A Comparison of Sleep Quality in Rheumatoid Arthritis and Osteoarthritis Patients

Taylor-Gjevre R, Gjevre J, Nair B, Skomro R, Lim H

University of Saskatchewan, Saskatchewan, Canada

Objectives: To evaluate and compare aspects of sleep quality in Rheumatoid Arthritis (RA) and Osteoarthritis (OA) patient populations.

Methods: Consecutive RA and OA clinic patients were invited to participate in a self-administered questionnaire study which included the multidomain Pittsburgh Sleep Quality Index (PSQI).

Results: The study population included 145 RA and 78 OA patients. No significant differences in PSQI global or domain scores were observed between diagnostic groups. PSQI global scores were abnormal in 62% of RA and 67% of OA patients. Increased abnormalities in subjective sleep assessment, sleep latency, sleep duration, sleep efficiency, daytime dysfunction and increased sleep aid medication use were observed in both populations. The most common abnormality reported by both RA and OA patients was increased sleep fragmentation with frequent disturbances.

Conclusions: A high prevalence of abnormal sleep quality in both RA and OA patient populations was observed. The most common abnormality was sleep fragmentation with an increased sleep disturbance score.

Assessing the Rate of Serious Infections in Rheumatoid Arthritis (RA) Patients who Receive Other Biologic Therapies after Discontinuing Rituximab (RTX)

Genovese M (1), Keystone E (2), Breedveld F (3), Emery P (4), Cohen S (5), Mateson E (6), Burke L (7), Chai A (8), Reiss W (9), Sweetser M (10), Shaw T (11)


Objectives: To describe the rate of serious infection events (SIEs) in RA patients (pts) treated with RTX and who subsequently received another biologic disease-modifying antirheumatic drug (BDMARD) while being potentially peripherally B-cell depleted as a result of RTX selectively targeting CD20+ B-cells.

Methods: Pts included in the study had moderately-to-severely active RA and received RTX + methotrexate (MTX) within an international trial program. After completion or withdrawal from their studies, pts entered a safety follow-up (SFU) during which peripheral B-cell counts were monitored at regular intervals for 48 weeks (who's) and BDMARDs could be received. All SIEs, defined as adverse events and/or infections that required IV antibiotics, were collected.

Results: As of September 2009, 3,189 RA pts had received at least 1 course of RTX, yielding a total follow-up number of 9,365.03 pt-yrs. 283 pts who entered SFU subsequently received another biologic (median time of 8.5 months (mo) after last RTX infusion). Of these 283 pts, 30.7% received their biologic within 6 mo of their last RTX infusion. The largest group (n=230 pts) received a TNF-inhibitor (TNFi) after RTX. The median follow-up time post-reception of the subsequent biologic was 11 mo. 83% of patients had peripheral B-cell counts below the lower limit of normal (<80 cells/µL) at the time of receiving further BDMARD treatment. For this group of 283 pts, 6.01 SIEs per 100 pt-yrs were reported during treatment with RTX and prior to receiving the biologic. Following BDMARD treatment initiation, the rate fell to 4.97 SIEs per 100 pt-yrs. The median time to SIE after initiation of BDMARD treatment was 11 mo. In 43 pts who received abatacept (ABA) as their initial BDMARD, 1 SIE before and 1 SIE after receiving ABA were reported (97.7 total pt-yrs). Overall, the infections were variable and typical for RA pts. No opportunistic or fatal infections were reported.

Conclusions: As indicated by this updated analysis, subsequent biologic therapies after RTX discontinuation were not associated with an increased rate of serious infections in pts who received biologics or in the subgroup who received TNFis. The SIE rate was consistent with rates observed in long-term safety data.

Safety Analysis of Tocilizumab (TCZ) in Rheumatoid Arthritis (RA) Patients (pts): Long-Term Extension Studies (Median of 3.1 Years of Treatment)

Van Vollenhoven R (1), Cividino A (2), Scalfi (3), Curtis J (4), Krasnow J (5), Vernon E (6), Alten R (7)

(1) Karolinska Institute, Stockholm, Sweden, (2) McMaster University, ON, Canada, (3) Hospital Durand, (4) University of Alabama at Birmingham, Alabama, USA, (5) Roche, (6) University of Berlin
**Long-term Safety, Under Routine Care, of Infliximab in Patients With Rheumatoid Arthritis in a Large Canadian Cohort**

Bensen B (1), Choquette D (2), Jones N (3), Sholter D (4), Yan A (5), Farawi R (6), Imhoff H (7)

(1) McMaster University, Ontario, Canada, (2) Hôpital Notre-Dame, Quebec, Canada, (3) University of Alberta, Alberta, Canada, (4) 124 Street Medical Group, Alberta, Canada, (5) N/A, Ontario, Canada, (6) Merck Canada Inc, QC, Canada

**Objectives:** The efficacy and safety of Infliximab (IFX) in Rheumatoid Arthritis (RA) has been demonstrated in several controlled clinical trials. Assessment of long-term safety under real-life conditions is necessary for the population based benefit-risk evaluation. This analysis describes for the first time the long-term safety profile of IFX in a routine care cohort of Canadian patients with RA.

**Methods:** The data for this analysis were obtained from an observational study of adult RA patients initiated on treatment with IFX and followed prospectively as per routine care since 2002. Patients enrolled were biologic naive or had initiated treatment with a biologic less than six months prior to enrolment. All adverse events were reported using preferred term and high-level System Organ Class codes, using the most severe intensity for that event.

**Results:** 765 patients were recruited with a mean (SD) age of 55.9 (13.4) years and mean (SD) duration of disease at baseline of 10.3 (9.9) years. After a mean follow up of 17.8 (16.9) months, 76 out of 765 patients (9.9%) reported 121 serious adverse events (SAEs). Among these, serious infections were reported by 23 patients (3.0% or 2.2 serious infections / 100 pt-yrs). Non serious AEs (NSAEs) were reported by 36.2% of patients, including 92 patients (12.0%) experiencing an infection. Malignancies were reported in 6 patients (0.8%) and 33 out of the 765 patients (4.3%) had infusion-related reactions, 85% of which were mild to moderate in severity.

**Conclusions:** The results of this real-life observational study demonstrate that a low rate of IFX dose optimization and a low rate of discontinuation are observed in Canadian RA patients treated with IFX. Additionally, the data from this cohort suggest that very few patients are dose optimized before discontinuing treatment due to lack of response or disease progression.

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**Low Rates of Infliximab Dose Titration and Discontinuation Are Observed in Rheumatoid Arthritis (RA) Patients in a Real-life Canadian Cohort**

Bensen B (1), Farawi R (2), Khalil H (3)

(1) McMaster University, Ontario, Canada, (2) N/A, Ontario, Canada, (3) Merck Canada Inc, Quebec, Canada

**Objectives:** The recommended dose of infliximab (IFX) in RA is 3 mg/kg given as an IV infusion followed by additional 3 mg/kg doses at 2 and 6 weeks after the first infusion then every 8 weeks thereafter. For patients who have an incomplete response, consideration may be given to adjusting the dose up to 10 mg/kg and/or treating as often as every 4 weeks. The aim of this analysis is to evaluate the dose changing patterns and related therapeutic response observed in RA patients treated with IFX in Canada.

**Methods:** The data for this analysis were obtained from an observational study of adult RA patients initiated on treatment with IFX and followed prospectively as per routine care since 2002. Patients enrolled were biologic naive or had initiated treatment with a biologic less than six months prior to enrolment. All adverse events were reported using preferred term and high-level System Organ Class codes, using the most severe intensity for that event.

**Results:** A cohort of 385 patients, who were enrolled up to May 31st 2006 and thus had the potential of treatment for at least 48 months, and who had at least one follow-up visit, were included in this analysis. At baseline, mean (SD) age was 56.4 (13.3) years and mean disease duration was 11.2 (10.3) years. During 48 months of follow up, 2075 infusions were recorded and the mean dose of IFX used was 3.46 (0.39) mg/kg. A similar value was obtained for patients (n=81) who ended their participation (median time to discontinuation was 38.2 months) due to lack or loss of response, disease progression or an adverse event (mean of 3.52 mg/kg (0.61) for a total of 337 infusions). Among patients discontinued due to lack/loss of response or disease progression (n=67), only 11 (16.4%) had an increased dose and/or frequency of IFX compared to their baseline levels (3 patients had an increased dose and 8 an increased frequency), while none of the patients who were discontinued due to an adverse event (n=14) was dose-optimized. For 17% of patients the initial dose of IFX was < 3 mg/kg. After 48 months of treatment, 83.1% of patients remained on a stable dose and frequency of IFX (n=320).

**Conclusions:** The results of this real-life observational study demonstrate that a low rate of IFX dose optimization and a low rate of discontinuation are observed in Canadian RA patients treated with IFX. Additionally, the data from this cohort suggest that very few patients are dose optimized before discontinuing treatment due to lack of response or disease progression.

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Profile of Patients with Rheumatoid Arthritis Treated With Infliximab in Canada—Trends Toward Less DMARD Use Prior to a Biologic, Earlier Use of Infliximab and Differences in Baseline Disease.

Bensen B (1), Atkins C (2), Sheriff M (3), Kelsall J (4), Khalil H (5)

(1) McMaster University, Ontario, Canada, (2) University of Victoria, (3) Nanaimo Regional General Hospital, (4) Mary Pack Arthritis Center and St Paul's Hospital, BC, Canada, (5) Merck Canada Inc, Quebec, Canada

Objectives: The efficacy of Infliximab (IFX) in Rheumatoid Arthritis (RA) is well established. Patient profiles and use of biologics have reportedly changed since their introduction. The aim of this analysis is to describe Canadian patient profiles at the time of initiation of IFX and treatment outcomes in the years 2002 until 2009.

Methods: The data for this analysis were obtained from an observational study of adult RA patients initiated on treatment with IFX and followed prospectively as per routine care since 2002. Patients enrolled were biologic naïve or had initiated treatment with a biologic less than six months prior to enrolment. Patients were analyzed by the year of their enrolment.

Results: A total of 757 patients were enrolled between 2002 and December 31st, 2009. A tendency was observed across years towards earlier IFX initiation upon disease diagnosis as indicated by the decrease in disease duration (12.4 years in 2002 vs 7.8 years in 2009) and treatment of patients with fewer DMARDs prior to study enrolment, as indicated by the decrease in proportion of patients who had received >4 DMARDs prior to initiation of IFX (25% in 2002 vs 5% in 2009). Furthermore, patients’ profile at baseline (BL) changed significantly across years towards less severe disease: mean DAS28-CRP 5.9 in 2002 vs 4.6 in 2009; mean HAQ 1.8 in 2002 vs 1.4 in 2009; mean SJC 13.9 in 2002 vs 7.4 in 2009; mean TJC 16.1 in 2002 vs 10.1 in 2009; mean PGA 7.2 in 2002 vs 5.9 in 2009; mean SGA 63.4 in 2002 vs 54.9 in 2009; mean pain (VAS) 60.1 in 2002 vs 50.6 in 2009. Interestingly, patients with provincial coverage (n=380) had higher DAS28 [5.5 (1.1) vs. 5.0 (1.3)], HAQ [1.9 (0.6) vs. 1.5 (0.7)], SJC [12.9 (7.0) vs. 10.8 (6.9)], TJC [15.0 (7.9) vs. 12.9 (7.7)], PGA [7.0 (1.8) vs. 6.1 (2.3)], SGA [64.8 (22.2) vs. 57.2 (26.0)], Patient Pain [62.4 (22.6) vs. 52.6 (25.0)] and AM stiffness [75.2 (43.4) vs. 67.2 (43.9)] compared to patients with private coverage (n=270).

Conclusions: The results of this study show a significant change in several clinical and patient outcomes towards lower disease activity at initiation of IFX treatment between 2002 and 2009. Patient management has also changed, with a trend to initiate IFX treatment after failure of fewer DMARDs. Finally, patients with public coverage appear to have a more severe disease profile at baseline compared to patients on private coverage.

Treating Rheumatoid Arthritis to Target: A Canadian Physician Survey

Harouzi B (1), Bessette L (2), Bensen W (3), Leclercq S (4), Thorne C (5), Wade J (6), Muratti E (7)

(1) Université de Montréal, Quebec, Canada, (2) Laval University and CHUQ-CHUL Research Centre, QC, Canada, (3) McMaster University, ON, Canada, (4) University of Calgary, Alberta, Canada, (5) Southlake Regional Health Care, (6) Royal University Hospital, Regina, SK, Canada, (7) University of British Columbia, British Columbia, BC, Canada

Objectives: To assess agreement and application of T2T recommendations in Canadian practice.

