



Tarik Asselah

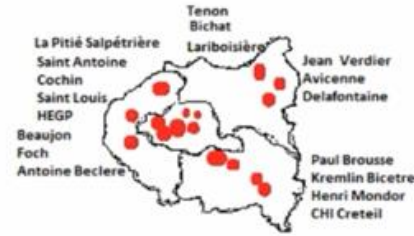
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Hepatitis Delta Prevalence in France

From 2010 to 2014

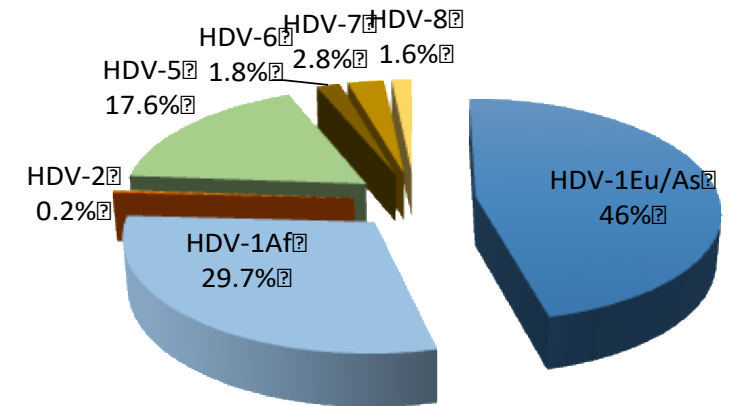
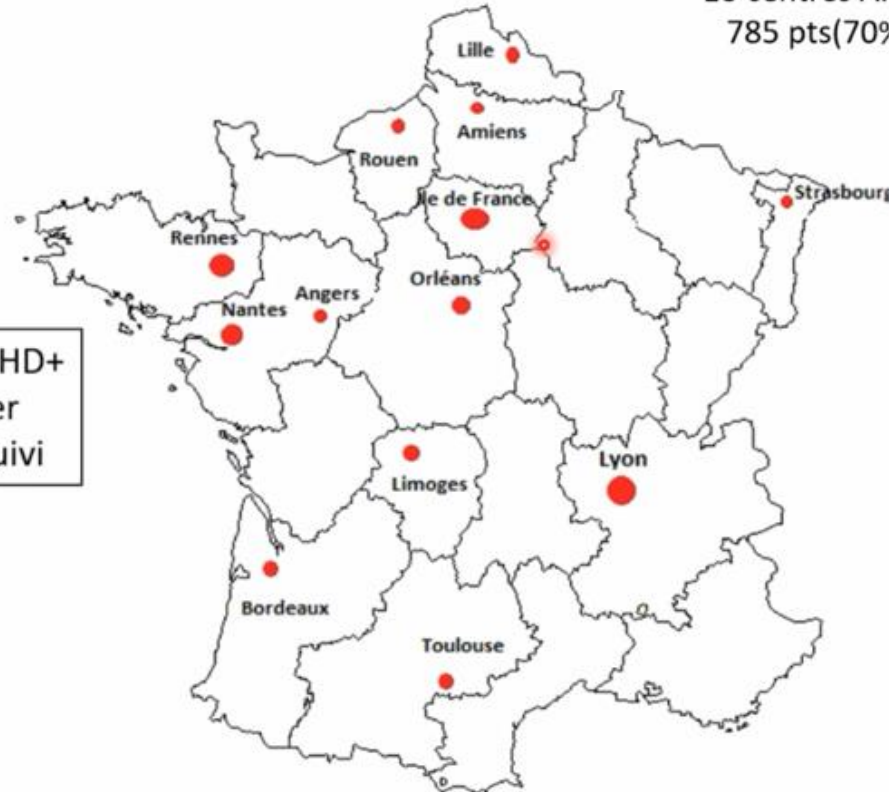
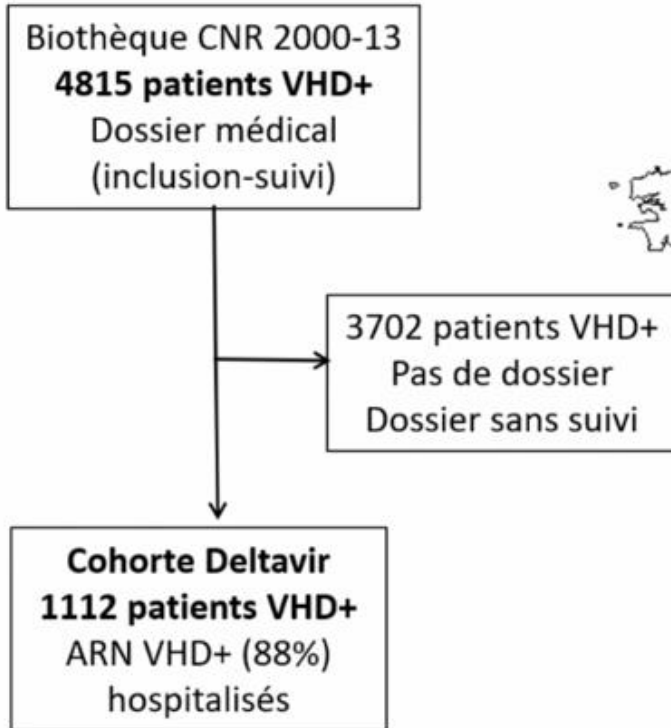
HDV in France : 3-4% HBsAg+ (150-200.000)

