**Audit examining the difference in clinical outcomes amongst originator biologic treated patients with RA, PsA and AxSpA who were switched to biosimilar versions and monitored routinely at St George’s University Hospital NHS Trust**

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Background: This audit aims to evaluate the difference in clinical outcomes in Remicade and Enbrel treated patients with rheumatoid arthritis, psoriatic arthritis (PsA) and axial sponyloarthritis who were switched to Remsima and Benepali respectively and monitored routinely at St George’s University Hospital NHS Trust.

Methods: Patients who switched from Remicade to Remsima and Enbrel to Benepali were included in the data analysis. A retrospective audit of case notes was performed to evaluate pain and disease activity scores as determined by the pain VAS, DAS-28, PsARC, BASDAI and where available BAS-G and BAS-FI at 2-4 months before the switch (pre-switch), at the time of the switch and 2-4 months after switching (post-switch). Reasons for stopping the biosimilar drug were recorded to determine the underlying cause for withdrawal.

Results: In the Remicade/Remsima group, DAS 28 scores were similar pre- and post- switch groups in the rheumatoid arthritis group. In contrast, PsARC scores were also similar in all domains measured apart from ESR and CRP where there was 52% improvement in ESR and 25% improvement in the CRP score respectively three months’ post-switch to Remsima. BASDAI, BASG, spinal VAS and BAS FI were all improved three months’ post switch by 3.8%, 16.2%, 51% and 34,7% respectively (see Table 1). In the Enbrel/Benepali Etanercept group, DAS 28 scores showed that remission persisted post-switch. For the PsA cohort, scores were again similar in all domains mentioned apart from ESR where there was a 50% improvement post switch, however there was a 72% worsening of CRP score. BASDAI, Spinal VAS and BASFI were similar in 3 months before and after Benepali in the axial spondylitis group (see Table 1). Four patients stopped Remsima and were switched to other biologics. Three patients in the Benepali Etanercept group switched back to Enbrel. Table 1 Disease activity 3 months prior to versus 3 months after the switch from Remicade to Remsima by diagnosis and Enbrel Etanercept to Benepali Etanercept by diagnosis.

Table

| **Disease Activity - Remicade to Remsima Group** |
| --- |
| **RA (n = 17)**  | 3 mo Pre Switch  | Switch  | 3 months Post switch  |
| DAS28  | 3 (1.39-5.39)  | 3.66 (1.67-6.72)  | 3.08 (0.91-5.66)  |
| ESR  | 28 (4-68)  | 32 (4-105)  | 17 (3-105)  |
| CRP  | 15.25 (2-20.5)  | 6.7 (0.8-116)  | 2.6 (1.2-26)  |
| Patient Global Score, mm  | 37.5 (10-80)  | 30 (10-80)  | 35 (5-100)  |
| **PsA (n = 6)**  |   |   |   |
| ESR  | 21 (7-35)  | 18.5 (2-35)  | 11 (2-39)  |
| SJC  | 1 (0-12)  | 2 (1-4)  | 2 (0-4)  |
| TJC  | 3.5 (2-5)  | 3.5 (1-12)  | 0.5 (0-22)  |
| Pre-switch Pt score  | 2 (2-3)  | 2 (1-4)  | 1.5 (1-22)  |
| Pre-switch Phy Score  | 2 (2-3)  | 2 (1-4)  | 1.5 (1-5)  |
| CRP  | 4 (4-4)  | 4 (4-4)  | 1 (1-3.7)  |
| **AxSp (n = 7)**  |   |   |   |
| BASDAI  | 5.9 (0.36-8.33)  | 5.41 (0.5-6.59)  | 5.67 (0.73-7)  |
| BAS-G  | 4.5 (0.15-7.75)  | 3.77 (0-6.35)  | 3.77 (0.35-7)  |
| Spinal VAS  | 7 (0.2-8.5)  | 2 (0.5-8.3)  | 3.4 (0.4-1.8)  |
| BAS-FI  | 6.5 (0.2-9.02)  | 4.065 (0.32-8.1)  | 4.24 (0.29-8.1)  |
| **Disease Activity Enbrel to Etanercept group**  |   |
| **RA (n = 36)**  | 3 mo Pre Switch  | Switch  | 3 months Post switch  |
| **Patient with available data**  |   |   |   |
| DAS28  | 2.87  | 3.53  | 2.07  |
| ESR  | 15  | 12  | 16  |
| CRP  | 2.9  | 4.7  | 3.1  |
| Patient Global Score, mm  | 50  | 50  | 40  |
| **PsA (n = 18)**  |   |   |   |
| ESR  | 11 (2-18)  | 7.5 (2-17)  | 5.5 (2-16)  |
| SJC  | 0 (0-8)  | 0 (0-4)  | 0 (0-1)  |
| TJC  | 1 (0-9)  | 1 (0-32)  | 1 (0-8)  |
| Pre-switch Pt score  | 2 (1-2)  | 3 (1-4)  | 2 (2-3)  |
| Pre-switch Phy Score  | 2 (1-2)  | 2 (1-3)  | 2 (1-3)  |
| CRP  | 1.8 (1-3.8)  | 2.5 (1-3.4)  | 6.65 (3.7-6.6)  |
| **AxSp (n = 18)**  |   |   |   |
| BASDAI  | 2.1 (0-5.43)  | 2.13 (0-6.15)  | 2.5 (1.6-5.68)  |
| Spinal VAS  | 3.9 (0-5.7)  | 2.45 (0-8.7)  | 3.25 (1-6.5)  |
| BAS-FI  | 0.1 (0.1)  | 0 (0)  | 0.1 (0.1)  |

Conclusion: This audit demonstrated that in a real world setting switching to the biosimilar molecule had no negative impact on disease activity scores.