FRI0201 ETANERCEPT RETENTION PATTERNS AND FACTORS ASSOCIATED WITH TREATMENT DISCONTINUATION: A RETROSPECTIVE COHORT STUDY USING CANADIAN CLAIMS-LEVEL DATA

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Background: Etanercept is a soluble TNF receptor (humanized protein) indicated for the treatment of immune-mediated inflammatory diseases such as rheumatoid arthritis (RA), psoriatic arthritis (PsA), ankylosing spondylitis (AS), and psoriasis (PsO). Limited information exists on the factors associated with long-term retention and use of etanercept in Canada in a real-world setting.
Objectives: To evaluate the 6-year retention rates of etanercept patients in Canada, and to identify factors associated with discontinuation.
Methods: A retrospective cohort study was conducted using longitudinal prescription drug claims data from QuintilesIMS Private Drug Plan database (PDP), Ontario Public Drug Plan database (OPDP), and Quebec Public Drug Plan database (RAMQ). Between 07/2008 and 06/2010, bio-naïve patients who initiated etanercept were identified and followed for 72 months. 12-month retention rates were evaluated in 1-year increments for all patients retained on therapy at years 1, 2, 3, 4 and 5 and compared to retention rates in the first year. The covariates associated with time to discontinuation over the entire 72 month period were identified using a Cox proportional hazards regression model.
Results: The study identified 4,528 etanercept patients (61% female, 85% rheumatic diseases, and 15% PsO) across Canada who started their therapy during the selection period. Overall, 12-month retention rates on etanercept increased significantly for patients following their first year on therapy ($p<.0001$), with 66% of patients retained at year 1 vs. 12- month retention rates of 79%, 82%, 84%, 83% and 79% at year 2, 3, 4, 5 and 6, respectively. A total of 17.1% (n=771) of patients were retained for the entire 72 month study. Regression analysis showed PsO patients were less likely to be retained on therapy than other indications (HR 1.199; $p<.0001$), older patients (65+) were more likely to be retained than younger patients (HR 0.802; $p<.0001$), and public plan patients (ODB HR 0.735, RAMQ HR 0.55; $p<.0001$) were more likely to be retained than private plan patients.
Conclusions: Etanercept patient retention likelihood increased the more years a patient was retained on therapy. This pattern was consistent across therapeutic areas, sex, age, and payers. Age, indication, and payer were found to have a significant impact in determining etanercept patients' time to therapy discontinuation. With better understanding of factors associated with retention, patient support programs can be designed to address the specific needs of at-risk groups while supporting patients stable on therapy.
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FRI0202 THE DIFFERENT EFFECT OF TNFα BLOCKERS AND SDMARDS ON LIPOPROTEIN SUBCLASSES IN RA PATIENTS. A PERSPECTIVE CONTROLLED LONGITUDINAL STUDY

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Background: The different antirheumatic drugs reduce inflammation in RA patients, causing alterations in cholesterol levels (mainly decreasing LDL and increasing HDL cholesterol levels), but HDL and LDL structure and function predict cardiovascular disease better than LDL and HDL cholesterol levels.
Objectives: The investigation of the qualitative changes of LDL and HDL lipoprotein subclasses in RA patients who are good responders, depending on the anti-inflammatory treatment (sDMARDs vs anti-TNFa+sDMARDs) and their in between associations.
Methods: 85 patients ((89%) 76females) with established RA (mean disease duration ≥5 yrs), mean age 57 yrs (SD: 12yrs), without known cardiovascular disease, D/M and thyroid disorders, on sDMARD (MTX, LEF, SSZ, low dose prednisolone or combination) and naïve to biologic treatment, were divided into two groups: the 1st one of 43 patients who had $DAS_{28}>3.2$ and were given in addition a TNFα inhibitor (23 patients had golimumab and 20 patients had certolizumab-pegol) for at least 54weeks (mean treatment duration 18 months) with good clinical response according to Eular and the 2nd group of 42 patients (disease control group) with $DAS_{28}\leq3.2$,who continued on sDMARDs and followed closely the same time period so as to ensure, as well, good clinical response without biologic therapy. Plasma electrophoresis was performed in two time points, before and after anti-TNFα administration and on the same time for the control group, with non-denaturing polyacrylamide gel (ND-PAGE) for size-based separation of lipoprotein subclasses, a standard laboratory technique that indentify various HDL subspecies separable on the basis of average diameter/size into 6 distinct subclasses (HDL-1, HDL2a, HDL2b, HDL3a, HDL3b, HDL3c), as well as LDL lipoprotein into 2 subfractions (LDL-B, LDL-A.)
Results: The RA patients on DMARDs had a percent reduction of LDL-B subfraction by 11.9% (p=0.014), but a significant increase of HDL-3c subclass by 2.38% (p=0.049). In a multivariate model of stepwise logistic regression the after (treatment)-LDL-B subfraction in these patients was found to have significant positive association only with pro-LDL-B subfraction (odds ratio: 10.95, %CI (1.59–62.79)). In the RA patients who took TNFα inhibitors was observed a prominent percent decrease of the more lipoprotein subclasses: LDL-B by 2.33% (p=0.005), LDL-A by 2.33% (p=0.0001), HDL3a by 11.63% (p=0.072) and HDLc by 4.65% (p=0.035). Accordingly, in stepwise logistic regression the after-(treatment) LDL-B subfraction had a significant positive association only with pro-LDL-B subfraction (odds ratio: 12.91,95% CI (2.2–75.83)), as well as, after-LDL-A with pro-LDL-A subfraction (odds ratio:36.16, 95% CI (5.05–258.89)), whereas the reduced after (treatment)-HDL3c subclass was significantly positively associated with pro-HDL3a subclass (odds ratio:8.15, 95% CI (1.04–63.65)) and after-HDLa subclass (odds ratio:22.09, 95% CI (3.56–137.18)).
Conclusions: The discrepancy of qualitative modification of lipoprotein subclasses (LDL and HDL) after treatment with different antirheumatic drugs (sDMARDs, anti-TNFa+sDMARDs) demonstrate their different effect on RA dyslipidemia and their subsequent antiatherogenic prospective.
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FRI0203 GOLIMUMAB IN BIOLOGIC-NAÏVE PATIENTS WITH ESTABLISHED RHEUMATOID ARTHRITIS (RA), PSORIATIC ARTHRITIS (PSA) OR ANKYLOSING SPONDYLITIS (AS) - SUBANALYSIS FROM THE NON-INTERVENTIONAL EVALUATION GO-NICE