~ 6000 to 8000 patients HDV+



34 centres
18 centres APHP
785 pts(70%)

DeltaVir Study



France:
G1 dominant (76%) : G1 Eu/As > G1 Af
G5,G6,G7,G8 africains



Bulevirtide Early Access RWD from France

Multicenter, prospective and retrospective observational real-world data of BLV 2mg

Compensated cirrhosis or severe liver fibrosis (F3)
OR
F2 fibrosis with persistent ALT > 2xULN for at least 6 months

Beyond cATU Analysis
N=145

BLV 2mg
n=77

Continuation of treatment
according to physician's
choice

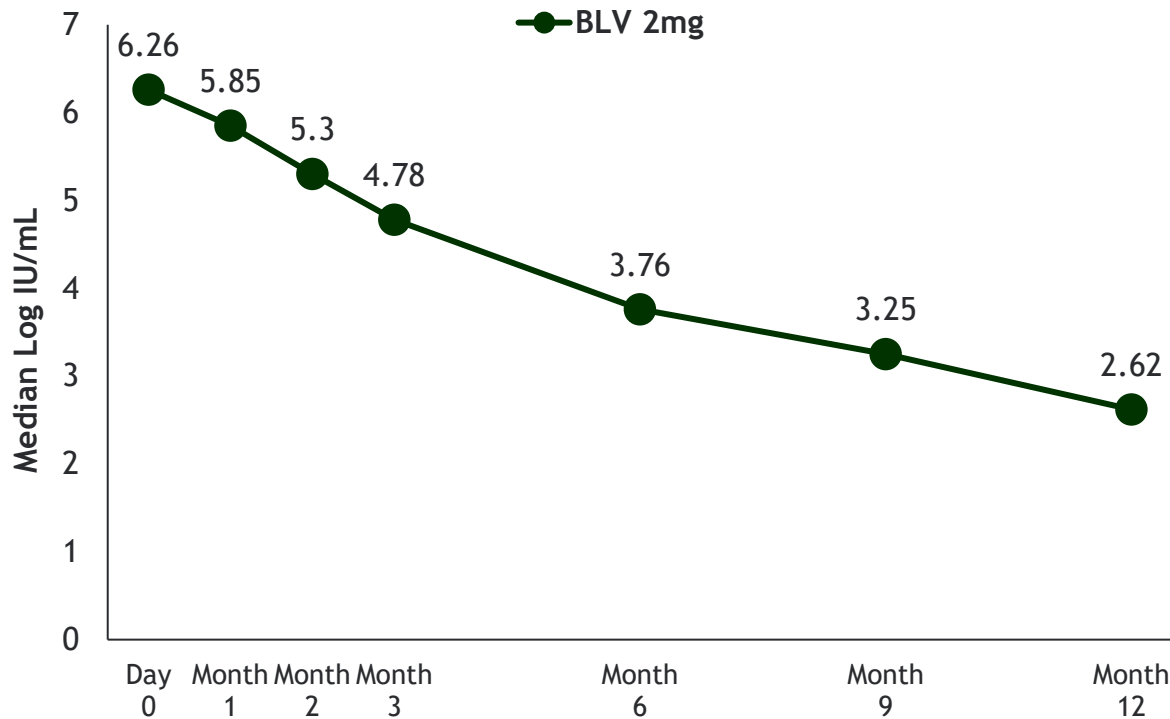
Baseline Characteristics	BLV 2mg n=77
Mean age, years (SD)	42 (12)
Men, n (%)	54 (70)
Cirrhosis, n (%)	48 (62)
Mean ALT, IU/L	69 (36)
Median HDV RNA, log IU/mL (IQR)	6.26 (1.3)
Undetectable HBV DNA, n/N (%)	49/72 (68)
HBeAg+, n (%)	9 (8)
Current NUC use, n (%)	64 (83)
HIV infection, n (%)	14 (18)



