in routine care. The outcomes were I) SB2 retention rate (RR) II) SB2 discontinuation rate due to a presumed NE, defined as lack of efficacy with no objective criteria for increased inflammation or non-objective and non-specific adverse event, either occurring after the switch and disappearing after back-switch or change of biologic. Criteria for NE/NSS in the historical cohort were the same lack of efficacy or subjective adverse events and disappearance after change of biologic BD. Medium-term (12 months) SB2 outcomes were assessed and compared with I) the data obtained in the short-term (34 weeks) II) the data from an historical cohort of CIRD patients treated by OI in the same rheumatology department, using Kaplan-Meier survival curve.

Results: Forty-five patients were prospectively included for the switch from March 2018 to August 2018: 17 with rheumatoid arthritis (RA), 28 with spondyloarthritis (SpA); 55% were women, mean age was 53.2 (SD: 2.1), and mean time under OI was 113.5 (SD9.3). For the historical cohort, the 52 patients treated with OI between December 2016 and January 2017 were included and their data collected at baseline and one year. Fifty-nine percent were women, mean age at inclusion was 50.25 (1.2), and mean time under OI was 94.8 (9.4).
SB2 RR did not differ from the OI RR in the historical cohort: 91.2% and 96.2% respectively at 34 weeks (p = 0.41); 84.4% and 88.5% respectively at 12 months (p = 0.52) (figure 1). The SB2 RR was significantly higher than in three other European cohorts at 34 weeks (mean RR 73.6%, p<0.05, ref.1) but not at 12 months (mean RR 80.9%, ref.2,3,4).

SB2 and OI discontinuations due to NE/NSS at 34 weeks were 2.2% and 1.9% respectively; at 12 months 6.6% and 1.9% respectively (p=0.6). The SB2 RR was significantly higher than in three other European cohorts at 34 weeks (mean RR 73.6%, p<0.05, ref.1) but not at 12 months (mean RR 80.9%, ref.2,3,4).

Conclusion: An intervention based on a tailored communication with a prominent role of nurses was effective in reducing the NE when switching from OI to SB2 in the short term, compared with an historical cohort and other European cohorts. The one-year follow-up showed no statistical difference in RR or NE compared with our historical cohort. The present study shows that appropriate interventions may be developed to improve the outcome of switches to biosimilars.

Figure 1: Treatment withdrawal free survival curves (SB2 in switched cohort and OI in historical cohort).

Kaplan Meir survival curves. Comparison with Log-Rank test between OI to SB2 cohort and historical OI cohort, p = 0.520. OI: original infliximab.

References:

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