POD08

Survival on Treatment After Transition to a Biosimilar: Population-Based Evidence from a Natural Experiment Due to a Policy Change

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Objectives: British Columbia's (BC) health policy mandated that all new biologics initiations after June 2017 use biosimilars when available, and in May-December 2019, a further policy mandated that current users of etanercept and infliximab transition to the corresponding biosimilar, providing the context for a natural experiment. Our study objective was to compare drug survival, as a surrogate marker of safety and effectiveness, between biosimilar switchers versus originator anti-TNF users for inflammatory arthritis (IA), after and before the health policy change.

Methods: Study Cohort: Using administrative data, we identified etanercept and infliximab users with rheumatoid arthritis (RA), psoriasis or psoriatic arthritis (Pso/PsA), or ankylosing spondylitis and other spondyloarthritis (SpA) in BC. Biosimilar switchers were current biologic users who transitioned to the corresponding biosimilar during the period of May to December 2019. Historical controls were randomly selected from all new users of originator etanercept and infliximab before July 2017, and matched to biosimilar switchers on sex, previous number of biologics used, and IA disease. Controls were assigned an index date such that the duration of the originator anti-tumor necrosis factor (anti-TNF) was the same at the switching/index date for switchers and controls. Outcomes: Discontinuation was defined as no prescription renewal for at least 6 months. Statistical analysis: We followed patients from switching/index date for 2 years or until discontinuation, moving out-of-province, or end of follow-up (04/30/2019 for originators and 12/31/2021 for switchers), whichever occurred first. Weighted Cox proportional hazards models with propensity score overlap weighting estimated the HR of discontinuing anti-TNF agents for controls and switchers, adjusting for duration of anti-TNF use at switch/index date, age, sex, socio-economic status, rural vs. urban residence, health authority, arthritis type, number of prior biologic agents, comorbidities, and other IA drugs used (MTX, non-MTX csDMARDs and glucocorticosteroids), measured at switching/index date.

Results: Our sample includes 1631 biosimilar switchers/controls (1402 etanercept; 229 infliximab): 556(67.2%) RA, 178(21.5%) SpA, 93(11.2%) Pso/PsA patients. Discontinuations were observed in 347 originator and 354 biosimilar etanercept users; and 44 originator and 36 biosimilar infliximab users. Discontinuation rates in biosimilar and originator users (etanercept: 15.42 vs. 15.63; infliximab: 8.76 vs. 11.29 per 100PY), and adjusted risk of discontinuation [aHR(95% CI): 1.02(0.87;1.19) p=0.718 for etanercept; and 0.85(0.54;1.36) p=0.503 for infliximab) did not differ significantly. [Figure 1] shows survival on treatment.

Conclusion: Population-based data from BC on real-world experience mandating transition from originator to biosimilar etanercept and infliximab for IA revealed the biosimilar transitions have comparable duration of treatment to the original medications. *Supported by a CIORA grant.*

TOUR2C

Assessing the Timeliness of Referrals in Rheumatology from a Centralized Referral System in Québec