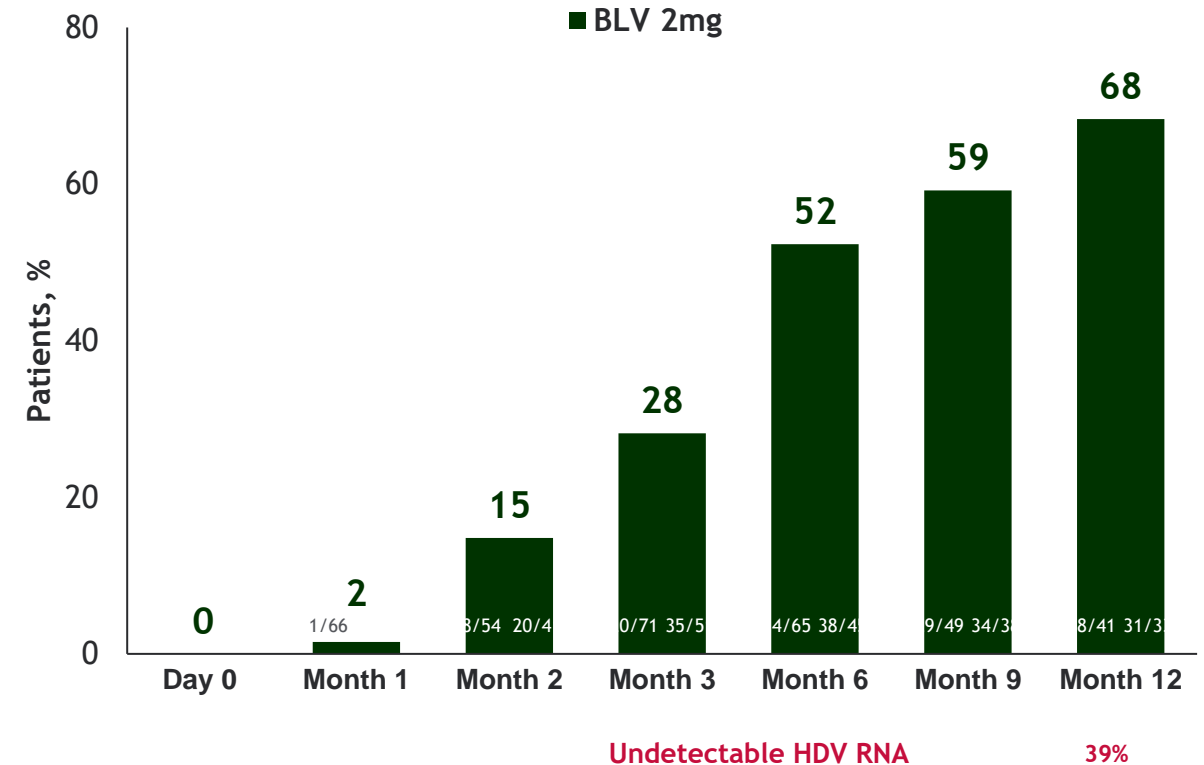


Virologic Response Over 12 Months

Changes in HDV RNA Levels Over Time (PP)