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Background: Golimumab (GLM) has demonstrated efficacy and safety in several randomized clinical trials with biologic-naïve patients. However, data from effectiveness and patient-reported outcomes (PROs) parameters in daily clinical practice in Germany are still lacking
Objectives: The aim of this subanalysis is to assess Golimumab on the effectiveness, and PROs in biologic-naïve patients with established RA, PsA or AS
Methods: This is a subanalysis of the non-interventional, prospective, 24-month study GO-NICE. Biologic-naïve patients with established RA, PsA or AS starting with GLM 50mg SC once monthly in a real life setting in Germany. Endpoint measures: disease activity DAS28, PsARC and BASDAI. PROs included QoL (EQ-5D-3L), functionality (FFbH), fatigue (FACIT-F). Safety data were also collected
Results: *RA patients* (n=265): Mean age 54.5 yr, 82.1% of the patients were female, 77.3% (n=204) were rheumatoid factor (RF) positive, and 76.4% (n=201) had anti-ccp antibodies at BL.
The DAS28 score at BL was 5.0 and dropped significantly to 2.9 within 24 months ($p<0.0001$ v. BL). After 3 months of treatment, 45.2% of patients had LDA (DAS28 ≤3.2), which increased to 50.8% after 6 month and 64.9% after 24 months.
PsA patients (n=247): Mean age 49.7 yr, 53.8% of the patients were female, 42.1% (n=104) had a nail involvement, 25.5% (n=63) dactylitis and 13.8% (n=34) enthesitis at BL. The proportion of patients achieving a response (mod PsARC) was 64%, 72.2% and 77.7% at 3, 6 and 24 months, respectively.
AS patients (n=246): Mean age 41.9 yr, 70.7% of the patients were male, 80.5% (n=198) were HLA-B27 positiv. Most common extraarticular manifestations were: enthesitis (12.6%), iritis (12.2%), IBD (3.7%), and dactylitis (2.8%) at BL.
The BASDAI at BL was 5.0 and dropped significantly to 2.0 within 24 months ($p<0.0001$ vs. BL). The proportion of patients achieving a response (BASDAI 50) was 62.2%, 66.9% and 76.9% at 3, 6 and 24 months, respectively.
An improvement of quality of life (QoL) by EQ-5D-3L was seen after 6 months and was maintained over 24 months. The patients' health state today (EQ VAS) improved from 52.3 at BL to 64.9 (RA), from 49.0 to 66.3 (PsA) and from 49.2 to 70.6 (AS). The functional ability (FFbH) improved significantly ($p<0.0001$ vs. BL) from 73.1 to 80.4 points (RA), from 73.0 to 82.2 (PsA) and from 72.8 to 81.2 (AS). The mean Fatigue score (FACIT-F) increased from BL: 33.3 to 39.5 points (RA), from 31.6 to 38.4 points (PsA), and from 31.6 to 40.2 points (AS) (each $p<0.001$ vs BL) within 24 months.
No new safety signals were detected.
Conclusions: GLM SC once-monthly showed after 3 months remarkable improvements in clinical effectiveness, patient-reported quality of life, functionality, and fatigue parameters and were maintained over 24 months in biologic-naive patients with established RA, PsA or AS.
At month 24, 64.9% of RA patients achieved LDA status, 77.7% of PsA achieved positive PsARC response and 76.9% of AS patients achieved BASDAI 50.
No new safety signals were detected.