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Objectives: Since 2018 in Québec, general practitioners (GP) are required to send patient requests for first rheumatology consultations to the regional centralized referral system (called CRDS), which allocates appointments according to the GP-specified reasons for consultation and level of priority using a standardized form. Our objectives were: to describe the delays for CRDS allocated rheumatology appointments compared with target waiting times in the CRDS, and to compare delays and characteristics of referrals between the pre- and peri-pandemic periods.
Methods: We collected data in one regional CRDS (490K inhabitants), over four periods of 4 months (November to February 2018 to 2022). We analyzed the characteristics of the demand for rheumatology referrals including priority levels and status of referrals as of September 2023. We calculated CRDS system delays, defined as the difference between the date of referral receipt and the date of first appointment allocation and compared these delays with the CRDS target waiting times for each priority level. Median delays and survival curves were compared between the pre- and peri-pandemic periods.
Results: There were respectively 283, 476, 468 and 385 processed rheumatology referrals for the four periods of observation. Overall, there were 91 priority B referrals (target waiting time < 10 days), 254 priority C (<28 days), 730 priority D (<90 days) and 270 priority E (< 365 days). The CRDS target waiting times were met for 74% of priority B, 63% of priority C, 24% of priority D and 40% of priority E. Median delays and Kaplan-Meier survival curves did not significantly differ between the pre- and peri-pandemic periods for high-priority referrals (B and C). However, priority D referrals (e.g.: suspicion of chronic polyarthritis, inflammatory spondylarthropathy, connective tissue disease) had significantly higher delays in the 2020-21 pandemic period versus the 2019-20 pre-pandemic period (respective medians: 532 and 124 days, $p < 0.001$).
Conclusion: These preliminary results, coming from one region of Québec with nearly 100% of the demand by GPs for rheumatology care managed by the CRDS, suggest that prioritization of the referrals in the CRDS helped mitigate the effect of the pandemic for high-priority referrals. Impact of the pandemic on the increased delays was however significant for priority D referrals. Next steps will document consequences of rheumatology first appointment delays on health care services utilization and will explore associations of patient and system factors with these delays.
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TOUR6C

Therapeutic Drug Monitoring of Azathioprine and Tacrolimus in Systemic Lupus Erythematosus Pregnancies: Preliminary Results from The Legacy Cohort

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Objectives: Pregnant systemic lupus erythematosus (SLE) women still face an unacceptably high risk of maternal and fetal morbidity, particularly when their disease is active. Though guidelines strongly recommend azathioprine (AZA) and tacrolimus (TAC) in specific SLE pregnancy scenarios, evidence to guide drug monitoring in this context is non-existent. Our aim is to evaluate the characteristics of SLE pregnancies according to the levels of AZA metabolites (erythrocyte-free 6-thioguanine, 6-TG) and TAC trough levels at the first pregnancy (baseline) visit.
Methods: LEGACY is a prospective cohort enrolling unselected SLE pregnancies ≤16 6/7 gestational weeks at 7 Systemic Lupus International Collaborating Clinics. We record demographics, disease activity, and drugs. In addition, whole blood samples are collected at baseline to determine AZA metabolites (e.g., 6-TG) and trough TAC levels if applicable. The present study included Montreal LEGACY participants prescribed either AZA or TAC ≥3 months prior to their first pregnancy visit. We characterized AZA metabolite and TAC levels as continuous and categorical variables (i.e., non-adherent, sub-therapeutic, therapeutic, and supra-therapeutic, using established cut-offs in non-pregnant populations). We defined patients as non-adherent if they had undetectable or barely detectable levels despite appropriate dosing.
Results: Of 70 LEGACY pregnancies enrolled in Montreal, 23 (33%) and 6 (9%) were prescribed AZA and TAC, respectively. Among those prescribed AZA, only 9% had therapeutic levels, while 91% were sub-therapeutic or non-adherent (Table 1). Compared to those with therapeutic levels, pregnancies with sub-therapeutic or non-adherent AZA levels were more likely to occur in women of non-Caucasian ethnicity/race, on steroids, with longer SLE duration, and with prior lupus nephritis (Table 1). Among those prescribed TAC, 50% (3/6) had therapeutic levels, while 33% (2/6) and 17% (1/6) were sub-therapeutic and supra-therapeutic, respectively. No patients on TAC were identified as non-adherent. Less than half (43%) of pregnancies non-adherent to AZA were in Lupus Low Disease Activity State (LLDAS) at baseline. Of the pregnancies with sub-therapeutic TAC levels, 50% (1/2) were not in LLDAS, while all (4/4) pregnancies with therapeutic or supra-therapeutic TAC levels were in LLDAS at baseline.
Conclusion: We observed that most SLE pregnancies prescribed AZA had sub-therapeutic levels, with nearly a third identified as non-adherent. Pregnancies with lower AZA and TAC levels may be less likely to achieve LLDAS. Despite low numbers, our preliminary results suggest the value of personalized drug monitoring as a novel approach to precision medicine in pregnant SLE women, that might improve efficacy, safety, and adherence in a high-risk population. *Supported by a CIORA grant.*

