

P1060 Is fixed-dose combination treatment regimen safer than single-dose drugs formulations in extrapulmonary tuberculosis?

Houda Ben Ayed^{1,2}, Koubaa Makram^{3,2}, Fatma Hammami^{*3,2}, Khaoula Rekik^{3,2}, Tarek Ben Jemaa^{3,2}, Maissa Ben Jemaa¹, Chakib Marrakchi^{3,2}, Jamel Dammak¹, Mounir Ben Jemaa^{3,2}

¹ Community Health and Epidemiology Department, Hedi Chaker University Hospital, SFAX, Tunisia, ² Extra-pulmonary tuberculosis research unit, Hedi Chaker University Hospital, SFAX, Tunisia, ³ Department of infectious diseases, Hedi Chaker University Hospital, SFAX, Tunisia

Background: Extra-pulmonary tuberculosis (EPTB) is one of the major causes of death from a curable infectious disease. EPTB treatment was previously based on separate-drugs preparation (SDP). In the hope of reducing treatment failures and resistance rates, the WHO have recommended the use of fixed-dose combination (FDC) for first-line in EPTB. We aimed to compare the tolerance and the clinical evolution between FDC and SDP regimens in EPTB patients.

Materials/methods: We conducted a retrospective study including 388 cases of EPTB hospitalized between 1996 and 2016. We compared anti-tuberculosis treatment outcomes and the disease evolution between patients receiving FDC and those receiving SDP.

Results: The main EPTB site was lymph node (39.2%). There were no statistical differences between the two groups in terms of musculoskeletal, hematological disorders, cutaneous events and hepatotoxicity. We noted that neurological disorders (OR=12; $p<0.001$), such as paresthesia (OR=16; $p<0.001$) and retrobulbar neuritis (OR=10; $p=0.006$), were significantly more frequent in SDP group. Similarly, gastro-intestinal intolerance (OR=4; $p=0.015$) including nausea (OR=8.9; $p=0.011$) and vomiting (OR=1.1; $p=0.005$) were significantly more frequent in patients treated with SDP. Complicated forms were statistically more frequent in SDP (OR=2.4; $p=0.003$) while there was no significant difference in relapse, sequelae and mortality rates between the two groups.

Conclusions: Our study highlighted similar safety and evolutionary profiles between the two anti-tubercular regimens, except neurological and gastro-intestinal disorders and more complicated forms in the SDP group.

