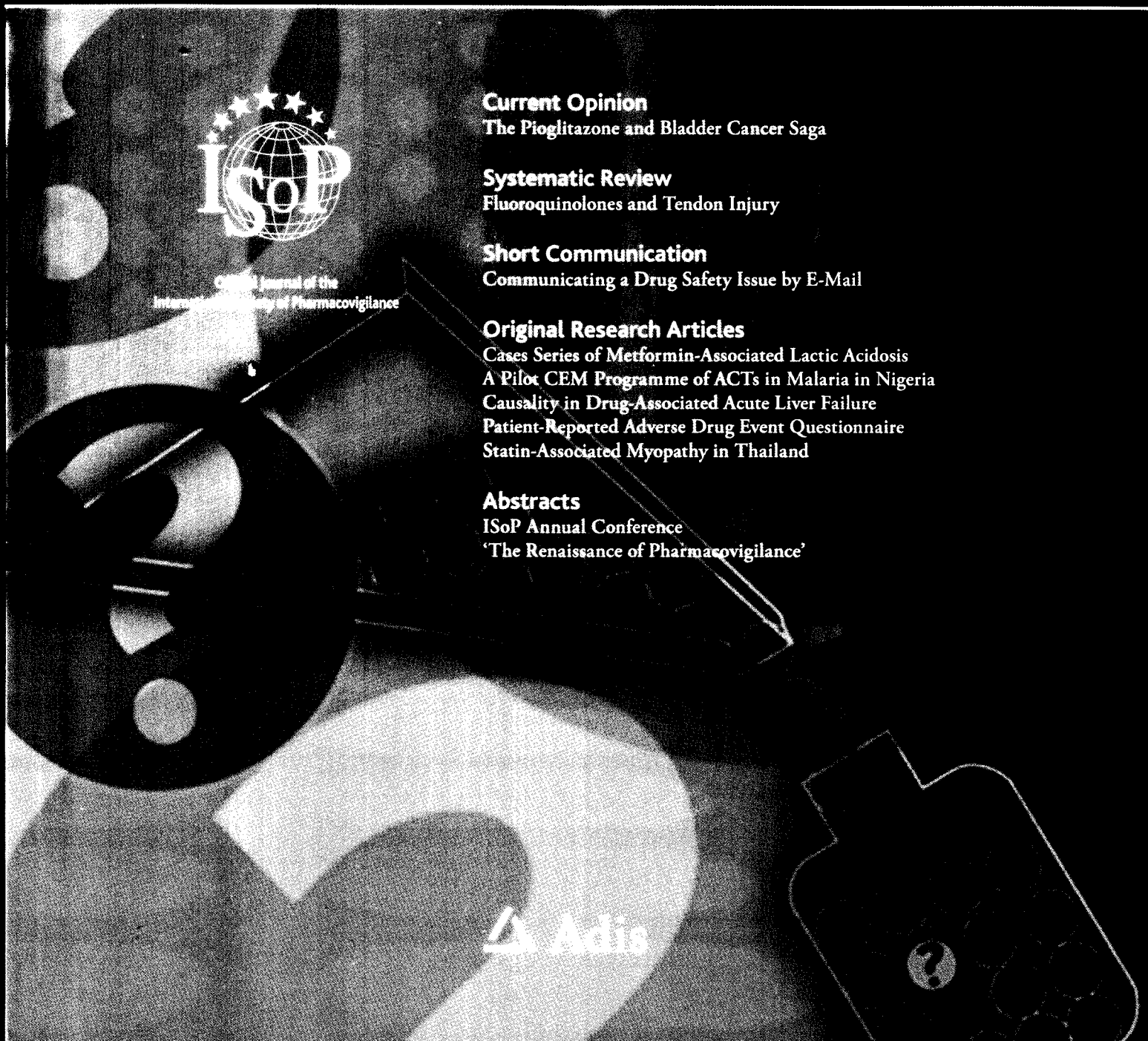
2013, Vol. 36, No. 9 (pp. 693–952)
ISSN: 0114-5916 (Print); 1179-1942 (Online)

Drug Safety



Adis

Drug Safety

Volume 36 · Number 9 · 2013

Indexed in *MEDLINE, EMBASE, International Pharmaceutical Abstracts (IPA), BIOSIS Previews, BIOSIS Reviews Reports and Meetings, Current Contents Clinical Medicine, SciSearch, Science Citation Index, Journal Citation Reports/Science Edition, Elsevier BIOBASE, Current Awareness in Biological Sciences (CABS), PASCAL, Chemical Abstracts Service, Sociedad Iberoamericana de Información Científica (SIIC)* and *Journals@OVID*

Drug Safety is the official journal of the International Society of Pharmacovigilance. The official representative for the Society is Dr. Hervé Le Louet from Henri Mondor Hospital, Créteil, France

Adis

Early Drug Induced Liver Injury After Intensive Phase of Tb Treatment in Indonesia: Primary Care Centers and Lung Hospital Study

J. Atthobari[1], U. Adhie Mulyani[2], D. Perwitasari[3], I. Darwis[4]

(1) Department of Pharmacology and Therapy, Faculty of Medicine, Universitas Gadjah Mada, Yogyakarta, Indonesia, (2) Institute of Research and Development, Ministry of Health Office, Jakarta, Indonesia, (3) Faculty of Pharmacy, Universitas Ahmad Dahlan, Yogyakarta, Indonesia, (4) Department Pharmacology, Faculty of Medicine, Universitas Lampung, Lampung, Indonesia

Background: Tuberculosis are still a problem for emerging countries such Indonesia. The program for controlling and eliminations had been addressed on the use of antituberculosis medicines. The safety profile of those drugs, particularly drug-induced liver injury (DILI), has been studied, however, this information on local or Indonesian capture is still minimum.