55

Mapping 24-Hour Movement Guidelines in Axial Spondylarthritis: Meeting Activity Targets but Missing The Mark for Sleep

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Objectives: The 2022 Canadian 24-Hour Movement Guidelines integrate evidence-based targets for physical activity, sleep and sedentary behaviours to achieve health outcomes in adults aged 18-64 years. The purpose of this study was to determine if patients diagnosed with axial spondyloarthritis (axSpA) are meeting these guidelines. The specific objectives were to: 1) profile moderate-vigorous physical activity (MVPA); 2) profile sedentary behaviours and sleep patterns and 3) evaluate discrepancy between objective and subjective measures of activity and sleep.
Methods: Participants with axSpA (meeting ASAS criteria) attending an urban academic rheumatology clinic were provided a wrist-mounted accelerometer, worn for 24 hours over a consecutive 7-day period. The average data validated for a 75% wear-time was used for analysis. Variables included time spent in MVPA per week; time spent in sedentary activity per 24 hours, and sleep/wake duration per 24 hours. Participants completed the International Physical Activity Questionnaire to measure subjective physical activity engagement and a 7-day sleep log to subjectively evaluate sleep quality. Univariate statistics were used to create profiles aligned with the guideline's core recommendations.
Results: Of the 41 participants, 37 (90%) had validated accelerometer data. Most participants were male (56.7%); mean age of 46.0 years (SD 12.6); mean disease duration 23.9 years (SD 11.4); mean Bath Ankylosing Spondylitis Disease Activity Index was 3.2 (SD.1); mean Bath Ankylosing Spondylitis Functional Index was 2.6 (SD 2.2). 35.1% had a history of peripheral joint involvement; 56.7% were receiving biologic treatment. All the cohort met the MVPA targets of ≥150 minutes of MVPA per week (mean 978.5 minutes, SD 387.9) and sedentary behaviour limits of ≤8 hours daily (mean 5.0 hours, SD 0.9). Only 37.8% of participants met the sleep target of ≥7 hours of sleep (mean 6.4 hours, SD 2.0), with multiple disruptions per sleep period (mean 17.7, SD 7.1), indicating poor sleep quality. Participants tended to underestimate their subjective engagement in physical activity and overestimate sleep quality.
Conclusion: The results of this study suggest people with axSpA are highly engaged in physical activity and demonstrate minimal sedentary behaviour, both which exceed recommended activity guidelines. These results are considerably higher when compared to the literature. There is a discrepancy between subjective and objective measures of activity and sleep. Sleep quantity and quality are concerned, with few people with axSpA meeting recommended targets. Further studies that examine sleep-wake patterns, understanding of sleep physiology and potential management strategies are recommended to address sleep deficiency in people with axSpA.
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64

Going Beyond Pain: Consensus Meetings to Expand The JIA Option Map With Other Symptoms and Functional Activities

