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ABSTRACT N. PO05

INTENSIVE FVIII REPLACEMENT IN HAEMOPHILIA PATIENTS WITH HYPERTROPHIC SYNOVIUM: A RANDOMIZED STUDY.

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Background and aims: Hypertrophic synovium (HS) is a marker of disease activity in patients with haemophilia (PwH). Although some recommendations suggest intensifying prophylaxis in PwH with HS, no validated schedules are available. We explored the efficacy of intensive Factor VIII (FVIII) replacement treatment in PwH with HS.

Methods: In a randomized, open-label study, PwH with HS were randomized to receive pharmacokinetics-driven prophylaxis targeting a FVIII through level of 8%-12% (intensive treatment arm [ITA]) or 3-5% (standard treatment arm [STA]). The primary outcome was HS reduction/resolution in the two treatment arms.

Results: A total of 39 PwH were randomized to ITA and 36 to STA. During the study, we found a lower Annual Bleeding Rate (ABR) and a higher rate of ABR zero in the ITA than in the STA. HS reduction/resolution was reported by 35.9% of cases in the ITA and by 8.4% in the STA. In detail, in the ITA 10.3% achieved HS reduction and 25.6% complete HS resolution, as compared to 5.6% and 2.8% in the STA. A COX regression showed that ITA was associated to HS reduction/resolution (Hazard ratio [HR]: 4.75, 95% confidence interval [CI]: 1.36-16.57, p=0.014) and to HS complete resolution (HR: 10.79, 95%CI: 1.38-84.45, p=0.023). The analysis on the 127 joints with HS (54 elbows, 41 knees and 32 ankles) consistently confirmed similar results.

Conclusions: In this randomized study, we found a ~5-fold higher rate of HS reduction/resolution and a ~10-fold higher rate of HS resolution in the ITA as compared to the STA.

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