HDV RNA Response (PP)
Undetectable HDV RNA or ≥ 2 log IU/mL decline



BLV 2mg monotherapy led to considerable HDV RNA declines

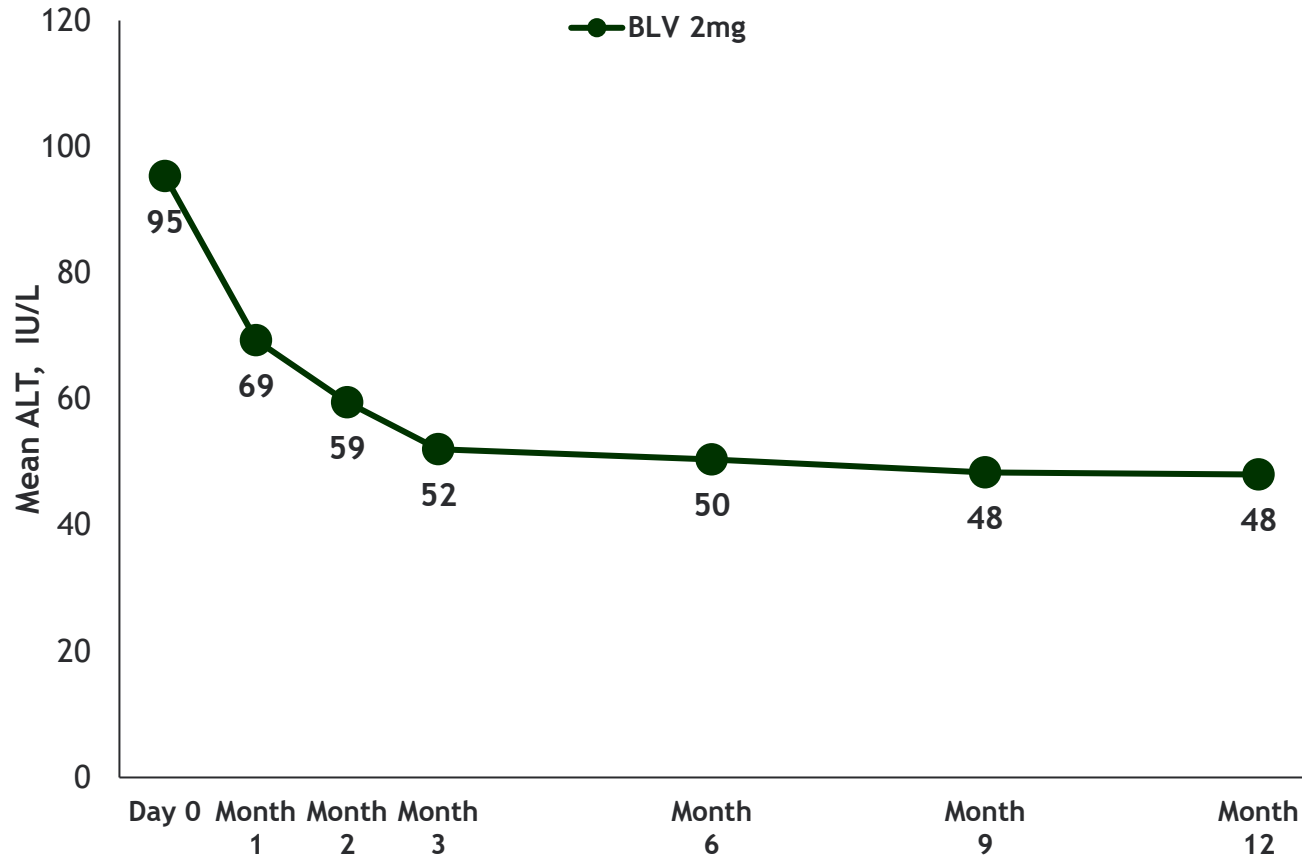
⁴ PP, Per protocol analysis. Study not powered to compare the two treatment regimens de Ledinghen V, et al. AASLD 2021. Oral 21



