

Clinical characteristics of 96 patients with drug-induced acute liver failure: a comparison between Traditional Chinese and Western Medicine

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Supported by Natural Science Foundation-funded Project: the Objectifying Research of Dialectical Olfactory Examination on Hepaticus Fetus in Hepatic Failure Patients Based the Breath Metabonomics (No. 81673806); the Specialized Research Fund of National Traditional Chinese Medicine Clinical Research and Base Construction Project: Clinical Features and Pathogenesis of Herb-induced Liver Injury (No. JDZX2015188); Creative Foundation of President of the 302 Military Hospital: A Prospective Study for Herb-induced Liver Injury Strategy Based on Integrated Evidencechain-based Causality Identification Algorithm (No. QNPY2015002)

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Accepted: February 27, 2017

Abstract

OBJECTIVE: To compare the causes, clinical symptoms, laboratory test results, and prognosis in patients with acute liver failure (ALF) induced by traditional Chinese medicines (TCM) and by Western Medicines (WM).

METHODS: The medical histories of patients who were diagnosed with drug-induced ALF (DALF) ($n = 96$) after hospitalization in the 302 Military Hospital between January 2010 and December 2015 were retrospectively examined.

RESULTS: Fifty-eight of the 96 DALF patients (60.4%) had a hepatocellular pattern of DALF, 16 patients (16.7%) had a cholestatic pattern, and 22 patients (22.9%) had a mixed pattern. DALF resolved in 24 patients (25.0%). Twenty-five patients (26.0%) developed chronic liver injury, 43 patients (44.8%) died, and 4 patients (4.2%) underwent liver transplantation. There were 42 ALF patients (43.8%) who received WM, and 32 ALF patients (33.3%) who received TCM. TCM-induced ALF patients had a higher average age [42.4 ± 18.4] vs [33.5 ± 17.9] years, $P = 0.04$] and higher creatinine and urine nitrogen levels [(155.2 ± 108.8) vs [97.5 ± 130.4] mmol/L, $P = 0.047$; [9.1 ± 7.7] vs [4.3 ± 5.0] mmol/L, $P = 0.002$, respectively]. Patients with TCM-induced ALF exhibited an increased risk of renal injury [odds ratio (OR), 3.75; 95% confidence interval (CI), 1.330-10.577]. The 14 patients with TCM-induced ALF who died exhibited higher creatinine levels than the 18 patients with TCM-induced ALF patients who survived [(218.7 ± 111.6) vs [105.8 ± 78.4] mmol/L, $P = 0.002$]. They were also more likely to exhibit ascites (85.7% vs 44.4%, $P = 0.017$) and hepatorenal syndrome (78.6% vs 22.2%, $P = 0.002$).

CONCLUSION: TCM-induced ALF was more likely to be accompanied by renal injury than was WM-induced ALF, especially in TCM-induced ALF patients who died.

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Keywords: Drug-induced liver injury; Jaundice, obstructive; Medicine, Chinese traditional; Creatinine; Hepatorenal syndrome

INTRODUCTION

Acute liver failure (ALF) caused by drug-induced liver injury (DILI) is uncommon, but it is a concern for clinicians and patients. DILI accounts for 7%-15% of ALF cases in Europe and the United States and it is the most frequent reason for the withdrawal of an approved drug from the market.¹⁻⁶ Previous studies reported that 6%-31.3% of patients with drug-induced ALF (DALF) die or undergo liver transplantation.⁷⁻⁹ The major cause of DALF in developed countries is intentional or unintentional acetaminophen overdose, and less frequently, prescription medication overdose.¹ In China, drugs are the most common cause of ALF. A multi-center retrospective study demonstrated that drugs caused 43% of ALF in China.¹⁰ Another study showed that a total of 7.8% of the DILI patients in 1985 in China developed liver failure.¹¹

A high mortality rate is observed in patients with DALF.¹ However, Traditional Chinese medicine (TCM) is the leading cause of ALF in China and account for 17% of patients with this disease.¹⁰ The present study compared the causes, clinical manifestations, laboratory test results, and prognosis between patients with DALF induced by TCM and patients with DALF caused by WM.