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Objectives: Young people with juvenile idiopathic arthritis (YPJIA) experience physical and psychological symptoms that negatively impact functional activities. YPJIA and their families need more information and decision support to manage symptoms and participate fully in functional activities. Our team previously developed the JIA Option Map, a web-based patient decision aid for JIA pain management. The current study aimed to expand the app to include treatment options for other relevant symptoms and tips to participate fully in activities. We recently conducted (1) virtual research team meetings and (2) an online survey of research team members to identify the range of symptoms and functional activities that could be added to the JIA Option Map. The current step aimed to obtain consensus on the symptoms and functional activities that should be integrated next into the JIA Option Map.
Methods: Our research team has 35 members, including patient partners, health care providers (HCPs) and researchers, with expertise in JIA, shared decision making and research methods. HCPs include pediatric rheumatologists, nurses, occupational therapists, physical therapists, psychologists, social workers and dietitians. We conducted two virtual consensus meetings with research team members using a modified nominal group process. Further team discussions helped determine how to integrate this information into the app and a prototype was developed with computer science researchers and students.
Results: A total of 18 people participated in the consensus meetings, including three patient partners and HCPs from four different professions. Both meetings had at least one patient partner, researchers and clinicians from at least three professions. Both meetings determined that fatigue, stress/anxiety, and joint stiffness were the most important symptoms to add next. All functional activities were considered important to add, with school and daily living activities rated as the most important. Research team members suggested to integrate this information into the steps in the app by asking YPJIA to (1) choose and rate the symptoms and functional activities that are important to them, (2) assess their preferences in terms of treatment options and (3) provide evidence-based information on the options that match their preferences.
Conclusion: Our team of patient partners, HCPs and researchers agreed on the most important symptoms and functional activities to integrate next into the JIA Option Map. The next step will be a systematic review of the literature for evidence-based approaches to manage these symptoms and tips to improve participation in functional activities that will be integrated into the app. *Supported by a CIORA grant*. Mapping 24-Hour Movement Guidelines in Axial Spondylarthritis: Meeting Activity Targets but Missing The Mark for Sleep

88

Comparable Safety Among New Users of Biosimilar Versus Originator Anti-TNFs in Inflammatory Arthritis: Population-Based Evidence from a Natural Experiment Due to a Policy Change

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Objectives: British Columbia's (BC) health policy mandated that all new biologics initiations after 06/2017 use biosimilars when available, providing the context for a natural experiment. Our study objective was to compare infections and healthcare resource utilization (HRU), as surrogate markers of safety, after initiation of etanercept or infliximab for inflammatory arthritis in new users of biosimilars versus originators, using historical controls pre-policy change.

Methods: Using administrative health data, we identified all incident users of a new biologic (i.e., without prior prescriptions over 6 months) with rheumatoid arthritis (RA), psoriasis or psoriatic arthritis (Pso/PsA), or ankylosing spondylitis (AS) in BC. The biosimilar cohort includes incident users starting etanercept or infliximab between 07/01/2017 and 12/31/2019, followed until 12/31/2020 (post-policy period). Historical controls include all incident users starting etanercept/infliximab originators between 01/01/2014 and 06/30/2016, followed until 06/30/2017 (pre-policy period). To control for temporal trends, we selected new users of adalimumab (no biosimilar available over those periods) as comparators. Outcomes included severe infections (hospitalization with infection diagnostic code in any position); mild infections (oral/IV antibiotics without hospitalization); number of: hospitalizations (any cause), hospital length of stay, physician, and emergency department visits. People were followed for ≤3 years from anti-tumor necrosis factor (anti-TNF) initiation until discontinuation, death, moving out-of-province, or follow-up end, whichever occurred first. Quasi Poisson Models estimated the adjusted rate ratio (aRR) of each outcome and propensity overlap weights controlled for potential confounders. To control for temporal trends, we employed the difference-in-difference (DID) method, comparing the aRRs for each outcome among new users of biosimilar versus originator etanercept/infliximab with new users of adalimumab post- versus pre-policy change, expressed as the ratio of the two aRRs. [Table1]

Results: Our sample includes 827 biosimilar etanercept users (RA:576, AS:171, Pso/PsA:80) and 271 infliximab users (RA:150, AS:54, Pso/PsA:67); 1312 etanercept and 230 infliximab originator users; and 2213 adalimumab originator users post- and 1773 pre-policy change. Outcome rates are reported. [Table1A] After adjusting for baseline covariates and accounting for temporal trends, [Table1B] there were no differences in infections or HRU except for a lower likelihood of mild infections observed in infliximab and etanercept biosimilar users (DID aRR(95%CI): 0.69(0.55,0.86) $p< 0.01$; and 0.88(0.77,1.01) $p= 0.061$, respectively); a lower likelihood of hospitalization in etanercept biosimilar users, and of family physician visits in infliximab biosimilar users.