Objectives: To assess the proportion of early drug-induced liver injury (eDILI) due to tuberculosis treatment (TBT) among Indonesian's TB patients during the intensive phase of treatment.

Methods: Prospective cohort study in 10 primary care centers and 2 lung hospitals based setting from 2 provinces (Yogyakarta and Lampung Provinces, Indonesia) were conducted in TB patients who used standard fixed combination regimens during the intensive phase of treatment. Patients with abnormal baseline AST and ALT level, lower hemoglobin level and HIV positive were excluded. The AST and ALT level were measured before treatment and after two months intensive phase of treatment. Early DILI (eDILI) was defined if the AST/ALT increasing above the upper normal limit.

Results: One hundred and fifteen subjects were followed, 58.3 % were male, age 38.6 years (±16.6), and 58.3 % were underweight BMI. The baseline of AST and ALT were in normal range value, 20.4 (±1.4) and 16.7 (±1.7), respectively. After intensive phase of treatment, 7.5 % patients were considered as eDILI. This group has significantly higher percentage of increase AST and ALT after intensive treatment compared to non-eDILI (63.3 (±0.22.4) vs. 39.1 (± .3.8), $p < 0.001$, respectively for AST, and 191.1 (± .67.6) vs. 78.1 (± .7.5), $p < 0.001$, respectively for ALT. This changed has still significantly difference after adjusting of age and BMI.

Conclusions: The incidence of drug-induced liver injury is around 10 % among Indonesian's TB patients who used standard fixed combination regimens. The TB program need to increase awareness on this potential liver injury related to TB drugs. Prospective studies are needed to know the DILI among these after continuation phase of treatment

Autoimmune Disease Induced by Anti-TNF Agents and Tocilizumab: An Analysis of the Italian and E... Pharmacovigilance Database

A. Marra[1], A. Bin[1], C. Cazzorla[2], G. Fresca[3], D. Fede... R. Carletti[1]

(1) Dipartimento Farmaceutico Interaziendale, Azie... Universitaria di Ferrara, Ferrara, Italy, (2) Facoltà ... Università degli Studi di Ferrara, Ferrara, Italy, (3) ... Farmaceutico Interaziendale, Azienda USL di Ferrara, ...

Introduction: Anti-TNF agents are increasingly being ... idly expanding number of rheumatic and systemic auto... As a result of this use, and of the longer follow-up per... ment, there are a growing number of reports of autoim... related to anti-TNF agents and tocilizumab, ranging fr... immunological alteration to life-threatening syste... disease.

Aim: The aim of this study was to make a comparison bet... and the English pharmacovigilance database on ADR rep... mune disease related to anti-TNF agents: adalimumab, ... tanercept, golimumab, ustekinumab, infliximab, and toci...

Methods: We used both the Italian Rete Nazionale di Far... (RNF) and the English MHRA (Medicines and Healthc... Regulatory Agency) databases to extract ADR data. We ... reports till March 13th 2013.

Results: Over the study period, the incidence of auto... related to those biological agents on the total of ADR ... 6.23 % in RNF and 4.06 % in MHRA. System organ ... involved in autoimmune ADR are: muscle and tissue disorders ... RNF, 31.97 % MHRA), skin disorders (35.92 % RNF, 30.7 ... and nervous system disorders (14.3 % RNF, 10.63 % MHR... representative autoimmune ADR reported in RNF are ... (17.5 %), pustular psoriasis (7.75 %), Lupus erythematosus ... litis (5.3 %), Crohn's disease (4.9 %), noninfectious pericar... sarcoidosis and uveitis (3.6 %). In the MHRA database, ... representative autoimmune ADR reported are: rheumat... (18.62 %), psoriasis (18.44 %), Crohn's disease (7.18 %, ... syndrome (6.18 %), pustular psoriasis (5.36 %), vasculitis ... Lupus erythematosus (4.45 %). Anti-TNF agents mostly ... autoimmune disease are adalimumab (7.27 % RNF, 3.96 ... etanercept (6.49 % RNF, 4.06 % MHRA), infliximab (6.5... 3.98 % MHRA), ustekinumab (5.88 % RNF, 11.15 % MHRA ... involved both in the two databases is the tocilizumab (1.55 ... 2.25 % MHRA).

Conclusion: Data suggest that the type of autoimmune ADR ... more or less the same in the two databases as the agents ...