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## Higher efficacy of sequential therapy with pegylated interferon-alpha 2b and tenofovir compared to tenofovir monotherapy in HBeAg positive chronic hepatitis B patients

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**Introduction**: Monotherapy with PEG-interferon (PEG-IFN-α) or nucleotide analogues (NA) are largely ineffective in chronic hepatitis B (CHB) patients. A sequential combination therapy may have better therapeutic effects by sustained viral suppression combined with immunomodulation.

**Aim**: To Study the high efficacy of sequential therapy with pegylated interferon-alpha 2b and tenofovir compared to tenofovir monotherapy in HBeAg positive chronic hepatitis B patients.

**Methods**: One hundred twenty six treated naive HBeAg (+) CHB patients with moderately elevated alanine aminotransferase (ALT) (48-200 IU/mL) received tenofovir 300 mg/day for 72 weeks with PEG-IFN-a2b 1.5 mcg/kg per week added after first 12 weeks (lead-in-period) for 24 weeks (sequential combination therapy; ST) or tenofovir monotherapy; 300 mg/day for 72 weeks (TM). Primary end point was rate of HBeAg loss. Biochemical and virological responses were assessed at weeks 12, 36, 48 and 72 weeks. Combined virological response (CVR) [HBeAg loss and HBV DNA<2000 IU/ml at week 72] was also determined.

**Results**: At week 72, HBeAg loss occurred in 35.8% in ST group and 17% in TM group (P=0.028; OR: 2.73, 95% CI: 1.09 to 6.79). Combined virological response (CVR) was seen in 20.8% and 11.3% (P<0.05), respectively. No patients on ST group had HBeAg seroreversion at last follow up. At week 72, undetectable HBV DNA was seen in 77.4% (ST group) vs. 71.7% (TM group); (p=0.51) and normal ALT was seen in 62.3% and 52.8% (p=0.32), respectively. Significantly more patients on ST group had >3Log HBV DNA reduction at week 36 (92.5%) compared to TM group (66%) (P=0.001). Four (7.5%) patients on ST achieved HBsAg loss compared with MT (1 patient, 1.8%) by week 72. No patient had treatment related major adverse effect requiring discontinuation of therapy.

**Conclusion**: 24 weeks of PEG-IFNa2b as add-on sequential regimen to TDF is safe and resulted in more HBeAg and HBsAg loss, when compared to TDF monotherapy in selected HBeAg (+) chronic hepatitis B patients. Long-term follow-up trials are needed to assess for sustained durable response.

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## Restaging rectal cancer after neoadjuvant chemo radiotherapy: For a down-staging classification

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Today neoadjuvant chemoradiation for T2 and T3 rectal cancers is widely adopted. Surgery is usually performed after 5-6 weeks from the beginning of the therapy and it is our policy to perform a restaging of the tumor at that moment, in order to obtain its down-staging, to discover possible complications related to the treatment, to confirm or adjust a surgical strategy, to evaluate risks for possible recurrence, and to schedule an adequate follow-up. For this, we have implemented a classification of the tumor down-staging, mainly based on radiological imaging results, contrast-enhanced computed tomography and magnetic resonance, and inspired to the current TNM scheme. Neoplastic regression inside rectal walls and mesorectum have been considered of prominent significance, and, therefore, discriminating in surgery. Besides, these aspects correlate well with the biological attitude of rectal cancer to regress following a centripetal way, starting from the most peripheral and recent zones of infiltration toward the central core of the tumor, where the tissue involvement is more marked. Interestingly, in our experience of 38 cases observed in the years 2012-2015, the down-staging score appears inversely correlated with the histological grading of the tumor, but directly with the Dowrak's tumour regression. Certainly our classification needs to be confirmed by further clinical studies, which will have to consider also the different molecular characteristics of rectal cancer.

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