Methods: A nationwide, web-based survey was conducted. Agreement with each recommendation was measured on a 10 point Likert scale (1 = fully disagree, 10 = fully agree). A 4 point Likert scale (never, not very often, very often, always) assessed application of each recommendation in current practice. Responders who answered “never” or “not very often” were asked whether they were willing to change their practice according to the particular recommendation.

Results: 78 physicians (approximately 26% of the Canadian rheumatology community) responded. The mean number of participants’ years in practice was 18 and the average number of patients seen per month was 98. Average agreement scores ranged from 6.92 for recommendation #5 (Measures of disease activity must be obtained and documented regularly, as frequently as monthly for patients with high/moderate disease activity or less frequently [such as every 3 to 6 months] for patients in sustained low disease activity or remission) to 9.1 for recommendation #10 (The patient has to be appropriately informed about the treatment target and the strategy planned to reach this target under the supervision of the rheumatologist). A majority of participants indicated that they apply T2T recommendations in their practice. However, recommendations #4 (Until the desired treatment target is reached, drug therapy should be adjusted at least every 3 months), #5, and #6 (The use of validated composite measures of disease activity, which include joint assessments, is needed in routine clinical practice to guide treatment decisions) received the highest number of “never” or “not very often” responses (15.38%, 33.33%, and 32.05% for recommendations #4, #5, and #6, respectively). In addition 92%, 73%, and 17% of participants who were not applying recommendations #4, #5, and #6, respectively, in their practice indicated that they were not willing to change their practice according to these recommendations. Busy practice and disagreement with inclusion of composite outcome measures in treatment decisions were the main reasons for objections.

Conclusions: Although a majority of Canadian rheumatologists agreed with and supported T2T recommendations, there was also resistance toward specific aspects of these recommendations. Efforts are needed to better understand reasons behind identified disagreements, upon which action plans to re-enforce application of T2T recommendations in Canada should be developed.

Results from the RESET Study: Rituximab Response Based on Reasons for TNFi-Discontinuation and Rheumatoid Factor Status

Harouzi B (1), Bokarewa M (2), Bykerk V (3), Kallmeyer I (4)

(1) University of Montreal, QC, Canada, (2) Sahlgrenska University Hospital, Sweden, (3) Mt Sinai Hospital (Toronto), Brigham & Women’s Hospital, MA, USA, (4) Hoffmann-La Roche, Medical and Regulatory Affairs

Objectives: To analyze the response to rituximab (RTX) based on the reasons for discontinuing a TNF-inhibitor (TNFi) as well as baseline characteristics that can be used as predictor of response.

Methods: RA patients (pts) receiving background methotrexate (MTX) (10-25 mg/week) received 1000 mg of RTX on Days 1 and 15, as per approved label. Key inclusion criteria comprised pts with moderate/severe RA with swollen joint count ≥6 and tender joint count ≥6 at baseline and treatment history with only one prior TNFi. Efficacy was assessed at weeks...
4, 12, 24, 36 and 48. Between Week 24 and 48, pts having achieved a clinically relevant response to the first course of RTX were eligible for one retreatment course of RTX. Efficacy assessments for the retreatment group were performed at week 12 and 24.

Results: The baseline characteristics (mean +/- SD) of the cohort were: age: 55.6 (+/- 10.2); disease duration: 13.9 (+/- 9.8) years; disease activity (DAS28): 6.4 (+/- 1.1); HAQ-DI: 1.7 (+/- 0.6). 73% of the population was rheumatoid factor (RF) positive and 73% of the population was female. Improvements in ACR 20, 50 and 70 were achieved after the first course of treatment in 58.0%, 27.0% and 7.0% of the population and in 63.0%, 32.0% and 8.0% of RF positive pts at week 24, respectively. Changes in DAS were observed as early as week 4 (< 0.9 by baseline) and had decreased by < 2.0 (-2.2 in RF positive pts) by week 24. ACR 20, 50 and 70 for pts who had discontinued treatment with their previous TNFi for the following reasons were: lack of initial response: 55; 24; 10; loss of response: 59; 26; 4; tolerability concerns: 67; 33; 8, respectively. After the second course of treatment, ACR 20, 50 and 70 improved in 57.1%; 30.0% and 10.4% of pts at week 24 and in 60.7%; 34.0% and 11% of RF positive pts, respectively. Changes in DAS had decreased by < 2.2 (-2.4 RA positive pts) by week 24. ACR 20, 50 and 70 were 48; 19; 5 for lack of initial response; 65; 31; 10 for loss of response and 80; 80; 20 for tolerability concerns, respectively.

Conclusions: Treatment with RTX resulted in clinically significant improvements in disease activity. Compared with the overall population, RF positive pts appear to have an enhanced response. RTX efficacy was not affected based on the TNFi-discontinuation reasons.

Time to and Level of Initial DAS28 Change With Certolizumab Pegol Predicts the Likelihood of Having Low Disease Activity at Years 1 and 2 in Patients With Rheumatoid Arthritis

Harouzi B (1), Van der Heijde D (2), Schiff M(3), Keystone E (4), Landewe R (5), Kvien T (6), Curtis J (7), Khanum D (8), Luittens K (9), Furst D (10)

(1) Université de Montréal, Quebec, Canada, (2) Liége University Medical Center, Netherlands, (3) University of Colorado School of Medicine, (4) Mount Sinai Hospital, Ontario, Canada, (5) Maastricht University Medical Center, The Netherlands, (6) University of Oslo, (7) University of Alabama at Birmingham, (8) UCLLA, CA, USA, (9) UCB, Belgium

Objectives: To investigate the predictability of the time to and level of DAS28 response on the likelihood of achieving low disease activity (LDA) at both Years 1 and 2 in rheumatoid arthritis (RA) patients treated with certolizumab pegol (CZP) + methotrexate (MTX).

Methods: Patients treated with every other week CZP 200 or 400 mg + MTX in RAPID 1 were combined for analysis (N=783). The proportion of patients who achieved DAS28 LDA (DAS28 ≤3.2) at Years 1 and 2 (during the open-label extension [OLE]) were assessed according to the level of DAS28 decrease from baseline [BL] (< 0.3, 0.6, 0.9, 1.2, 1.5 and 1.8 units) by various time points (Weeks 1, 2, 4, 6, 8, 10 or 12). Between Week 24 and 48, pts having achieved a clinical relevant response (i.e., DAS28 decrease from baseline [BL] < 0.3, 0.6, 0.9, 1.2, 1.5 and 1.8 units) by various time points (Weeks 1, 2, 4, 6, 8, 10 or 12). DAS28, failure to respond by Week 12 was more predictive of failure to achieve LDA at both Years 1 and 2 compared with failure to respond by earlier time points.

Conclusions: The majority of patients responded to treatment with CZP by Week 12. These data stress the importance of significant early response by Week 12, in order to achieve long term low disease activity and help the clinician in the treatment decision process.

Comorbidity is Commonly Reported in Early Inflammatory Arthritis

Hitchon C (1), Dooley J (2), Boite G (3), Harouzi B (4), Pope J (5), Thorne C (6), Ferland D (7), Bykerk V (8), of Early Arthritis Researchers N

(1) University of Manitoba, Manitoba, Canada, (2) Université de Sherbrooke, QC, Canada, (3) University of Montreal, QC, Canada, (4) University of Western Ontario, Ontario, Canada, (5) Southlake Regional Health Care, The Arthritis Prog, ON, Canada, (6) Hospital Maisonneuve, (7) Mount Sinai Hospital, Ontario, Canada, (8) Canada

Objectives: To determine the prevalence of co-morbid medical conditions in patients with recent onset inflammatory arthritis.

Methods: Patients in CATCH are age >16 years old, have symptoms for 1 week, and have ≥ 2 swollen joints or 1 swollen metacarpophalangeal or proximal interphalangeal and ≥1 of positive rheumatoid factor (RF), anti-cyclic citrullinated peptide (anti-CCP), morning stiffness > 45 minutes, response to non-steroidal anti-inflammatory drug or painful metatarsophalangeal squeeze test. Comorbid medical conditions are self reported at baseline and new diagnoses identified at each visit. Patients in the CC cohort have inflammatory arthritis involving at least 2 joints of less than 1year duration; comorbidity is assessed annually by patient self report (SR) and physician reported Charlson comorbidity index (CCI).

Results: Baseline comorbidity data was available for 803 CATCH subjects (74% female; 81% Caucasian, mean age 53; mean symptom duration 5.3±2 months; mean DAS28(3)CRP 4.34 (1.31). 539(67%) reported at least one comorbid medical condition (median 1, range 0-8). The following non-rheumatic conditions were reported at baseline: hypertension (213(27%), hypercholesterolemia (112(14%), diabetes (DM) (65%), thyroid disease (101(13%), CVD (angina, other heart disease, stroke) (89(11%), neurologic disease(73(9%), respiratory (107(13%), hematologic (50(7%), gastrointestinal 94(12%) and cancer (51(6%). CATCH subjects reporting at least one comorbid condition had higher baseline DAS28(3) CRP (4.44 vs 4.13 p=0.003) and higher baseline HAQ_scores (1.05 vs 0.85 p= 0.001). In the CC cohort (75% female, mean age 49 years, DAS28(3) CRP 3.74 (1.37); self report comorbidity data was available at baseline (n=291), and at one year (n=143). At least one non-rheumatic comorbid condition was reported by 239(82%)(median range 3 range 0-14); hypertension 55(19%), DM 24(8%), CVD (any cardiac and stroke) 26(9%), neurologic (neurologic conditions, any headache) 123(42%), any respiratory 73(25%), hematologic 36(12%), gastrointestinal 76(20%), and cancer 9(3%). The physician reported baseline CCI was median 0 range 0-5;MI (2%), cerebrovascular disease (0.4%), ulcer (3.2%), diabetes (4.4%), diabetes with complications (1.2%), end stage renal disease (0.4%), tumor (1.6%), leukemia (0.4%). Paired baseline and one year CCI were available for 101 subjects and were similar. New diagnoses (SR or CCI) at one year included: hypertension (6) heart disease (2), diabetes (1), cancer (3), respiratory (7), gastrointestinal(7).

Conclusions: Comorbid medical conditions are common in early arthritis and may be associated with more active disease. Further longitudinal follow up is needed to determine the extent of comorbidity accrual in early disease.
Objectives: The goals of the Ontario Biologics Research Initiative (OBRI) are to determine the long term effectiveness and safety of Biologics in actual practice and to develop and evaluate a range of strategies to facilitate best practice implementation. To describe the disease characteristics of RA patients being prescribed a new biologic, in Ontario.

Methods: Patients registered in the OBRI, and prescribed a new biologic at the time of their enrollment, where included in the analysis. Two groups were identified: patients receiving their first biologic prescription (i.e., biologic naïve, n = 73) versus patients who had previously used a biologic (i.e., non naïve, n = 441). Rheumatologist reported data at the time of enrollment included patient demographics and measures of disease activity. t-tests of the means were used to compare the two groups.

Results: A total of 150 (25%) of the 579 patients registered in the OBRI study were prescribed a new biologic at the time of enrollment. Their mean age was 53.2 years (SD of 12.9), and 85% were females. The mean RA duration was 12.9 years (10.7), physician global 5.9 (2.1), patient global 5.8 (2.5), mean ESR 33.3 mm/hr (23.1), and CRP 14.5 mg/l (19.6). Erosions on X-rays were reported in 80% of patients and 77% of patients were positive for Rheumatoid Factor. Two or more comorbidities were reported in 60% of patients. Mean tender joint count was 9.3 (6.7), swollen joint count 9.0 (5.8), mean DAS 28 was 5.5 (1.2), SDAI was 33.5 (14.2), and CDAI was 30.4 (14.1). The majority of these patients were on concurrent Methotrexate at the time of the new biologic prescription (69%). Enbrel was the most commonly prescribed biologic (33% of patients), followed by Humira (28%), and Rituxan (9.3%). When the biologic naïve patients were compared to those patients who had previously used a biologic, there were no statistically significant differences in any of the above measures.

Conclusions: While the biologic naïve patients were found to have higher DAS 28, SDAI, CDAI and patient and physician global scores, when compared to patients who had previously used a biologic, these differences were not found to be statistically significant.