Conclusion: Real-world population-based data showed that incident users of biosimilar etanercept and infliximab had similar rates of infections and HRU compared to originators, suggesting comparable safety for inflammatory arthritis. *Supported by a CIORA grant.*

99

N-Terminal Pro-Brain Natriuretic Peptide and Adverse Pregnancy Outcomes in Women With Systemic Lupus Erythematous: A Pilot Cross-Sectional Study

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Objectives: Cardiovascular disease (CVD) is the leading cause of death in SLE women. However, traditional risk factors fail to explain the premature CVD observed in young SLE women. Limited evidence suggest that a history of adverse pregnancy outcomes (APO) increases CVD risk in SLE women. N-Terminal pro-Brain Natriuretic Peptide (NT-proBNP) is a key biomarker for cardiovascular events and death. Although increased concentrations of NT-proBNP have been reported in SLE, to date no study has examined its association with APO in SLE. We assessed NT-proBNP in a cross-sectional sample of SLE women prospectively followed for pregnancy and investigated associations with APO.

Methods: Serum NT-proBNP was measured in SLE patients enrolled in the McGill Lupus Cohort, between 03/22-04/23 at annual visits. The "Lupus in prEGnAnCY (LEGACY)" cohort is a prospective cohort enrolling unselected SLE pregnancies < 17 gestational weeks at 7 Systemic Lupus International Collaborating Clinics, including McGill. The present study included LEGACY participants concomitantly followed in the McGill Lupus Cohort. We determined APO (occurring prior to NT-proBNP measurement and defined as ≥3 fetal losses < 10 weeks, ≥1 fetal loss ≥10 weeks, and/or preeclampsia/eclampsia) through the LEGACY detailed case report form. Factors associated with APO and NT-proBNP were evaluated.

Results: We identified 20 SLE patients [median age 36, interquartile range (IQR) 33-40 years] with NT-proBNP measured within a median of 2.1 (IQR 1.2-2.7) years from baseline pregnancy visit. [Table 1] Overall, 10/20 (50%) women experienced an APO, including 4/20 (20%) ≥3 fetal losses < 10 weeks, 4/20 (20%) ≥1 fetal loss ≥10 weeks, and 6/20 (30%) preeclampsia/eclampsia. Although results failed to reach statistical significance, there was a trend for increased mean and median NT-proBNP in SLE women with prior APO [respectively 120 pg/mL (96%CI 35, 204) and 70 (IQR 52-221)] versus those without prior APO [mean 71 pg/mL (95%CI 36, 106); median 56 pg/mL (IQR 33-114)]. In multivariate analysis controlling for aPL, NT-proBNP in the highest quartile (> 118 pg/mL) were associated with APO (OR 2.5; 95%CI 0.2, 28.0), although the CI was wide and included the null value. Unsurprisingly, aPL were also strongly associated with APO (OR 10.5; 95% CI 1.2, 9.8).

Conclusion: Our preliminary results suggest that NT-proBNP might be higher in childbearing-age SLE women with prior APO compared to those without. Our novel research offers some

insights on the association between APO and CVD in SLE, highlighting the need to explore NT-proBNP as an early predictor of CVD in SLE females of reproductive age. *Supported by a CIORA grant.*

100

Biosimilars of Rituximab in ANCA-Associated Vasculitis Compared to The Originator (Bravo): Baseline Characteristics of a Canadian Multicentre Study

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Objectives: Rituximab (RTX) is a first-line induction and maintenance treatment in granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA), the two most common forms of ANCA-associated vasculitis (AAV). Starting in 2020, reimbursement for RTX across Canada became increasingly restricted to biosimilars (including mandatory switching for prevalent users), despite little to no data on their comparative safety and effectiveness to the originator in AAV. We report baseline characteristics of a Canadian multi-centre AAV cohort starting RTX originator or biosimilars for induction or maintenance between 2018-2023.

