis (AST/ALT) ratio in DILI is generally greater than one (in 82% of cases).

Conclusions: Despite the increasing prevalence of DILI according to literature, we have not been able to confirm this trend. In our opinion this is partially due a logistic difficulty- the absence of a specific diagnosis code for DILI, *i.e.,* patients whose main diagnosis is DILI are coded under another major diagnosis and the DILI is "Hidden" under a general hepatic diagnoses such as "Elevated Liver Enzymes" or even under a non-hepatic diagnosis as a free text. We respectfully submit that the ICD coding system should include DILI as a major diagnosis. We suggest considering using the De Ritis ratio as a diagnostic aid. Our study did not include a control group of viral hepatitis patients, so we can rely only on information from the literature, but this information is consistent across a large number of studies–Viral hepatitis is characterized by a De Ritis ratio <1, In contrast to that, most of the patients in our study are characterized by a De Ritis ratio>1.

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