Regional Variation of the Profile of Patients With Rheumatoid Arthritis Treated With Infliximab in Quebec and Ontario

Methods: The data for this analysis were obtained from an observational study of adult RA patients initiated on treatment with IFX and followed prospectively as per routine care since 2002. Patients enrolled were biologic naïve or had initiated treatment with a biologic less than six months prior to enrolment.

Results: A total of 514 RA patients were enrolled between 2002 and 2010, whereof 156 (30.4%) were from Quebec (QC) and 358 (69.6%) from Ontario (ON). Patient baseline (BL) characteristics differed between the two provinces with patients from ON having a significantly higher ESR (34.9 mm/hr vs. 28.2 mm/hr) (P = 0.004) and a significantly higher number of prior disease-modifying antirheumatic drugs (DMARDs) (58% of QC patients treated with 1 DMARD vs. 39.6% of ON; P = 0.007) despite the comparable disease duration (8.6 years in ON vs. 9.5 years in QC; P = 0.413). The vast majority of patients starting IFX in both provinces had a high disease activity (DAS28>5.1). Treatment with IFX resulted in statistically (P = 0.001) and clinically significant reductions in the DAS28 (∆DAS28ON: -1.4 and -1.7, ∆DAS28QC: -1.9 and -2.2 at 6 and 12 months, respectively) and HAQ (∆HAQON: -0.3 and -0.4, ∆HAQQC: -0.5 and -0.6 at 6 and 12 months, respectively). However, significantly lower DAS28 and HAQ values were achieved by 6 and 12 months in patients from QC compared to ON (P < 0.001). Similarly, lower disease activity was achieved in patients from QC compared to ON as indicated by the EULAR definition of response (P6mo=0.008 and P12mo=0.003) and DAS28 categories (P6mo=0.008 and P12mo=0.019). Regression analysis over time showed that all parameters observed (CRP, ESR, AM stiffness, HAQ, pain, patient and physician global assessment, tender and swollen joint count and DAS28-CRP) improved significantly. The only difference between provinces was a stronger decrease in CRP in ON.

Conclusions: The results of this study have shown a significant regional variation in Canadian RA patients with patients from ON having higher ESR and having been treated with more DMARDs before initiation of IFX. All patients showed a significant response to IFX treatment with patients from QC reaching lower disease activity.

Sex Differences in Pain Level and Location in Inflammatory Arthritis: A Systematic Review and Meta-Analysis

Objectives: Patient sex may influence the disease experience for patients with inflammatory arthritis (rheumatoid arthritis (RA), ankylosing spondylitis (AS), psoriatic arthritis (PsA) and spondyloarthropathy (SpA)), with implications for treatment expectations and predicted response. Our objective was to determine if there are differences in pain level or location reported by females and males in inflammatory arthritis studies.

Methods: A search of PubMed (1950 to April 2010) and EMBASE (1980 to April 2010) was supplemented by manual searches of conference abstracts. We identified studies reporting sex-stratified pain measures (visual analogue scale (VAS), bodily pain component of the 36-item Short Form Health Survey (SF-36BP) or pain location, in biologic naïve populations. Effects analyzed were a) standardized mean difference (SMD) for pain measures (cross-sectional analyses), b) percentage improvement in pain measure (longitudinal analyses), and c) proportion reporting pain at a particular location. The systematic review for pain measures included 26 cohorts and 1 randomized controlled trial (23 in RA, 1 inflammatory polyarthritides, 1 AS and 1 PsA), and for pain location includes 12 publications (9 in AS, 2 PsA and 1 SpA). The meta-analysis for pain measures includes 16 cohorts reporting pain by VAS and 3 cohorts reporting pain by SF-36BP (all RA).
Results: Meta-analysis revealed a significant difference in the SMD in pain levels measured by VAS in RA (SMD 0.21 (95%CI 0.16-0.26), p< 0.001), likely of modest clinical significance. This difference held when stratified by disease duration at measurement (RA < 1 year SMD 0.30 (95%CI 0.15-0.45), established RA SMD 0.20 (95%CI 0.14-0.23)). The SMD for SF-36BP was not significant (SMD -0.14 (95%CI -0.49, 0.20), p=0.411). In longitudinal studies, pain levels in females with RA improved to a greater degree than in males, but were still higher at any time point. In AS, PsA and SpA, males experienced more inflammatory back pain at any time point during their disease (66% vs 51%) and females experienced more pain due to peripheral arthritis (69% vs 51%).

Conclusions: Females with RA experience overall higher pain levels than males, but do have a greater degree of improvement with treatment. Although this analysis does not explore confounding factors to explain this, clinicians should be aware of sex differences in pain when managing inflammatory arthritis. In AS, PsA and SpA, females will develop peripheral arthritis more frequently, with fewer manifestations of inflammatory back pain. This may have diagnostic implications in the clinical setting.

Conclusions: Sex does not influence pain perception in this multinational cohort of early inflammatory arthritis patients. This suggests that differences seen in established RA in other studies may have been influenced by disease duration and other factors.

Objectives: The use of computers in rheumatology clinical practice is increasing with many clinicians developing their own databases, the use of institutional e-charts and the NIH Patient-Reported Outcomes Measurement Information System. This topic is of particular importance in rheumatology as current guidelines recommend tight monitoring of patient outcomes as a component of optimal care. Our objective was to develop a conceptual framework for the design of real-time systems for clinical monitoring and research in rheumatology.

Methods: Phased feasibility pilot to develop and evaluate technical prototypes combined with a scoping study which included a review of the literature and key informant interviews with experts within the fields of rheumatology, health informatics, ethics, privacy and security, patients and rheumatologists.

Results: We found that few of the established initiatives address the complex dynamics of a clinical research environment and issues related to ethics, privacy and data security. The E-Rheum infrastructure was developed through a series of phased feasibility studies funded by the CIHR. Phase one included key informant interviews with a range of stakeholders; testing of various types of devices and technologies for data entry; and the development of a prototype patient data capture interface that allowed patients of various types combined with a scoping study which included a review of the literature and key informant interviews with experts within the fields of rheumatology, health informatics, ethics, privacy and security, patients and rheumatologists.

Objectives: Pain levels in established RA are on average higher in women than men. We sought to determine if patient sex influences pain levels in a prospective multinational cohort of early inflammatory arthritis patients treated to remission.

Methods: As of May 2010, 819 females and 307 males were recruited to the Canadian Arthritis CoHort (CATCH). Patients enrolled are over the age of 16 with ≥ 2 swollen joints or 1 swollen MCP or PIP, with symptom duration of 6 weeks to 12 months, and ≥1 of: positive RF, anti-CCP, morning stiffness, response to NSAID or painful MTP squeeze test. Patients are treated at the discretion of their rheumatologists. Sex-stratified analysis of pain measures recorded in CATCH, including the Visual Analogue Scale (VAS), Patient Global Assessment (PGA) and pain components of the Rheumatoid Arthritis Disease Activity Index (RADAI), was performed to identify differences in pain levels between females and males.

Results: The cohort includes patients with a mean disease duration of 6 months at first visit, with a mean (SD) baseline DAS28 of 4.85 (1.50) in females and 4.97 (1.80) in males. Females and males had similar levels of disease activity by DAS28 and RADAI at all assessments, and a similar proportion achieved DAS28 remission. No significant differences were found in pain measures between females and males at baseline, year 1 or year 2 assessments. The mean (SD) VAS at baseline for females and males respectively was 5.40 (2.79) vs 5.49 (2.93); year 1: 2.81 (2.57) vs 2.87 (2.67); and year 2: 2.64 (2.64) vs 2.58 (2.66). The mean (SD) PGA at baseline for females and males respectively was 5.80 (2.90) vs 5.54 (3.08); year 1: 2.85 (2.66) vs 2.93 (2.83); and year 2: 2.73 (2.71) vs 2.62 (2.45). The mean (SD) total joint score of the RADAI at baseline for females and males respectively was 2.58 (1.91) vs 2.78 (1.99); year 1: 1.30 (1.42) vs 1.27 (1.34); and year 2: 1.16 (1.47) vs 1.19 (1.58).

Conclusions: Sex does not influence pain perception in this multinational cohort of early inflammatory arthritis patients. This suggests that differences seen in established RA in other studies may have been influenced by disease duration and other factors.

Smolik I (1), Robinson D (2), Tan Q(3), Hart D (4), Newkirk M (5), Bernstein C (6), Wang X (7), El-Gabalawy H (8)

(1-4, 6-8) University of Manitoba, Winnipeg, Canada; (5) McGill University, Quebec, Canada

Objectives: We have shown that in a North American Native (NAN) population in Central Canada, the prevalence of RA is 2-3 times higher than that seen in most other populations, with a high frequency of familial disease. There is also a high prevalence of anti-citrullinated protein antibodies (ACPA) and rheumatoid factor (RF) in the first-degree relatives (FDR) of RA patients. We sought to get a better understanding of the relationship between joint symptoms and RA autoantibodies in disease-free FDR who may be at risk for developing future RA.

Methods: The prevalence of joint symptoms was compared in three distinct groups: 1) FDR of NAN RA patients (n=306), 2) NAN controls (NC, n=330), and 3) Caucasian controls (CC, n=293). The two control groups had no family history of RA or related autoimmune diseases. Study subjects completed a questionnaire which included demographic data, health related habits, family health history, and six questions probing into whether they experience pain, swelling, or stiffness of the hands or of other joints. Anti-CCP2 antibodies were tested by ELISA and RF by nephelometry.

Results: The mean age of FDR=35±13, NC=32±11, CC=42±13, p=0.0001. The percentage of females was FDR=69%, NC=63%, and CC=63%, p=ns. In all groups, females reported more symptoms (OR=1.6, p=0.01). Compared to both control groups, FDR were more likely to report joint symptoms in the hands: pain (54%, 35%, 18%); for FDR, NC, CC, respectively; all comparisons p<0.0001. Similar findings were reported for other joint areas. Compared to NC, FDR had more joint symptoms, and more joint symptoms in FDR living in urban vs. rural locations (79% vs. 60%, P=0.0001). The prevalence of anti-CCP2 was: FDR = 8.3%, NC = 1%, and CC = 1%, p<0.0001, and RF was: FDR = 4.8%, NC = 1%, and CC = 1%, p<0.05. Logistic regression demonstrated that age and FDR status were strong independent predictors of joint symptoms (p=0.0001 for both), while gender, RF, and ACPA status were not.

Results: A total of 440 patients, who were enrolled up to 31 May 2006 for RA and thus had the potential of treatment for 48 months, were included in this analysis. Mean (SD) age was 56.4 (13.6) years and mean (SD) disease duration at baseline was 11.0 (10.2) years. Mean (SD) SDAI at month 0, 6, 12, 24, 36, and 48 were 44.0 (16.5), 18.8 (13.9), 16.5 (13.1), 13.5 (12.0), 13.4 (11.9) and 10.6 (9.8), respectively. Mean (SD) CDAI at months 0, 6, 12, 24, 36, and 48 were 41.6 (15.9), 17.5 (13.4), 15.0 (11.9), 12.3 (11.7), 11.5 (11.6) and 8.7 (9.7), respectively. Mean (SD) DAS28-4 CRP at month 0, 6, 12, 24, 36 and 48 were 5.0 (1.1), 3.3 (1.2), 3.2 (1.2), 3.0 (1.1), 2.9 (1.2), and 2.6 (1.0), respectively. HAQ scores at month 0, 6, 12, 24, 36 and 48 were 1.8 (0.7), 1.3 (0.8), 1.2 (0.8), 1.2 (0.8), 1.1 (0.8) and 1.0 (0.8), respectively. These results show that by 6 months of treatment significant changes (P<0.05) were observed using all scores. Further slight improvement in between 6 months and 48 months were observed with all analyzed scores.

Conclusions: The results of this real-life observational study demonstrate that over four years of treatment infliximab is effective in reducing symptom severity and improving outcomes in patients with Rheumatoid Arthritis using different scores. Also, the data from this registry confirmed the validity of the SDAI and CDAI as disease activity measures in a real-life RA cohort.
Conclusions: RA-like joint symptoms are more common in the FDR of NAN RA patients than they are in either NAN or Caucasian controls having no family history of RA. This finding is not explained by a higher prevalence of ACPA and RF in FDR. These data suggest that pre-clinical joint symptoms, based on biological or psychosocial factors, may be part of the risk profile for developing future disease in high risk individuals.

