4CPS-137 NATALIZUMAB: A REVIEW OF ITS USE IN THE MANAGEMENT OF MULTIPLE SCLEROSIS, EXPERIENCE IN A UNIVERSITY HOSPITAL

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10.1136/ejhpharm-2019-eahpconf.286

Background Natalizumab is the first licensed treatment, given by infusion, monthly, for highly active relapsing-remitting multiple sclerosis or rapidly evolving severe MS. It is not a cure, its safety issues represent a relevant limitation and impose strict clinical surveillance mainly because of the risk of progressive multi-focal leukoencephalopathy (PML), (a potentially lethal brain disorder.

Purpose Review of use: effectiveness, safety, reason for start or switch.

Material and methods Retrospective observational study 2015–2018.

Treatment history, demographic and clinical data were collected from medical records

We assessed effectiveness by the change in expanded disability status scale (EDSS), defined by Fernandez *et al*: improvement, a decrease of ≥1 point, stability, a change of <1 point and worsening, an increase of 1≥point, and also by the number of patients with outbreaks during the year prior to treatment and at least 12 months after.

Safety was assessed by analysing the incidence of adverse reactions and risk for PML stratified in high, medium and low based on three major risk factors: duration of treatment >2 years, prior immunosuppressive treatment and positive serum JC virus antibodies.

Results Fifty-six patients, 57% female, mean age at diagnosis 26.4.

Eleven patients received Natalizumab as first option and 45 were switched because of lack of efficacy with one or two immunomodulatory drugs prior to Natalizumab.

Most patients were still ambulatory when they began treatment (median EDSS 2.00).

Mean treatment duration was 3.3 years (1–10 years).

Over the study period, the age of starting natalizumab has decreased and the total number of treated patients has increased from 31 to 56. Natalizumab was generally well tolerated, as only four left for the reason of inefficacy and one for PML.

Stabilisation of EDSS was achieved for 70% of patients:; only 10% showed worsening.

Forty patients showed no risk for PML (<1:10000) and moderate risk from the rest.

Ninety-three per cent had relapsed at least once in the year prior to natalizumab and 12 months after, the proportion decreased to 15%.

Conclusion Natalizumab provides efficacy in slowing disease progression and reducing relapses, effective particularly in patients with less disability and without prior treatment. As long as the risk of PML is managed effectively and patients are constantly informed about their benefit-risk level, it remains a valuable therapeutic option.

REFERENCES AND/OR ACKNOWLEDGEMENTS

No conflict of interest.

4CPS-138 BIOSIMILARS' UTILISATION UNDER HOSPITAL PHARMACY MANAGEMENT POLICY

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10.1136/ejhpharm-2019-eahpconf.287

Background Since October 2017 our university hospital implemented a Fully Integrated Biosimilars' utilisation management System (FIBS) managed by the hospital pharmacy.

Purpose To assess the effectiveness of hospital pharmacy management in the biosimilars policy and compare it to other similar public hospitals.

Material and methods FIBS is based on prescription and dispensing by international non-proprietary name. If biosimilars are available, the recommendations from the Hospital Medicines and Therapeutic Committee (HMTC) focus on the biologic drug with the best economic value. Non-biosimilar utilisation needs clinical justification on a patient-by-patient basis by prescribing physicians. The latter exceptions require validation by the Hospital board, HMTC and hospital pharmacy, which acts as a system gatekeeper. FIBS allow total traceability including biologic identification by tradename and batch number. Policy implementation was assessed by the extent of switching to, or initiation of, biosimilars by disease area. Policy effectiveness was assessed comparing our hospital biosimilars' utilisation benchmarked to other public hospitals with similar characteristics.

Results This analysis included all 718 patients using biologic therapy in rheumatic (31.3%), gastrointestinal (26.5%), haematologic (26.9%) and nervous system (11.1%) diseases and others (4.2%), since October 2017 when biosimilars for etanercept, infliximab and rituximab became available. Median follow-up time was 7.3 months. Switching to, or initiation of, biosimilars (SWT and INI) by disease area occurred in: rheumatic (84.9% and 6.7%), gastrointestinal (61.6% and 29.0%), haematologic (9.8% and 66.3%) and nervous system (60.0% and 15.0%) diseases and others (60.0% and 30.0%). The current overall proportion of patients in biosimilars' therapy was 85.2% and by biologic drug (SWT and INI): etanercept (82.6% and 9.8%), infliximab (69.7% and 22.2%) and rituximab (26.0% and 49.7%). Our hospital presented consistently higher rates of biosimilars' utilisation in comparison to other similar public hospitals: etanercept (92.4% vs 27.6%), infliximab (91.9% and 51.3%) and rituximab (75.7% and 35.1%).

Conclusion Hospital pharmacy management of the biosimilars policy was associated with substantial and rapid biosimilars' incorporation and utilisation. Our hospital has one of the best biosimilars' utilisation policy effectiveness in the country.

REFERENCES AND/OR ACKNOWLEDGEMENTS

None to declare.

No conflict of interest.