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FRI0581 HEPATITIS B INCREASE MORTALITY IN PATEINTS WITH OSTEOPOROTIC VERTEBRAL FRACTURES

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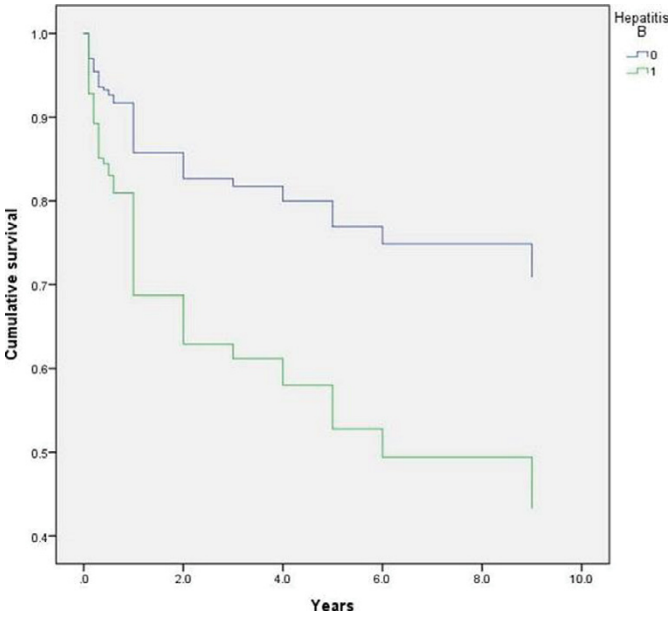
Background: Hepatitis B virus (HBV) is a major cause of chronic liver diseases worldwide, particularly cirrhosis and hepatocellular carcinoma, and the most important liver disease in Taiwan. However, little is known the impact of hepatitis b on osteoporotic patients.
Objectives: This study aimed to determine if hepatitis b can increase the risk of mortality in patients with osteoporotic vertebral fracture.
Methods: This retrospective study reviewed of cases of osteoporosis patients with acute vertebral fractures between 2001 and 2008. All associated co-morbidities were recorded. Kaplan-Meier and cox regression analysis were performed.
Results: There were 432 patients with acute vertebral fractures. The mean age of 72.85±9.28. 31 (7.2%) patients had chronic hepatitis b. Using the Kaplan-Meier curve, hepatitis b had a significant effect on mortality ($p<0.001$, by log rank text). After adjusting for potential confounders, patients with hepatitis b still had a high mortality rate (p=0.019; HR: 2.436∼5.136) 2.137, 95% CI: 1.156∼5.136). The mortality rate also increased among smokers (p=0.026; HR: 3.6043.891; 95% CI: 1.056∼12.301).

Table 1. Multivariable Cox regression analysis of the hazard ratios for adjacent fracture

Variables	Regression coefficient	P value	HR (95CI)
Gender	-0.127	0.764	0.88 (0.383–0.022)
Age	0.004	0.785	1.004 (0.976–1.032)
Smoking	1.282	0.041	3.604 (1.056–12.301)
Alcohol consumption	-0.701	0.396	0.496 (0.098–2.508)
Body mass index (kg/m^2)	0.024	0.446	1.024 (0.964–1.088)
Hepatitis B	0.891	0.019	2.436 (1.156–5.136)
Diabetes	-0.185	0.538	0.831 (0.461–1.498)
Hypertension	-0.271	0.31	0.762 (0.451–1.288)
Stroke	-0.696	0.248	0.499 (0.153–1.625)
Kidney disease	0.809	0.145	2.246 (0.758–6.656)
Cardiovascular disease	0.037	0.946	1.038 (0.351–3.069)
Pulmonary disease	-0.971	0.349	0.379 (0.050–2.883)

Abbreviations: HR, hazard ratio; SE, standard error.



Conclusions: In this study, hepatitis b increase mortality in osteoporotic vertebral fracture patients. So we should pay attention to this group in osteoporotic management.
References:
[1] Chong-Shan Wang et al. Am. J. Trop. Med. Hyg., 66(4), 2002, pp. 389–393.
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Other orphan diseases

FRI0582 OPEN-LABEL, MULTICENTER, DOSE-ESCALATING PHASE II CLINICAL TRIAL ON THE SAFETY AND EFFICACY OF TADEKINIG ALPHA IN ADULT ONSET STILL'S DISEASE

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Background: Adult Onset Still's Disease (AOSD) is a severe systemic autoinflammatory disease. Elevated interleukin (IL)-18 levels correlate with AOSD disease activity, suggesting a central role
Objectives: To examine the safety and efficacy of IL-18 blockade in AOSD with the administration of Tadekinig alpha, a recombinant human IL-18 binding protein
Methods: Patients (Pts) with AOSD according to Yamaguchi criteria were included if they had been previously treated for at least one month with corticosteroids (CS). The pts received either 80 mg (group 1) or 160 mg (group 2) Tadekinig alpha sc three times weekly for 12 weeks. Oral CS and/or conventional DMARDs were allowed at stable dose in combination with Tadekinig alpha. After 3 wks, group 1 pts qualified as non responders (CRP levels did not decrease by ≥50% from baseline values or absence of temperature normalization) could be up-dosed to 160 mg for an additional 12 weeks. The primary endpoint was safety and secondary endpoints included early signs of efficacy
Results: 23 pts were included (10 and 13 in group 1 and group 2, respectively). 6 pts of group 1 were up-dosed to 160 mg. Baseline characteristics and safety and efficacy results are described in Table 1. Most adverse events (AEs) (47) were considered as mild or moderate. Three serious AEs (SAE) were reported including two that were considered not related to the study drug and one possibly related according to the investigator (toxic optic neuropathy). Four premature discontinuations were related to AEs, including 3 cases of injection site reactions and 1 SAE. Systemic response as defined by ≥70% decrease of serum C-reactive protein (CRP) or normalization of CRP and ferritin levels was obtained in 2/10 and 6/13 pts of groups 1 and 2, respectively in the ITT analysis, and in 2/9 and 6/9 pts of groups 1 and 2, respectively, in the PP analysis.

Table 1. Baseline characteristics and safety and efficacy results

	Group 1 (80 mg) (N=10)	Group 2 (160 mg) (N=13)
Age, median (IQR)	49.5 (34.3–58.8)	35 (30–58)
Median disease duration, months (IQR)	25.5 (8.7–44.2)	11.6 (2.1–37.6)
Pts with previous conventional DMARDs	6	7
Pts with previous biological DMARDs	4	5
Pts with SAEs	2	1
Discontinuations due to AEs*	1	3
Discontinuations due to lack of response*	1	2
Arthritis improvement (≥20% reduction in tender and swollen joint count)**	3/9	4/10
Skin rash resolution**	6/7	2/5
CRP level reduction by ≥70%**	2/10	6/13
Normalization of ferritin levels**	0/7	1/5

*Number of Pts, **Denominator corresponds to Pts with clinical manifestations or abnormal values at baseline.

Conclusions: IL-18 blockade by Tadekinig alpha has an acceptable safety profile and is efficacious, in particular at the 160 mg dosage, in patients with refractory AOSD
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