Efficacy and Safety of Certolizumab Pegol Plus Methotrexate in Patients With Rheumatoid Arthritis: 3-Year Data From the RAPID 2 Study

Smolen J (1), Van Vollenhoven R (2), Kavanaugh A (3), Fichtner A (4), Strand, V (5), Vencovsky J (6), Van der Heijde D (7)

(1) Medical University of Vienna, Vienna, Austria, (2) Karolinska Institute, N/A, Sweden, (3) University of California San Diego, CA, USA, (4) UCB, (5) Stanford University, CA, US, (6) Institute of Rheumatology, Leiden University Medical Center, Netherlands

Objectives: To evaluate the sustainability of improvements in rheumatoid arthritis (RA), inhibition of joint damage progression and tolerability of CZP + MTX over 3 years in patients who completed 24 weeks of double-blind treatment with CZP 200 mg or 400 mg EOW + MTX (completers) in RAPID 2 and entered an open-label extension (OLE) of CZP 400 mg EOW + MTX.

Methods: ACR responses, DAS28(ESR), HAQ-DI, pain VAS (0–100-mm scale) are shown over 3 years (148 weeks) from the RAPID 2 baseline (BL) for CZP completers who entered the OLE; modified Total Sharp Scores (mTSS) are shown over 2.5 years (128 weeks). Patients who withdrew from the OLE for any reason or took rescue medication in the OLE had data imputed from that time point onwards. For mTSS, linear extrapolation (Lin ext) was used. For DAS28, HAQ-DI and pain VAS, last observation carried forward (LOCF) and ACR responses (non-responder imputation). Analyses include patients who received ≥1 CZP dose.

Results: Of 494 patients treated with CZP + MTX, 355 completed RAPID 2, of these, 342 (96%) entered the OLE. Completers entering the OLE had high disease activity at the RAPID 2 BL (mean: DAS28: 6.8; HAQ-DI: 1.6; pain VAS: 60.7); mean mTSS at the RAPID 2 BL was 33.6. After 3 years, 79% of CZP completers continued to receive OL CZP; only 2 patients withdrew due to lack of efficacy. ACR responses and improvements in DAS28, HAQ-DI and pain from BL were sustained in the OLE to 3 years in CZP completers. Inhibition of progression of structural damage observed during the placebo-controlled phase was sustained up to the last X-ray evaluation at 2.5 years. The incidence of AEs by Week 148 of this analysis was 108.17/100 patient-years, and SAEs 13.35/100 patient-years. Most AEs were assessed at each visit (after first study drug administration) from the RAPID 2 BL. Safety analyses were based on the ITT population. AEs and serious AEs (SAEs)/100 patient-years are presented for all pts who received ≥1 CZP dose.

Conclusions: In RA pts who had an initial response to CZP, efficacy was maintained in the OLE after CZP dose decrease from 400 mg to 200 mg EOW + MTX.

Number Needed to Treat to Achieve Broad Relief From the Burden of Rheumatoid Arthritis (RA) in Patients Treated With Certolizumab Pegol Plus Methotrexate

Strand V (1), Van Vollenhoven R (2), Kriens T (3), Combe B (4), Khanna D (5), Burmester G (6), Nikai E. (7), Coteur G (8), Smolen J (9), Schiff M (10)

(1) Stanford University, CA, US, (2) Karolinska Institute, N/A, Sweden, (3) University of Oslo, (4) Hôpital LaPeyronie, cedex 5, France, (5) UCLA, CA, USA, (6) Charité - University Medicine Berlin, (7-8) UCB, - Belgium, (9-10) Medical University of Vienna, Vienna, Austria, (11) University of Colorado School of Medicine

Objectives: To determine the number needed to treat (NNT) to achieve minimum clinically important differences (MCIDs) in multiple patient reported outcomes (PROs) following treatment with certolizumab pegol (CZP) 200 mg + MTX compared with placebo (PBO) + MTX in the RAPID 1 and RAPID 2 trials.
Methods: The proportion of patients reporting improvements ≥MCID in RAPID 1 (Weeks 24 and 52) and RAPID 2 (Week 24) was determined for the following PROs: arthritis pain (0–100-mm visual analogue scale [VAS], MCID ≥10 mm), fatigue (Fatigue Assessment Scale, 0–10 numeric rating scale, MCID ≥1 point), physical function (Health Assessment Questionnaire-Disability Index, MCID ≥0.22 points), patient’s global assessment of disease activity (PtGA, 0–100-mm VAS, MCID ≥10 mm), and HRQoL (SF-36 Physical and Mental Component summaries [PCS, MCS], MCID ≥2.5 points). NNT and benefit ratios (BR, % responders in active treatment/% responders in PBO) to achieve improvements ≥MCID in at least 1, 2, 3, 4, 5 or 6 out of the 6 considered PROs were calculated.

Results: The NNT to achieve clinically meaningful improvements in up to 5 of 6 PROs following treatment with CZP 200 mg + MTX was 2–3 additional patients after 24 weeks (RAPID 1 and RAPID 2) and remained similar at 52 weeks (RAPID 1); the NNT for improvements in all 6 PROs was 5 patients. Patients having achieved MCIDs in at least 5 of 6 PROs by Week 52 were more likely to be reported in pain, fatigue, physical function and PtGA than SF-36 PCS and MCS. Of the patients who reported improvements ≥MCID in 5 of 6 PROs, 29% and 46% of patients did not report changes ≥MCID in SF-36 PCS and MCS at Week 52, respectively. In contrast, 2–12% of patients did not report changes ≥MCID in the other PROs. Compared with PBO + MTX, CZP 200 mg + MTX patients were 4–6 times more likely to achieve improvements ≥MCID in at least 1, 2, 3, 4, 5 or 6 PROs. Compared with PBO, 2–12% of patients did not report changes ≥MCID in SF-36 PCS and MCS at Week 52, respectively. In contrast, 2–12% of patients did not report changes ≥MCID in the other PROs. Compared with PBO + MTX, CZP 200 mg + MTX patients were 4–6 times more likely to achieve improvements ≥MCID in at least 5 of 6 PROs, and 6–7 times more likely to report improvements in all 6 PROs.

Conclusions: Low NNTs indicate relatively few patients need to be treated with CZP + MTX to achieve RA relief.

Long-Term Safety of Rituximab (RTX): Rheumatoid Arthritis (RA) Clinical Trials and Retreatment Population

Van Vollenhoven R (10), Blocka K (10), Emery P (10), Bingham C (4), Keystone E (6), Fleischmann R (6), Furst D (10), Macey K (6), Sweetser M (6), Lehane P (6), Farmer P (10), Long S (10)

(1) Karolinska Institute, Stockholm, Sweden, (2) University of British Columbia, BC, Canada, (3) Leeds General Infirmary, Leeds, UK, (4) Johns Hopkins University, (5) University of Toronto, ON, Canada, (6) University of Texas Southwestern Medical Center, (7) Rheumatology Division, UCLA Medical School, (8,10) Roche Products Ltd, (9) Biogen Idec Inc, (10) Genentech Inc.

Objectives: To assess the long-term safety of RTX in RA patients (pts) in clinical trials.

Methods: Safety data from a global clinical trial program were pooled and analyzed to evaluate safety in pts treated with RTX + methotrexate (MTX). RTX retreatment was offered to all pts based on physician’s decision of clinical need, including assessment of active disease. Pts receiving placebo during placebo-controlled study periods were pooled to provide a placebo population.

Results: As of September 2009, 3189 pts had been treated with RTX, for a total exposure of 9342 pt-years (yrs). The analysis contained >9 yrs of follow-up with up to 15 courses of RTX. Over 1500 pts were followed for >3 yrs and 587 pts for >5 yrs, with 1724, 1392, 1036 and 656 pts receiving ≥3, ≥4, ≥5 and ≥6 courses, respectively. The safety profile of RTX was comparable to the placebo population or general RA populations, with the exception of infusion-related reactions (IRR). The most frequent adverse event (AE) in RTX patients was IRR; most were CTC grade 1 or 2 and occurred after the first infusion of the first course (23%), with 0.5% considered serious (over all courses). Generally, rates of serious AEs and infections remained stable over time and over multiple RTX courses, and in pts in long-term follow-up (≥5 yrs). Similar overall rates of serious infection were observed between RTX and placebo populations [4.35 (3.19 in >5 yrs follow-up) vs. 4.29 events/100 pt-yrs, respectively]. Lower respiratory tract infections were the most frequent serious infections, with pneumonia being predominant (2%). Serious opportunistic infections were rare, with a rate comparable to the placebo population (0.04 vs. 0.01/100 pt-yrs, respectively). Myocardial infarction and stroke rates in the RTX group (0.49 and 0.25 events/100 pt-yrs, respectively) were consistent with rates in the general RA population (0.34–0.59 and 0.112–0.76 events/100 pt-yrs, respectively).

Conclusions: Data from long-term follow-up of RA pts treated with RTX in clinical trials indicate that RTX continued to be well tolerated over time and over multiple courses, with safety profiles similar to that of the placebo population and consistent with published data on pts with moderate-to-severe RA. No new safety signals were observed in both the all-exposed population and in the >5 yrs exposure group.

The Role of the Patient Ambassador in Support of the Identified Theme of Hope in the Needs of Patients Attending an Inflammatory Arthritis Education Program at The Arthritis Program (TAP).

Bain L, Mulligan J, Mieldel S, Thorne C

Southlake Regional Health Centre, Ontario, Canada

Objectives: Patient Ambassador Pilot Project— to determine the response and success of the pilot patient ambassador role within the inflammatory arthritis education program. QA Project — to trend the monthly identified individual goals of patients attending the inflammatory arthritis education program to determine if these goals were being met by attendance and completion of the program.

Methods: Patient Ambassador Pilot: Patients who had attained self-management and empowerment over their disease process and who were seen an dynamic and good orators were identified by TAP. They were asked to consider participating in group speaking engagements within the inflammatory arthritis education program. Some predetermined guidelines were given for use in the talks to groups. QA Project: patients participating in the QA project were asked questions by the TAP team social worker about their educational needs and the goals they hoped to achieve as a result of attending the two-week inflammatory arthritis education program.

Results: Sample patients that attended the inflammatory arthritis education program identified the need to hear hopeful information on treatment options and disease prognosis. The majority of patients in the sample described a “hopeful” outlook as a result of attending TAP’s inflammatory arthritis education program. This finding was in support of our pilot initiative of developing the role of the patient ambassadors within the inflammatory arthritis program. Identifying patient ambassadors to express their own experiences may be a way to improve the outlook of other patients.

Conclusions: Based on the results gathered, the patient ambassador role is now being considered for pilot in other education programs within TAP and the Chronic Disease Management Portfolio.

Does age influence choice of pharmacotherapy for rheumatoid arthritis?

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Objective: To assess TCZ long-term efficacy in RA pts treated with TCZ and DMARDs/ methotrexate (MTX).

Methods: Two populations from ongoing long-term extensions (GROWTH95, GROWTH96, open-label phase of LITHE) of phase 3 trials were analyzed: 1) pts who previously had inadequate response to DMARDs (DMARD-IR: OPTION, TOWARD, LITHE) 2) pts with no previous failure or exposure to MTX (AMBITION). Besides pts from the AMBITION study who received TCZ monotherapy, pts received ≥1 DMARDs/MTX in the phase 3 or extension trials. Pts from AMBITION with <50% reduction from baseline in tender and swollen joint counts (TJC, SJC) were eligible for DMARDs/MTX in the extension. In the original studies and in the extensions, outcomes were assessed every 4 wks and every 8 (LITHE) or 12 (GROWTH95/96) wks from initial TCZ exposure to Aug 28, 2009, respectively. For pooling, data were assigned to the nearest 12 wk point. Due to withdrawal or failure to reach later assessments, the number of pts with assessments decreased over time. Results included pts who had assessments at each visit, with no imputation for missing data. Data were included until <10% of the baseline pts was reached.

Results: TCZ + DMARDs/MTX in the phase 3 or extension trials. Pts the AMBITION study who received TCZ monotherapy, pts received ≥1 DMARDs/MTX in the extension. In the original studies and in the extensions, outcomes were assessed every 4 wks and every 8 (LITHE) or 12 (GROWTH95/96) wks from initial TCZ exposure to Aug 28, 2009, respectively. For pooling, data were assigned to the nearest 12 wk point. Due to withdrawal or failure to reach later assessments, the number of pts with assessments decreased over time. Results included pts who had assessments at each visit, with no imputation for missing data. Data were included until <10% of the baseline pts was reached.

Conclusions: Increasing and sustained numbers and/or proportions of pts achieving ACR50/70, LDA, and DAS28 remission support TCZ as an effective, long-term treatment for RA pts.