Methods: We included adults with GPA or MPA who started RTX originator or biosimilar induction or maintenance 1) in the 6 months prior to enrollment, or 2) after January 2018 if followed within an existing vasculitis cohort. We also recruited patients who switched from originator to biosimilar RTX in the prior 6 months. Demographic and disease characteristics at Month 0 (time of starting RTX induction, maintenance, or switching) included disease activity, damage, prior RTX or cyclophosphamide use, and current vasculitis medications. We examined differences between originator and biosimilar subgroups at Month 0 using the 95% confidence interval (CI) for the difference in mean or proportion.

Results: We recruited 201 participants from 9 centres: 127 induction (52 originators; 75 biosimilar), 57 maintenance (23 originator, 35 biosimilar), and 17 switching from originator to biosimilar maintenance. [Table 1] Mean age was 57.2 (SD 17.4), 52% were female, and 79% were White. The majority had GPA (69%) and were PR3-ANCA+ (64%). Vasculitis manifestations at last flare included ear/nose/throat (54%), pulmonary (58%), renal (53%), and musculoskeletal (39%). The originator induction group was younger compared to the biosimilar induction group (mean age 50.3 vs 59.8, difference 9.5 [95%CI 3-16]). The originator maintenance group had longer disease duration compared to the biosimilar maintenance group

(mean 7.7 vs 2.4 years, difference 5.3 [95% CI 1.5-9.1]), and a greater proportion had PR3-ANCA (87% vs 56%, difference 31% [95%CI 7-50%]), had suffered a prior relapse (57% vs 12%, difference 45% [95%CI 20-64%]) and had previously received RTX induction (57% vs 26%, difference 30% [95%CI, 4-51%]).
Conclusion: This multi-centre cohort will evaluate real-world outcomes following treatment with RTX originator and biosimilars for AAV. Differences in baseline characteristics between RTX originator and biosimilar recipients (i.e., the latter group having older age when starting RTX induction, and less relapsing disease/shorter disease duration when starting RTX maintenance) might suggest less restricted access to RTX for AAV coinciding with the availability of biosimilars. *Supported by a CIORA grant.*

101

Work Disability in Patients With Systemic Lupus Erythematosus: A Pan-Canadian Qualitative Study

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Objectives: Work participation and disability have meaningful influences on mental wellbeing, health-related quality of life, and disease-related outcomes in individuals with systemic lupus erythematosus (SLE). Previous studies estimate that 20-50% of SLE patients experience some form of work disability (WD). The objective of this study was to identify psychosocial and workplace factors associated with WD to create an SLE-related functional profile that is grounded in a WD prevention framework.

Methods: SLE patients (n= 41) were purposively recruited from multiple medical centres across Canada representing four provinces. Using a WD prevention framework, semi-structured interviews were conducted to qualitatively identify factors associated with WD and explore lived experiences of SLE-related WD across their employment history. The work disability prevention framework recognizes that disability in the workplace is not only due to the workers' characteristics, but also due to environmental factors. The framework indicates that personal, workplace, healthcare, and compensation systems are influential to a worker's health and wellbeing. Interview data was transcribed verbatim. Thematic analysis was utilized to inductively and deductively organize the data into underlying concepts and relevant themes.
Results: Three themes [Figure 1] emerged from the data: a) the illness experience and its impact on work, b) stigmatization of illness disclosure, c) availability of workplace resources and accommodations. Fatigue, physical limitations, and impaired mental health were frequently reported as barriers to work function. Participants reported that participation in work with reduced physical and mental demands, and increased personal control and workplace flexibility were more desirable and subjectively prevented WD.
Conclusion: WD in SLE necessitates the recognition of the complexity, multidimensionality, and temporal dimensions of SLE and its relationship to work. This study provides evidence that a collaborative, multidisciplinary intervention including the patient, the healthcare worker and their workplace is needed to effectively mitigate influential psychosocial and workplace factors to establish a goal-oriented preventative framework could improve WD outcomes in individuals with SLE. *Supported by a CIORA grant.*