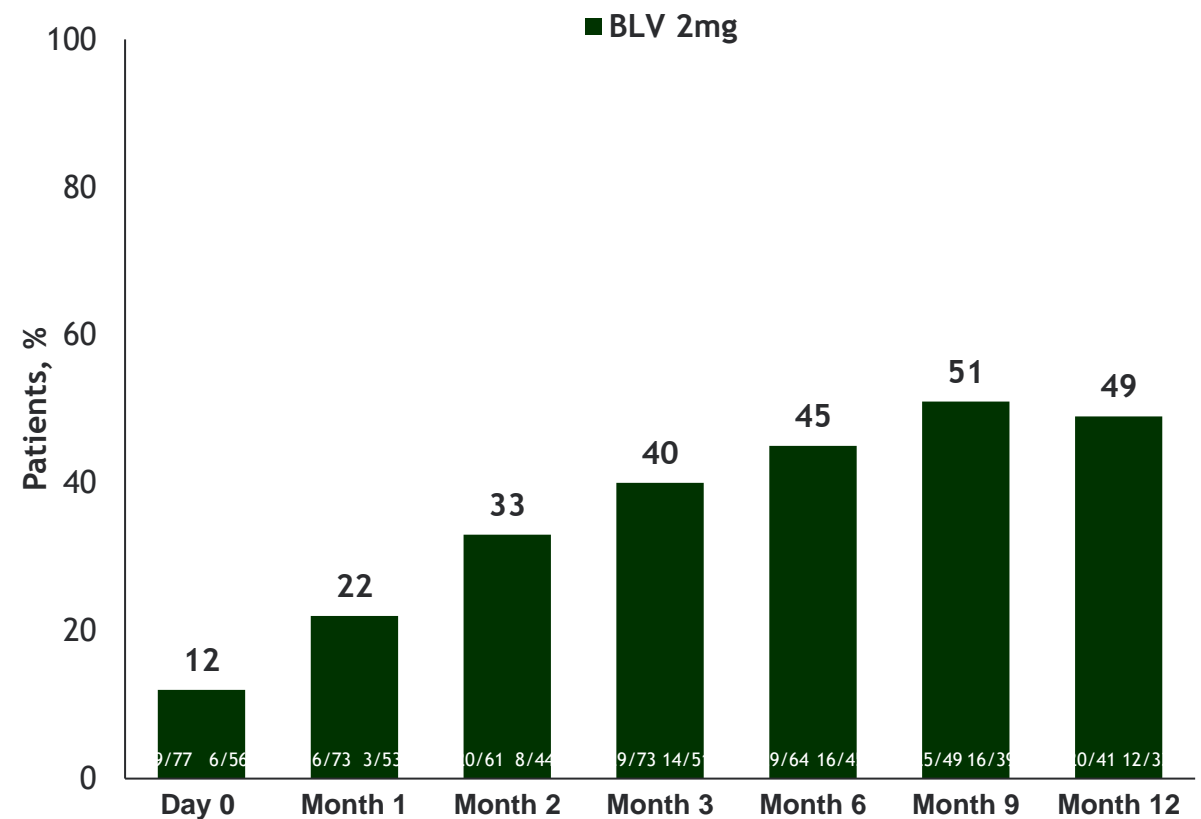


Biochemical Response Over 12 Months

Changes in ALT Over Time (PP)



Normal ALT Level (PP)



High levels of normal ALT were achieved with BLV 2mg in this real world cohort

PP, Per protocol analysis.

⁵ Normal ALT defined as <40 IU/L. Missing does not equal failure. Adapted from de Ledinghen V, et al. AASLD 2021. Oral 21



Important for our patients : Need to Cure HDV

- HDV might be under-estimated at > 60 million infected individuals (Stockdale et al. 2019, Miao et al. 2019)
- HDV increases risk of cirrhosis (Fattovich et al, Seminars in Liver Diseases 2003)
- Previous treatment recommendation of HDV is PEG-IFN-alfa for 48 weeks. For patients who failed PEG-IFN-alfa, there has been no therapeutic option available until recently.
- First EU conditionally-approved drug to treat HDV available in 2020: Bulevirtide (Hepcludex®): However 50% non responders at 48 weeks
- Drugs in development for HDV: prenylation inhibitors, peginterferon lambda and HBsAg secretion inhibitors.