(167)
C1-C026
Age Differences in the Prescription of Biologics versus DMARDS
Navi C, Davis P, Makaymowsky W, Yacyshyn E
University of Alberta, Alberta, Canada

Objective: The treatment of patients with Rheumatoid Arthritis (RA) has reported to have age bias in elderly patients. We investigated whether a similar bias occurred in our database of patients on biologics versus leflunomide.

Methods: We performed an analysis of our RA Clinical Registry patients to determine whether an age difference existed between initiation with a biologic versus leflunomide. Data was collected from the RAPPORT database. Information collected included date of birth, previous therapies, demographic factors, and disease activity at initiation. Treatment choices were compared between the 2 groups.

Results: Data of 1271 patients with RA were analyzed. A modest age difference of patients initiated on biologics were younger by 3.83 years. Disease severity was higher in elderly patients initiating biologics in analysis of both the HAQ and DAS scores.
Prevalence of and predictive factors for Sustained Remission in Early RA: Results from SONORA Study

Akhavan P (1), Chen M (2), Li X (3), Bombardier C (4)

(1-4) University of Toronto, ON, Canada; (5) Clinical Decision Making & Health Care, ON, TORONTO, CANADA; (6) University Health Network, Ontario, Canada

Objectives: Remission constitutes the best achievable state in patients with rheumatoid arthritis (RA). Current measures of Disease Activity - such as the DAS28 - define the patient’s remission status at a given point in time. While, for the patient, sustained remission over time is the ultimate goal. The purpose of this study is to assess the frequency and predictors of sustained remission in a large cohort of early RA patients in regular clinical practice.

Methods: A total of 994 patients diagnosed as early RA (symptoms ≤3 and ≤12 months) by a board-certified rheumatologist across North America were recruited in this study. We analyzed remission and sustained remission in 851 patients who had two-year complete follow up information. Remission was defined as less than 2.6 for DAS28 and sustained remission was defined as consecutive remission at year 1 and year 2. Univariate logistic regressions were used to explore the predictors for sustained remission and multivariate logistic regression at year 2 were used to explore the remission probabilities controlling for significant factors.

Results: The mean age of patients was 53 years (SD, 14.8), with 72% female and 90% Caucasian. The mean RA symptom duration was 170 days (180). 61% were seropositive for rheumatoid factor and 43% anti-CCP positive (>20 unit/ml) at baseline. Seventy-four percent of patients had received DMARDs at baseline compared to 90% at year 1 and 87% at 2. Two percent of the subjects were on Biologics at baseline compared to 15%, 23% at year 1 and 2. Remissions at any one of the two visits were seen in 238 (28%) patients. Among them, 68 (8%) patients achieved sustained remission. The univariate logistic regression showed that low baseline DAS28 score, HAQ score, disease duration and CRP are significant predictors for sustained remission. The multivariate logistic regression showed that HTQ was no longer significant when other factors (low baseline DAS28, low CRP and short disease duration) were included in the model. Therefore it was excluded. In this final multivariate analysis the low baseline DAS 28 (OR 0.66, 95% CI: 0.54-0.81; p=0.0001), disease duration (months) (0.88, 0.8-0.97; p=0.0091) and baseline CRP (0.83, 0.72-0.96; p=0.013) remained significant.

Conclusions: Low sustained remission rates were observed in this early RA cohort recruited before the wide use of biologics. The multivariate model predicts the probability of sustained remission using easily accessible clinical and laboratory variables. These identified factors can help guide rheumatologists in making treatment decisions for early RA patients.

Experience with Accelerated Rituximab Infusion for Rheumatoid Arthritis in a Single Community Practice

Farawi R, Roth K

McMaster University, ON, Canada

Objectives: Background: Rituximab, a chimeric monoclonal anti-CD20 antibody for treatment of NHL, CLL and RA, is administered as a slow infusion (255 minutes [4.25 hours]), due to the potential for infusion reactions, which is greatest with the initial infusion. However, the long infusion duration is resource intensive. Recently, short-infusion protocols (60 & 90 min) have been shown to be well tolerated in the oncology setting. Little data are available on short infusions in rheumatology.

Objectives: To evaluate the practicality, safety and tolerability of a rapid-infusion rituximab protocol in RA patients.

Methods: RA patients meeting the criteria for rituximab treatment were recruited to participate in evaluation of the rapid-infusion protocol. Each treatment course consisted of 2 rituximab 1000-mg infusions, 2 weeks apart. The first infusion followed the recommended schedule (255 min). Second and subsequent infusions were administered over 120 min (2 hr) as follows: 0–30 min: 100 mg; 30–60 min: 200 mg; 60–90 min: 300 mg; 90–120 min: 400 mg. Premedication for all infusions consisted of acetaminophen 1000 mg, diphenhydramine 50 mg, and methylprednisolone 100 mg. Vital signs were recorded at baseline and at 15, 30, 60, 90 and 120 min.
Results: Results: To date, 10 patients have been recruited and 36 infusions administered; of the 36 infusions, 26 followed the rapid-infusion protocol. All patients had failed or did not tolerate at least 1 TNF-α inhibitor. Patients range in age from 28 to 65 (mean 50.6) years, with RA diagnosed for <2 to >23 (mean 11.4) years. The mean DAS was 5.9 at the first rituximab infusion. The average duration between rituximab infusion courses was 9.2 months. The rapid infusion was safe and well tolerated by all patients. One patient experienced a minor infusion reaction (headache, chest tightness, and shortness of breath), which resolved during the infusion. No infections were reported.

Conclusions: Conclusion: An accelerated rituximab infusion is safe and well tolerated in the community setting. The accelerated protocol optimizes patient, nurse, and physician time, and all patients were satisfied with the short infusion duration. Rapid rituximab infusion is a practical option in a community setting.

Baseline Characteristics and Effectiveness of Treatment With Infliximab in Canadian Patients With Rheumatoid Arthritis: Comparison of an Individual Practice With the BioTRAC Registry

Farazwii R (1), Otawa S (2)

Objectives: The efficacy of Infliximab (IFX) in Rheumatoid Arthritis (RA) has been well established in controlled clinical trials. Small area variations with respect to patient profile and outcomes may affect global assessment of real-life effectiveness of treatment. The aim of the current analysis is to compare the patient profile and outcomes of an Individual Rheumatology Practice cohort in Ontario to that of the entire Ontario and Canadian RA cohorts.

Methods: The data for this analysis were obtained from BioTRAC, an observational prospective registry of adult RA patients initiated on IFX since 2002 and managed as per routine care.

Results: A total of 70 RA patients were enrolled in the Individual Rheumatology Practice (IRP) between 2002 and 2010 while 695 patients comprised the total registry (Canadian) and 291 patients the Ontario cohort (ON). Patient baseline characteristics differed between the 3 cohorts with patients in the IRP cohort having significantly lower mean age (50.1 vs. 56.4 and 57 years in the IRP, Canadian and ON cohorts, respectively), disease duration (5.7 vs. 11.1 and 9.4 years, respectively), ESR (25.5 vs. 33.8 and 37.1 mm/hr, respectively) HAQ (1.5 vs. 1.7 and 1.7, respectively), pain (50.9 vs. 58.8 and 59.1, respectively), Physician's Global Assessment of Disease Activity (PGA) (4.5 vs. 6.8 and 7.0, respectively), swollen joint count (SJC) (7.9 vs. 12.2 and 12.4, respectively) and DAS28 (4.8 vs. 5.3 and 5.4, respectively) compared to the Canadian and ON cohorts. Regression analysis over time showed that morning (AM) stiffness, Patient's Global Assessment of Disease Activity (SGA), HAQ, tenderness joint count (TJC), SJC, and DAS28-CRP improved significantly in all cohorts without significant between-group differences. However, median time to discontinuation due to treatment failure (adverse event, disease progression, lack of response) was significantly longer in this IRP cohort vs. Canadian (P=0.004) or ON (P=0.011) cohorts. After mean follow-up of 12.8, 13.0 and 13.3 months for the IRP, Canadian and ON cohorts ACR20/50/70 response rates were 54%/52%/52%, 49%/46%/43% and 40%/38%/33%, respectively.

Conclusions: The results of this real-life observational study demonstrate that significant variation in patient baseline characteristics in individual rheumatology practices may exist within the BioTRAC registry. This may impact individual physician experience with respect to median time to discontinuation due to treatment failure. Nevertheless, treatment with IFX for up to 4 years is effective in reducing symptom severity and improving outcomes in patients with RA in this Individual Rheumatology Practice, Canadian and ON cohorts within the BioTRAC registry.

Incidence of Post-operative Complications following Orthopaedic Procedures in Patients with Rheumatoid Arthritis treated with TNF-α Inhibitor Therapy

Somayaji R, Barnabe C, Martin L

University of Calgary, Alberta, Canada

Objectives: TNF-α inhibitor therapies (TNFi) have improved the management of rheumatoid arthritis (RA). The therapies are however associated with an increased risk of infection and delayed wound healing. This observation raises concerns particularly in patients who are having surgical procedures. Although complications following orthopaedic procedures are commonly reported in RA patients there are limited data regarding RA patients being treated with TNFi. In this study, we examined the incidence of post-operative complications following orthopaedic surgery in such patients and sought to identify other potential risk factors for complications.

Methods: We identified all TNFi –treated RA patients who underwent an orthopaedic procedure between January 1st 2005 and December 31st 2009 in the Calgary Health Region. Data on these patients is included in our Pharmacovigilance database. Demographic and clinical data, which included the type of orthopaedic procedure, disease duration, co-morbidities and current therapies, were recorded for each patient. Patients were followed for a minimum of one year and post-operative complications were recorded. The complication rates were compared between surgery types, and with the rates recorded in the literature.

Results: Between January 1st 2005 and December 31st 2009, a total of 57 patients on TNFi therapy underwent 90 orthopaedic procedures. A total of 16 complications occurred (17.7%) which was higher than the 6% complication rate reported for orthopaedic procedures in RA patients. The complications were stratified into post-operative wound infections (11/90, 12.2%) and other types of complications (5/90, 5.5%). No independent predictors for post-operative complications were identified in this group.

Conclusions: TNF therapy in RA patients appears to confer an increased risk of post-operative complications. Larger scale studies are required to elucidate how best to manage RA patients who are receiving TNFi therapies when they are to undergo orthopaedic surgical interventions.

Sleep Evaluation Before and After Initiation of Anti-Tumour Necrosis Factor Therapy in Rheumatoid Arthritis

Taylor-Gjeeve R, Gjeeve J, Nair B, Skomron R, Lim H

University of Saskatchewan, Saskatchewan, Canada

Objectives: To evaluate sleep before and after anti-TNF-α (tumor necrosis factor) therapy initiation in rheumatoid arthritis (RA) patients.

Methods: This was a prospective evaluation of RA patients with poor sleep (abnormal Epworth Sleepiness Scale (ESS) and/or Pittsburgh Sleep

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Quality Index (PSQI) score who were to initiate anti-TNF-α therapy. This study utilized overnight polysomnography (PSG) and questionnaire data including: pain, fatigue, global function, modified Health Assessment Questionnaire (mHAQ), depression, stress, SF-36 scores, Rheumatoid Arthritis Disease Activity Index (RADA1), ESS, PSQI, Berlin score for obstructive sleep apnea, and International Restless Leg Syndrome Study Group (IRLSSG) diagnostic criteria. Study patients underwent two PSGs and questionnaires; prior to starting anti-TNF-α therapy and again after initiation. A referent group of RA patients with normal ESS and PSQI scores participated in the baseline evaluation.

**Results:** Twelve RA patients met inclusion criteria, of which ten initiated anti-TNF-α therapy and underwent repeat PSG and questionnaire studies. Following anti-TNF-α therapy initiation improvements were apparent in the pain, fatigue, mHAQ, RADA1 scores. No change in ESS, PSQI, Berlin scores were evident. A trend towards improvement was observed for sleep efficiency (p = 0.031), sleep latency (p > 0.05), and ‘awakening after sleep scores were evident. A trend towards improvement was observed for the pain, fatigue, mHAQ, RADAI scores. No change in ESS, PSQI, Berlin score for obstructive sleep apnea, and International Restless Leg Syndrome Study Group (IRLSSG) diagnostic criteria. Study patients underwent two PSGs and questionnaires; prior to starting anti-TNF-α therapy and again after initiation. A referent group of RA patients with normal ESS and PSQI scores participated in the baseline evaluation.

