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Liver biopsy may not be the optimal option for assessing treatment efficacy in chronic hepatitis delta (CHD) infection

Aysun Kartal [1], Mehmet Berk Örüncü [1], Berna Savaş [2], Ramazan Idilman [1], Fatma Yavaş[3], Cihan Yurdadın [1]

[1]*Ankara University School of Medicine, Department of Gastroenterology, Ankara, Turkey*
[2]*Ankara University School of Medicine, Department of Pathology, Ankara, Turkey*
[3]*Ankara University School of Medicine, Department of Nursing, Ankara, Turkey*

INTRODUCTION: Phase 3 studies with new compounds for treatment of CHD are expected to start in 2019. Liver histological assessment have been used in studies of nucleoside analogs in chronic hepatitis B (CHB). Aim of this retrospective analysis is to explore the suitability of liver biopsy for assessing treatment efficacy in CHD in phase 3 studies. For this, we did a retrospective analysis of our CHB and CHD patient cohorts with compensated liver disease and compared pretreatment liver biopsy characteristics.

METHODS: Pathologic specimens were assessed in our pathology department. All biopsies were obtained with a 16 or 17-gauge Menghini aspiration needle. Biopsies were scored and read by an expert liver pathologist (BS). Data on biopsy length, number of portal tracts and tissue fragmentation were noted. Stepwise multivariate logistic regression was used to evaluate independent factors associated with biopsies containing higher than 11 portal tracts.

RESULTS: Patient cohort consisted of 122 and 116 patients with CHB (median age: 46.5, 85 male) and CHD (median age: 49, 84 male), respectively. CHD vs CHB patients had higher median serum GGT (45 vs 29, p=0.035), lower ALT (41 vs 47, p=0.028), lower albumin levels (4.1 vs 4.3, p=0.023) and lower platelet counts (205 vs 163, p<0.0001). APRI and FIB-4 scores were higher in CHD vs CHB patients (0.68 vs 0.52, p=0.0033 and 1.24 vs. 1.87, p<0.0001). Liver biopsy specimens of CHD vs CHB patients had fewer median portal tracts (10 vs. 14, p=0.0004) and were more likely to be fragmented (17 vs. 30%, p=0.022). In 136 biopsy specimens ≥11 portal tracts were available and in 102 not. In biopsy specimens with ≥11 vs. <11 portal tracts the mean longest tissue specimen and total length were longer (18.3mm vs 11.6 and 32.7 vs 20.8, p<0.001 for both comparisons) and liver tissue was less likely to be fragmented (11 vs. 40%, p<0.001). Biopsies with ≥11 vs <11 portal tracts were seen in 41 and 59% of CHD patients (p=0.007). By multivariate analysis, CHB (vs CHD) and longest biopsy length independently predicted an optimal liver biopsy with ≥11 portal tracts (OR:2.27, 95%CI 1.20-4.30, p=0.012 and OR:1.091, CI 1.10=1.31, p=0.003).

CONCLUSION: Histologic assessment in CHD patients is more difficult than in CHB as CHD patients may have more advanced. disease. Aspiration needles may not be suitable in CHD. Liver histology assessment may not be considered as primary endpoint in phase 3 studies in CHD.

Keywords: chronic hepatitis D, liver biopsy, hepatitis B