MATERIALS AND METHODS

We retrospectively analyzed the clinical data from 96 DALF patients who were hospitalized in the 302 Military Hospital (Beijing, China) between January 2010 and December 2015 because of liver injury. The following DALF diagnostic criteria were used:⁶ (a) evidence of coagulation abnormality, generally with an INR ≥ 1.5 , together with any degree of mental alteration (encephalopathy) without preexisting cirrhosis, and an illness duration < 26 weeks; (b) a history of drug use but not of viral hepatitis A to E or non-hepatotropic viral hepatitis, autoimmune liver disease, hepatolenticular degeneration, or other liver diseases; and (c) a Roussel Uclaf Causality Assessment Method (RUCAM) score > 3 .

The Council for International Organizations of Medical Sciences (CIOMS) guidelines suggests that drug-induced liver failure be classified as hepatocellular, cholestatic, or mixed. The ratio of ALT (as a multiple of its ULN) to ALP (as a multiple of its ULN) is referred to as the R value. The R values for hepatocellular, cholestatic, and mixed DALF are ≥ 5 , ≤ 2 , and between 2 and 5, respectively.

The following hepatic encephalopathy staging criteria were used: (a) changes in behavior with minimal change in level of consciousness; (b) gross disorientation, drowsiness, possibly asterixis, inappropriate behavior; (c) marked confusion, incoherent speech, sleeping most of the time but rousable to vocal stimuli; and (d) comatose, unresponsive to pain, decorticate or decerebrate posturing.¹²

Chronic liver injury was defined as follows:¹³ failure of liver enzymes or bilirubin to return to pre-DILI baseline levels and/or other signs or symptoms of ongoing liver disease (e.g., ascites, encephalopathy, portal hypertension, coagulopathy) 6 months after DILI onset.

Hepatorenal syndrome (HRS) was defined as follows:¹⁴ a significant increase in serum creatinine following exclusion of other known causes of renal failure. HRS is generally diagnosed for therapeutic purposes only when serum creatinine is $> 133 \mu\text{mol/L}$ (1.5 mg/dL). Repeated measurements of serum creatinine over time, particularly in hospitalized patients, aid in the early diagnosis of HRS.

Data analysis

Analysis of variance and an independent *t* test, χ^2 test and the rank sum test were performed to examine the differences between groups. Logistic regression was used to evaluate prognostic predictors. *P* value < 0.05 (two-tailed) was considered statistically significant. Data was processed with SPSS 19.0 (IBM Corp. Released 2010. IBM SPSS Statistics for Windows, Version 19.0. Armonk, NY, USA).

RESULTS

Clinical characteristics

A total of 1150 liver failure patients were admitted between January 2010 and December 2015. Ninety-six (8.3%) of these patients were diagnosed with DALF. The mean age was (37 ± 19) years (age range, 1-80 years). The ratio of males to females was 1 : 3.2. Figure 1 shows the distribution of age at disease onset.

All 96 patients were included in the present study. Forty-two patients (43.8%) had WM-induced DALF, 32 patients (33.3%) had TCM-induced DALF, and 22 patients (22.9%) had DALF caused by a combination of WM and TCM. The clinical features of WM-induced and TCM-induced DALF were compared (Table 1). The 32 patients with TCM-induced DALF had a higher average age [(42.4 ± 18.4) vs (33.5 ± 17.9) years, *P* = 0.04] and higher levels of creatinine and urine nitrogen [(155.2 ± 108.8) vs (97.5 ± 130.4) mmol/L, *P* = 0.047; (9.1 ± 7.7) vs (4.3 ± 5.0) mmol/L, *P* = 0.002, respectively] than did the 42 patients with WM-induced DALF. Patients with TCM-induced ALF exhibited an accompanying increase in renal injury (*OR*, 3.75; 95% *CI*, 1.330-10.577). There was no significant difference between patients with DALF caused by TCM and

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