**Conclusions:** Improvement in sleep efficiency, sleep latency and ‘awakening after sleep onset’ time were observed following initiation of anti-TNF-α therapy.

The Relationship between Function and Disease Activity as Measured by HAQ DI and DAS Varies by Rheumatoid Factor Status in ERA. Results from the CATCH cohort.

**Objectives:** Older publications have compared the relationship between function and disease activity over the course of RA. Some have found HAQ correlated significantly with DAS scores in the earlier phases of RA while others have found a strong correlation throughout the disease course. Our goal was to investigate the relationship between disease activity and functional capacity in the early stages of inflammatory arthritis using data collected in the CATCH cohort and to determine if the correlations changed; and whether they were similar when studying the effects of age and RF status.

**Methods:** Data from patients (n=1145) enrolled were collected from the Canadian Early Arthritis Cohort (CATCH); a multi-site observational cohort of early inflammatory arthritis. The HAQ and DAS28 were assessed at each visit. Correlations were done between HAQ and DAS every 3 months for the first year and then at 18 and 24 months. Data were then stratified by age (65 vs ≥65), and RF status (positive versus negative).

**Results:** Mean HAQ and DAS scores were highest at first visit. All correlations between HAQ and DAS scores were significant at all time points (p<0.01). At baseline, there was a good correlation between HAQ and DAS (r = 0.49) whereas at 6, 9, and 12 months the correlation was weaker (r=0.39, r=0.29, and r=0.38, respectively). However, correlations between HAQ and DAS were strongest at 18 months (r = 0.52) and 24 months (r = 0.53). Age did not change the association between HAQ and DAS (r≥0.05, N=868) vs. ≥65 (r=0.48, N=254). The correlation between HAQ and DAS was stronger with RF+ patients (r=0.63, N=636) than RF negative (r=0.47, N=477).

**Conclusions:** Through comparison of correlations of HAQ and DAS at different time points in early RA, we were able to determine how strongly these measures were associated in a population with a relatively short duration of symptoms; most of whom had not yet experienced significant joint damage which would lead to irreversible functional impairment. Functional capacity was strongly influenced by disease activity in early RA. Although associated, the scores are measuring different aspects of RA and both are necessary to determine activity and function in ERA.
**Objective:** Comprehensive effective treatments for Rheumatoid Arthritis (RA) require patient-centered approaches that identify and address patients’ needs and encourage patients to work in partnership with their health care providers. The goal of this study was to evaluate the extent to which medical, psychological, and social needs of people with RA are being met. Findings will be used to tailor interventions to optimize treatment and self-management.

**Methods:** Participants were recruited from the general rheumatology clinics at a major urban university hospital. Two focus groups of RA patients were held in August 2010 to elicit discussion about patient experiences and preferences. Sessions were audio-taped, transcribed, and analyzed using grounded theory methodology.

**Results:** Nine women and 2 men participated with a mean (SD) age of 53.6 (18.3), disease duration of 17.8 (13.3) yrs, and HAQ of 1.6 (0.8). Patients reported an average of 23.6 (22.7) minutes of morning stiffness, pain of 33.6 (28.4) and patient global function score of 42.1 (35.0). Nearly half (46%) were on DMARDs and/or biologics. Almost all endorsed a need for more information about their disease, RA medications, ways to effectively maneuver the health care system for prompt care, self-management and complementary/alternative treatments (CAM), along with ways to identify and access credible resources. Uncertainty related to RA (disease course, medications, disability, prognosis) increased patients’ need for emotional support from family, friends, employers, health care providers, and the community at large. Current community-based services were seen as infrequent and inadequate to meet emotional and information needs, particularly with respect to self-management. Patients expressed a strong desire to partner with providers through ongoing communication and active participation in treatment decisions. Most described creating effective partnerships with providers by being assertive and taking initiative. Continued care with patient-centered multi-disciplinary providers was highly valued. Referral and access to specialists knowledgeable about the needs of RA patients and coordination of services is suboptimal.

**Conclusions:** While new therapies and treatment paradigms have changed RA outcomes, many daily challenges remain under-recognized and unaddressed. Timely, reliable information in an accessible format is needed about disease process, as well as conventional and CAM therapies. Support to remain active in family, work and community roles, creation of multi-disciplinary treatment teams and emphasis on creating and sustaining patient-centered partnerships offer important opportunities to improve quality of life. Evidenced-based methods to address unmet needs (e.g., information toolkits, support groups, patient-provider communication skills training) warrant investigation.

**Safety of Infliximab Treatment in a Real-World Clinical Setting: Description and Evaluation of Infusion Reactions**

Kelsall J (1), De Vera M (2), Rogers P(3), Galindo G (4), Klinkhoff A (5)

(1) University of British Columbia, BC, Canada, (2) Arthritis Research Centre of Canada, BC, Canada, (3) Mary Pack Arthritis Program, BC, Canada

**Objective:** The purpose of this study was to describe acute and delayed infusion reactions in a large cohort of RA patients treated with infliximab (IFX).

**Methods:** We conducted a retrospective chart review of patients treated with IFX at the Mary Pack Arthritis Centre between 2000 and 2008. Primary outcome was the occurrence of acute infusion reactions occurring during or up to 2 hours after each infusion and secondary outcome was the occurrence of delayed infusion reactions occurring between 1 to 14 days after an infusion. Descriptive statistics were used to characterize demographics, clinical histories, and acute and delayed infusion reactions. Rates of acute and delayed reactions were calculated as the number of reaction episodes divided by the number of INF infusions during the follow-up. Analysis were conducted for all patients and for patients with rheumatoid arthritis (RA) separately, who represented the largest proportion of patients in the cohort.

**Results:** Overall, we report on 200 patients: 135 (67%) patients had RA, 23 (12%) psoriatic arthritis, 22 (11%) ankylosing spondylitis, 6 (3%) ocular inflammatory disease, and 14 (7%) other inflammatory arthritis. Mean disease duration at first infusion for all patients and RA patients were 15.8 ± 10.9 and 16.7 ± 11.2 years, respectively. Altogether, patients received 4,399 IFX infusions over mean 140 ± 132 weeks of follow-up. Of these, 135 were patients with RA who received 2,977 IFX infusions over mean follow-up of 138 ± 132 weeks. 258 episodes of acute reactions were observed for an overall acute reaction rate of 5.9% (5.2% for RA patients). Acute reactions were mostly mild (42.6%) and moderate (43.8%) in presentation and the most commonly affected sites were head and neck (31.5%) and skin (21.1%). 37 delayed reaction episodes were observed (0.84% for all patients; 0.81% for RA patients) and were also mostly mild (16.2%) and moderate (64.9%) in presentation.

**Conclusions:** This study provides a description of acute and delayed infusion reactions in 200 patients treated for rheumatologic conditions in a real world clinical setting. Overall, data demonstrate that acute and delayed infusion reactions occur infrequently and when they do occur, are mostly mild to moderate in severity.

**A Description of Surgical Procedures Among Patients with Rheumatoid Arthritis on Infliximab Treatment**

Kelsall J (1), De Vera M (2), Rogers P(3), Galindo G (4), Klinkhoff A (5)

(1) University of British Columbia, BC, Canada, (2-4) Arthritis Research Centre of Canada, BC, Canada, (5) Mary Pack Arthritis Program, BC, Canada

**Objective:** Despite the growing use of biologics in rheumatoid arthritis (RA), there is limited information on the characteristics of patients undergoing surgeries during treatment courses with these agents. Our objective was to characterize RA patients undergoing surgeries during treatment on infliximab (IFX) in a real world clinical setting.

**Methods:** We conducted a retrospective chart review of RA patients treated with IFX at the Mary Pack Arthritis Centre between 2000 and 2008. Extracted clinical data included demographic information, RA disease characteristics, comorbidities, medication history, and information over all infusions performed. A detailed history of all surgical procedures occurring after a first IFX infusion was collected. Surgeries were classified according to specialty (i.e., orthopedic, cardiothoracic) as well as type (i.e., arthroplasty, bypass procedure). For each surgery, we calculated the elapsed period from a prior and subsequent IFX infusion. Descriptive statistics were used to present the data. To compare characteristics of RA patients who received surgery with those who did not, we used independent samples t-tests for continuous variables and chi-square tests for categorical variables.

**Results:** A total of 135 RA patients (79% female) received 2,977 IFX infusions over mean follow-up of 138 ± 132 weeks. At baseline (1st IFX infusion), mean age was 54 years and RA duration was 16.7 ± 11.2 years. Overall, 39 RA patients (29%) underwent at least one surgical procedure during treatment with IFX. RA patients who underwent surgery did not differ from RA patients who did not undergo surgery across baseline disease characteristics. Among the 39 surgical patients, a total of 78 procedures were recorded during treatment with IFX (24 patients underwent 1 surgery, 6 patients underwent 2 surgeries, 4 patients underwent 3 surgeries, 1
patient underwent 4 surgeries, 2 patients underwent 5 surgeries, 1 patient underwent 7 surgeries, and 1 patient underwent 8 surgeries). The most frequent type of surgery was orthopedic: 58% (n=45) of these 47% were joint prostheses; 10% (n=8) were cardiothoracic surgeries; 9% (n=7) were nodal excisions and tendon repairs, 8% (n=6) involved abdominal procedures such as colostomies; 4 were dental procedures, 4 were geriatric urinary procedures and 4 miscellaneous, including ophthalmological procedures.

**Conclusions:** This study provides a description of surgical procedures in RA patients undergoing IFX treatment in a real world clinical setting. Overall, data demonstrate that surgical patients did not differ from non-surgical patients at baseline disease and that orthopedic procedures represent the most common surgeries in these patients.

**Results:**

**Standardized Effect Size (SES) at 6 months, Generalized Estimating Equations (GEE) analysis to evaluate repeated measures.**

**Methods:** A patient-based needs assessment and ongoing patient feedback prior to and during recruitment guided program development. An interprofessional arthritis care team, adult educators, clinical researchers and an arthritis consumer were involved in determining and refining program format, duration and content. The interprofessional team was involved in developing and delivering program content and adapting the program to patient needs following the completion of the present study. Patients attended a single day (6 hours) education session which combined didactic, small group and large group modalities. This was a non-randomized, wait-listed control (with cross-over) trial of patients with inflammatory arthritis. Data was collected at baseline, following intervention (I), at 6 months [cross-over: control group (C) receives I], following cross-over and at 1 year. Self-report measures included: demographics, disorder-related, arthritis self-efficacy, arthritis knowledge, coping efficacy, illness intrusiveness. Outcomes assessed using reliable and valid measures. Analysis included: baseline comparison (I vs C), Standardized Effect Size (SES) at 6 months, Generalized Estimating Equations (GEE) analysis to evaluate repeated measures.

**Results:** Patient interest was very high. The one-day program format combined with the non-randomized study design made participation and attendance feasible for patients. Program and study modifications based on patient input made recruitment possible. 42 persons participated (I n=23; C n=19) with 93% follow-up at 1 year. No significant baseline differences between groups. Comparison of change at 6 months (I vs C) showed moderate effect sizes (SES ranging from 0.5 to 0.7). GEE analysis showed significant main effect, pre to post RxEd, in both groups across outcomes.

**Conclusions:** Program feasibility was dependent on patient feedback and program adaptations. This study provides evidence that the RxEd program is feasible, improves arthritis self-efficacy, arthritis knowledge and other outcomes. The program is now successfully being implemented as part of usual care, supported by ongoing program evaluation.

**Objectives:** To assess educational needs of people with rheumatoid arthritis (RA); specifically, to investigate the topics of information that they consider most important, where people go to look for that information, and how they evaluate the information they find.

**Methods:** We performed a qualitative study using focus groups with people with RA. Participants were recruited from people having attended multidisciplinary outpatient arthritis services for rheumatoid arthritis in the preceding 2 years or having attended the Learning Centre at the Mary Pack Arthritis Centre in Vancouver. Eligible participants had to be older than 18 years, English-speaking, live in the Greater Vancouver region and have a physician-confirmed diagnosis of rheumatoid arthritis. Each focus group included 6 to 8 participants and was moderated by an experienced facilitator who used predefined open-ended questions and probes to stimulate group discussion. The sessions were audio-taped, transcribed, and analyzed using content analysis to identify key concepts emerging from the data.

**Results:** To date, one out of the 5 expected focus groups has been conducted (n = 7, median age 57 years, 6 women). Preliminary analysis revealed that the three most important topics of information about RA to them were emotional and psychological well-being, RA medications, and current research findings. A diverse range of sources were used by the participants in their search for information on these topics. Participants placed great importance on emotional and psychological well-being, yet these areas were greatly lacking in resources. For medications and other information related to their disease management, people often sought and found information from secondary health care providers, rather than from their physician. In evaluating the information that they found by themselves, people reported authenticity of the source and the presence of red flags as important in determining the credibility of the information. General characteristics of useful resources for RA were discussed, including that it should be realistic, at an appropriate level of detail, and easily accessible.

**Conclusions:** While there is an abundance of general information available about RA, the most important topics of information to people with RA are not being addressed adequately. People were dissatisfied with the paucity of resources dealing with the emotional and psychological issues around RA. By understanding how people evaluate the information they find, as well as what characteristics people with RA find useful in a resource, effective educational interventions can be created to address topics of information most relevant to people with RA.

**Objectives:** Arthritis is a chronic, debilitating disorder characterized by inflammation, pain and joint destruction. Effective patient education about arthritis and its treatment is an important component of patient care, complementing medical treatment by teaching people to self-manage their disease. This evaluation was designed to assess the feasibility of a one-day, interprofessional, inflammatory arthritis education program and to explore the effect of the program on arthritis self-efficacy, arthritis knowledge and other outcomes. This presentation examines the knowledge translation and adaptive strategies that made the evaluation, implementation and integration of the program possible at an urban teaching hospital.

**Methods:** A patient-based needs assessment and ongoing patient feedback prior to and during recruitment guided program development. An interprofessional arthritis care team, adult educators, clinical researchers and an arthritis consumer were involved in determining and refining program format, duration and content. The interprofessional team was involved in developing and delivering program content and adapting the program to patient needs following the completion of the present study. Patients attended a single day (6 hours) education session which combined didactic, small group and large group modalities. This was a non-randomized, wait-listed control (with cross-over) trial of patients with inflammatory arthritis. Data was collected at baseline, following intervention (I), at 6 months [cross-over: control group (C) receives I], following cross-over and at 1 year. Self-report measures included: demographics, disorder-related, arthritis self-efficacy, arthritis knowledge, coping efficacy, illness intrusiveness. Outcomes assessed using reliable and valid measures. Analysis included: baseline comparison (I vs C), Standardized Effect Size (SES) at 6 months, Generalized Estimating Equations (GEE) analysis to evaluate repeated measures.

**Results:** Patient interest was very high. The one-day program format combined with the non-randomized study design made participation and attendance feasible for patients. Program and study modifications based on patient input made recruitment possible. 42 persons participated (I n=23; C n=19) with 93% follow-up at 1 year. No significant baseline differences between groups. Comparison of change at 6 months (I vs C) showed moderate effect sizes (SES ranging from 0.5 to 0.7). GEE analysis showed significant main effect, pre to post RxEd, in both groups across outcomes.

**Conclusions:** Program feasibility was dependent on patient feedback and program adaptations. This study provides evidence that the RxEd program is feasible, improves arthritis self-efficacy, arthritis knowledge and other outcomes. The program is now successfully being implemented as part of usual care, supported by ongoing program evaluation.

**Objectives:** This study provides a description of surgical procedures in RA patients undergoing IFX treatment in a real world clinical setting. Overall, data demonstrate that surgical patients did not differ from non-surgical patients at baseline disease and that orthopedic procedures represent the most common surgeries in these patients.
Objectives: To evaluate the reliability of repeat tuberculin skin tests (TSTs) and Interferon Gamma Release Assays (IGRAs) in detecting latent tuberculosis infection (LTBI) in people on anti-Tumor Necrosis Factor (TNF) medication.

Methods: We conducted a prospective, observational study of patients referred to the Saskatoon Tuberculosis (TB) clinic prior to starting anti-TNF medication. A chest x-ray (CXR), 2-step TST and IGRA were performed at baseline. Those patients with a positive TST > 5 mm and/or a positive IGRA were followed with a clinic visit, CXR, TST and IGRA at 3 and 6 months after starting anti-TNF medication.

Results: Of 106 potential patients, 91 consented to participate. Twenty-eight patients had a positive TST or IGRA at baseline. Twelve patients started and stayed on anti-TNF medication during the 6-month follow-up and had all testing done. The baseline mean TST measurement for the 12 participants was 13.92 mm (SD 11.35), this increased to a mean of 16.83 mm (SD 9.32) post-booster. At 3 months post-anti-TNF initiation, there was an overall decrease in TST measurement (mean = 10.00 mm; SD 9.32; p = 0.013). By the 6-month TST, a response recovery was observed with a mean TST measurement of 14.50 mm (SD 7.65). The IGRA was unchanged throughout the study period in all patients. The overall agreement between TST and IGRA was poor (kappa coefficient = 0.160, p = 0.033).

Conclusions: We demonstrated a transient but significant decrease in TST response in the first six months of anti-TNF therapy.

(128)
C1-CC041

Clinical Trials in Canada – a review of study design and selection criteria in rheumatoid arthritis (RA) trials:

Kars, T (1), Maguir, L (2), (CRRC) C (3)

(1) Ottawa Hospital, Riverside Campus, Ontario, Canada, (2-3) CRRC, Ontario, Canada

Objectives: Current clinical trial design for pharmacologic interventions in rheumatoid arthritis (RA) do not reflect the innovations in RA diagnosis, treatment and care in Western countries over the past decade. The objective of this project was to develop evidence-informed entry criteria and to make recommendations about additional study design requirements that best meet the Canadian RA population characteristics and current best practices for usual care in Canada.

Methods: Initial recommendations were developed by an expert panel of rheumatology trialists and other experts affiliated with the Canadian Rheumatology Research Consortium. A scoping review methodology was then used to examine the evidence available to support or refute each initial recommendation. Scoping reviews can include a literature review and a key informant consultation phase. Research considered in this project included recommendations about additional study design requirements that best meet the Canadian RA population characteristics and current best practices for usual care in Canada.

Results: Of 106 potential patients, 91 consented to participate. Twenty-eight patients had a positive TST or IGRA at baseline. Twelve patients started and stayed on anti-TNF medication during the 6-month follow-up and had all testing done. The baseline mean TST measurement for the 12 participants was 13.92 mm (SD 11.35), this increased to a mean of 16.83 mm (SD 9.32) post-booster. At 3 months post-anti-TNF initiation, there was an overall decrease in TST measurement (mean = 10.00 mm; SD 9.32; p = 0.013). By the 6-month TST, a response recovery was observed with a mean TST measurement of 14.50 mm (SD 7.65). The IGRA was unchanged throughout the study period in all patients. The overall agreement between TST and IGRA was poor (kappa coefficient = 0.160, p = 0.033).

Conclusions: We demonstrated a transient but significant decrease in TST response in the first six months of anti-TNF therapy.

(128)
C1-CC042

Disconnect Between Disease Activity and Joint Space Narrowing for Patients with Early RA Treated with Adalimumab plus Methotrexate but not Methotrexate Alone: Case for Anti-TNF Cartilage Protection

Landew, R (1), Keystone, E (2), Smole, J (3), Goldrin, M (4), Guérett, B (5), Patra K (6), Cifaldi M (7), Van der Heijde D (8)

(1) Maastricht University Medical Center, N/A, The Netherlands, (2) Mount Sinai Hospital, Ontario, Canada, (3) Medical University of Vienna, Vienna, Austria, (4) Weill Cornell Medical College, NY, United States, (5) Abbott, - France, (6-7) Leiden University Medical Center, Leiden, Netherlands

Objectives: Joint space narrowing (JSN) is inhibited by treatment with the combination of adalimumab (ADA) and methotrexate (MTX). Importantly, it is not known whether ADA+MTX treatment exerts these protective effects solely by controlling inflammation or also by a specific effect on cartilage as has been shown for joint erosions. The objective of this analysis was to compare the relationship between disease activity (DAS28) and progression of JSN in patients with early rheumatoid arthritis (RA) treated with ADA+MTX vs. MTX.

Methods: Two-year data of the PREMIER study (a randomized controlled trial comparing MTX with ADA-MTX in patients with early RA) were used to perform this analysis. Data were from patients (n=225) randomized to MTX or ADA-MTX. DAS28 was time-averaged (TA-DAS28) over 3 intervals from baseline: 26, 52, and 104 weeks, and multivariate analyses were performed to assess the impact of treatment and TA-DAS28 on change in JSN after 26, 52, and 104 weeks of treatment. To control for continuous between-group variations in DAS28, we compared groups by TA-DAS28 quartile.

Results: All results are changes in JSN expressed by quartile (range) of TA-DAS28. In the MTX group, JSN increased as TA-DAS28 increased [Week 26 (observed): Q1 (< 3.6): 0.38; Q2 (3.6–< 4.4): 0.39; Q3 (4.4–< 5.1): 0.64; Q4 (≥5.1): 2.43. Week 52 (observed): Q1 (< 3.2): 0.60; Q2 (3.2–< 4.0): 1.05; Q3 (4.0–< 4.8): 1.38; Q4 (≥4.8): 3.97. Week 104 (linear imputation): Q1 (< 3.3): 0.82; Q2 (3.3–< 4.2): 2.11; Q3 (4.2–< 5.1): 2.98; Q4 (≥5.1): 8.14. However, this relationship was not apparent in the ADA-MTX group [Week 26: Q1 (< 3.6): 0.15; Q2 (3.6–< 4.4): 0.17; Q3 (4.4–< 5.1): 0.06; Q4 (≥5.1): 0.63. Week 52: Q1 (< 3.2): 0.52; Q2 (3.2–< 4.0): 0.43; Q3 (4.0–< 4.8): 0.55; Q4 (≥4.8): 0.53. Week 104: Q1 (< 3.3): 0.56; Q2 (3.3–< 4.2): 0.90; Q3 (4.2–< 5.1): 1.02; Q4 (≥5.1): 1.60]. Week 104 results were similar using either observed data or linear imputation.

Conclusions: The typical relationship between TA-DAS28 and progression of JSN was observed in patients treated with MTX; however, this relationship was not apparent in patients treated with ADA+MTX. These results suggest that ADA+MTX may have direct protective effects on cartilage that are beyond its ability to control for disease activity, potentially through the inhibition of catabolic activities in chondrocytes.
Clinical and Radiographic Implications of Time to Treatment Response in Patients With Early Rheumatoid Arthritis

Keystone E (1), Weinblatt (2), Harauzi B (3), Guérette B (4), Mozaffarian N (5), Patra K (6), Kavanaugh A (7)

(1) Mount Sinai Hospital, Ontario, Canada; (2) Brigham & Women's Hospital, MA, USA; (3) University of Montreal, QC, Canada; (4) Abbott, IL, US; (5) University of California San Diego, CA, USA

Methods: PREMIER was a 104-week, phase 3, randomized, placebo-controlled trial in a MTX-naive population with early RA. In this post hoc analysis, observed data comparing MTX with ADA + MTX therapy are presented. Clinical outcome measures included the 28-joint Disease Activity Score (DAS28) and mean change from baseline in modified Total Sharp Score (DmTSS) at 52 weeks. Patients were categorized on the basis of clinical response (DAS28 improvement >1.2 or 20%/50%/70% improvement in ACR score) at 12 and 24 weeks: “early responders” achieved the clinical target at week 12 and maintained the response at week 24; “delayed responders” did not meet the clinical target until week 24. The percentages of patients at 52 weeks with LDAS (DAS28 < 3.2), clinical remission (DAS28 < 2.6), and RRP (DmTSS > 3 units/year) in each group were determined.

Results: In both treatment groups, early clinical responses were associated with better long-term outcomes than delayed responses. Achieving early or delayed ACR70 responses did not result in treatment group differences in the proportion of patients achieving LDAS or clinical remission at week 52. However, delayed responses to MTX resulted in a high proportion of patients with RRP. Indeed, delayed ACR70 responses were associated with an RRP prevalence of 40%. In addition, even an early improvement of DAS28 > 1.2 with MTX was insufficient to slow radiographic progression (41% RRP). In contrast, early or delayed clinical responses to ADA + MTX resulted in low proportions of RRP at 52 weeks, even for patients with a delayed ACR20 response (11% RRP). Of note, ADA + MTX delayed responders had less RRP than MTX-treated early responders.

Conclusions: MTX-treated patients with early RA who fail to achieve an ACR70 within 12 wks of treatment are at risk for RRP and should be considered for treatment adjustment. In contrast, ADA + MTX treatment is associated with better clinical outcomes and less severe radiographic progression at 52 wks, even among patients with a delayed clinical response.

Psychometric Properties of Self-Administered Early Inflammatory Arthritis Detection Tool

Bell M (1), Tavares R (2), Scarf J (3)

(1,3) Sunnybrook Health Sciences Centre, Ontario, Canada; (2) McMaster University, Ontario, Canada

Objectives: To evaluate the discriminant validity, comprehensibility, test-retest reliability and internal consistency of an Early Inflammatory Arthritis (EIA) Detection Tool self-administered questionnaire.

Methods: A total of 166 adult English-literate outpatients attending Sunnybrook Health Sciences Centre and Mt. Sinai Hospital have participated in one of four study groups: 1.EIA (n=37): A rheumatologist’s assessment of, or established diagnosis of either AS, PsA, RA, ReA, other SpA or undifferentiated IA with a symptom duration of six to 52 weeks; 2.Established Inflammatory Arthritis (IA) (n=41): A rheumatologist’s assessment of established IA with more than 52 weeks of symptom duration; 3.Musculoskeletal (MSK)/non-IA (n=50): A rheumatologist’s established diagnosis of osteoarthritis, osteoporosis, fibromyalgia, arthralgia, bursitis, tendonitis, or other rheumatologist-determined and documented, established non-inflammatory MSK condition; and 4.Non-IA/non-MSK (n=38): Hospital outpatients without bone or joint complaints and no history of arthritis, willing to consult with a study rheumatologist. Discriminant validity is reported using a Kruskal-Wallis test for nonparametric differences in total questionnaire Yes responses (Score) between groups including Mean (+/- SD), and Median (+ range). Comprehensibility is defined as the percentage of patients who agree or strongly agree with the comprehension of the tool. The EIA Detection Tool is delivered a second time (T2), at one to 2 weeks after the first time (T1) to ascertain Test–Retest reliability, (Kappa +/- SD). Patients who report a change in symptoms will be omitted from the assessment of reliability. To measure Internal Consistency, one question is repeated within the tool, (Kuder-Richardson-20, binary equivalent to Cronbach Alpha). Study participants will be blinded to the specific purpose of the study.

Results: Discriminant validity for Group 1.EIA: Mean score 6.7+/-.2 8 Median 7 (0–11); 2.Established IA: Mean score 5.2+/-.2 3 Median 5 (2–10); 3.MSK/non-IA: Mean score 5.3+/-.2 9 Mean 5 (1–11); 4. Non-IA/non-MSK: Mean score 2.7+/-.3 1 Median 2 (0–9) p=0.006. Over all groups Comprehensibility ranged from 94.6%–97.3%, while within Group 1.EIA, Comprehensibility ranged from 91.3%–100.0%. Kappa = 0.85+/-.0 8 across all questions for Test–Retest reliability. Finally, Internal Consistency had a value of KR-20=0.990 at T1 and KR-20=0.985 at T2.

Conclusions: The EIA Detection Tool shows very good discriminant validity between the four study groups, and excellent Comprehensibility, Test–Retest reliability and Internal Consistency. Further analyses will be conducted to determine if weighting scales and/or decision rules may be imposed on the EIA Detection Tool to improve its discriminative properties.

Demyelinating events in Seniors with Rheumatoid Arthritis (RA): A Population-based Study

Wildfield J (1), Bernatsky S (2), Paterson M (3), Gunraj N (4), Thorne C (5), Pope J (6), Civisano L (7), Bombardier (8)

(1) University Of Toronto, On, Canada; (2) McGill University Health, Quebec, Canada; (3) Institute for Clinical Evaluative Sciences, Ontario, Canada; (4) Southlake Regional Health Care, The Arthritis Program, ON, Canada; (5) University of Western Ontario, Toronto, Canada; (6) McMaster University, ON, Canada

Objectives: Up until recently, demyelinating syndromes were reported only rarely in RA. However, since the introduction of RA therapies targeting tumour necrosis factor (TNF), numerous case reports have arisen in the literature. Currently there are very few cohort-based assessments of the incidence of demyelinating events in RA, and/or the possible influence of drug exposures. The Ontario Biologies Research Initiative (OBRi) is an innovative undertaking to promote real-world rheumatic drug surveillance.
Using Ontario’s administrative healthcare databases we were able to assess the risk for developing demyelinating events in seniors with RA, and explore the potential drug effects in this sample.

Methods: We studied a population-based RA cohort using physician billing and hospitalization data (1992-2008) for patients aged > 65. RA diagnosis was based on > 2 billings with a diagnosis code of RA >2 months apart but > 5 years and >1 prescription for an oral glucocorticoid, DMARD or biologic. Cohort entry was defined by the first RA billing code; we excluded any individuals with a diagnosis of a demyelinating event, prior to their entry into the RA cohort. Our primary outcome was assessed over 1998-2008. Our case definition of a demyelinating event was based on >1 hospitalization diagnoses, or >2 billing claims diagnoses (> 8 weeks apart, but < 2 years). Cases were matched (on age, sex, and date of cohort entry) to up to 5 controls from the same RA cohort. We calculated the incidence rate of demyelinating events in seniors, and described medication use in relationship to these events.

Results: In 85,458 seniors with RA (over 614,915 person-years), 51 demyelinating events occurred. This provides an event rate of 8.3 events/100,000 person-years. Biologic exposures were rare in our cohort, and none of the cases of demyelinating events in our RA cohort had been exposed to an anti-TNF agent at the time of the event, or within the 12 months preceding the event. In both cases and controls, the most common medication exposures were NSAIDs/COXIBs, glucocorticosteroids, hydroxychloroquine, and methotrexate.

Conclusions: We provide novel data on the incidence of demyelinating events in a cohort of seniors with RA. The incidence rate is comparable to recent rates for Canadian seniors in the general population. None of these events appeared to have been triggered by anti-TNF drug exposures. Estimating the risk for demyelinating events due to these agents was problematic in our sample, given relatively low drug exposure rates.

(108) C1-CC046

The Incidence of Herpes Zoster in Seniors with Rheumatoid Arthritis: A Population-Based Study

Widdifield J, Bernatsky S, Patterson M, Gurraj R, Thorne C, Pope J, Cividino A, Bombardier C

(1,8) University Of Toronto, On, Canada, (1,4) McGill University, Quebec, Canada, (1,4,11) Institute for Clinical Evaluative Sciences, Ontario, Canada, (2) Southlake Regional Health Care, The Arthritis Prog, ON, Canada, (3) University of Western Ontario, Ontario, Canada, (5) McMaster University, ON, Canada

Objectives: Herpes zoster (HZ) is a painful cutaneous eruption caused by varicella-zoster reactivation. It results in substantial morbidity, particularly in elderly and/or immunocompromised patients. Recent literature suggests that patients with rheumatoid arthritis (RA) are at particular risk for HZ. The Ontario Biologics Research Initiative (OBRI) conducts real-world surveillance through administrative database linkage with primary data collection, based in Canada’s largest province (population > 13 million).

Methods: An RA cohort was assembled from Ontario billing, hospitalization and prescription data, 1992-2008. Analyses were limited to subjects aged >65 who filled ≥1 prescription for a disease-modifying agent (DMARD), oral corticosteroid, or biologic. We studied cases of HZ identified from physician billing and hospitalization diagnoses over 1998-2009. RA controls (age, sex and time matched) were randomly selected by risk-set sampling. Multivariate conditional logistic regression assessed the independent effects of concomitant drug treatments on HZ, adjusted for demographics, co-morbidity, and markers of RA severity (rheumatologist visits, extra-articular RA features, joint replacement).

Results: A total of 3,999 cases of HZ were recorded among 85,458 seniors with RA during 614,915 person-years (6.5 events/1000 person-years). Comparing these HZ cases to 19,995 RA controls, 21.9% of cases versus 10.8% of controls were exposed to prednisone at the time of infection. Multivariate models demonstrated that risk of HZ was higher among current and previous users of current and past use of all DMARD groups. There was a notable increasing trend for higher risk of HZ with increasing steroid doses. Due to low rates of biologic drug exposures in our sample, the estimated effects of these agents were imprecise, but also consistent with a higher risk.

Conclusions: Our estimates emphasize an association of anti-rheumatic therapies with the occurrence of HZ. However, potential limitations of our study include the possibility of incomplete ascertainment of biologic exposures, disease activity and ‘channeling bias’ (where persons at highest risk for infections may not be prescribed biologics).

(130) C1-CC067

Primary anti-TNF Failures Experience Better Clinical Responses but Similar Health Care Utilization to a Second anti-TNF Agent than Secondary Failures: Analysis of the Alberta Rheumatoid Arthritis Biologics Registry

Maksymowych W, Ohinmaa A, Martin L, Russell A, Barr S, Sholter D, Penney C, Charles Y, Jacob P

(1,8) University of Alberta, Alberta, Canada, (1,4) Institute of Health Economics, Alberta, Canada, (3,5) University of Calgary, Alberta, Canada, (6) 124 Street Medical Group, Alberta, Canada

Objectives: Meta-analysis of anti-TNF switching data from observational cohorts has concluded that responses are inferior in those switching due to primary compared to secondary anti-TNF failures but limitations include small sample size of individual studies, failure to define response, and selection bias. We assessed the impact of switching anti-TNF agents at different time points in the Alberta Biologics Registry; an observational cohort of RA patients starting anti-TNF therapy in 2004, where collection of outcome data on all patients is requested by the Provincial pharmaceutical formulary.

Methods: The Alberta Biologics Registry collects clinical, employment, and health economic data at baseline, 3 months, and every 6 months thereafter. Health-related quality of life is measured with the EQ-5D and self-reported health care utilization is measured for the six months prior to each visit. We analyzed responses according to time of switch (3 month versus subsequent time points) and according to specific anti-TNF agent switches.

Results: From 1,222 patients in the registry, 649 patients had 27 month follow up assessment and 498 (76.7%) of these remained on the first anti-TNF during the study period. There were 28 (4.3%) primary failures and 123 (19%) secondary failures who switched a median of 15 months from baseline. The response rate to the second anti-TNF was somewhat better in the primary versus the secondary failures (p=NS) at 3 months after initiation of the second anti-TNF for HAQ, DAS, EQ-5D. By 27 months, switchers due to primary failures had attained comparable reductions in outcomes to non-switchers while changes in secondary failures were from 50% (HAQ) to 68% (EQ-5D) lower compared to non-switchers (p<0.05). Health care utilization was significantly reduced in four measured parameters over 27 months: number of rheumatologist visits (-0.31 visits, p=0.001), family physician visits (-0.95, p<0.001), % having ≥1 outpatient visit (-0.22, p<0.001), and % having day surgery (-0.026, p<0.001). This reduction was comparable between switching groups and non-switchers.

Conclusions: The results from this mandatory registry show that primary failures to anti-TNF show similar responses to patients responding to their first anti-TNF agent. Clinical responses in secondary failures are less optimal. Despite this, there is no significant difference between primary and secondary failures in the significant reduction in the health care utilization while receiving their second anti-TNF agent over the course of the 27 month follow up period.
Management of Rheumatoid Arthritis in the Peri-operative Period: A look at the literature and local practices

Zawadowski M, Taylor-Gjevre R
University of Saskatchewan, Saskatchewan, Canada

Objectives: There is a paucity of data looking at optimal rheumatoid arthritis therapy in the periarthroplasty period. The objective of this study was to review the literature for guidelines and to review local practice.

Methods: A literature review was conducted to ascertain current guidelines and recommendations of pharmacotherapy perioperatively in the RA patient. Additionally, chart reviews were performed on RA patients undergoing elective joint replacement surgery.

Results: A review of current literature suggests that biologic therapies be discontinued one week or two half lives prior to arthroplasty. Studies on the safety of methotrexate periarthroplasty suggest that it can be continued, except in patients with specific comorbidity profiles. Other sources make suggestions for DMARD management perioperatively on the basis of pharmacokinetics. We reviewed 49 charts of RA patients who had TKR or THR between January 2006 and March 2010. We collected demographic, anti-rheumatoid medications, surgical risk factor and complication data. We deemed anti-rheumatoid management appropriate if it did not conflict with current guidelines or with what current literature suggested was appropriate management. 41 were deemed eligible for the study; 6 were excluded for lack of anti-rheumatoid treatment, and 2 were excluded for unclear management. 21 (51%) patients had appropriate anti-rheumatoid management, while 20 (49%) had inappropriate. Of the 15 patients on biologic therapy, 9 (60%) were treated appropriately, 6 (40%) inappropriately. Of 9 patients on leflunomide, none were managed appropriately.

Conclusions: In conclusion, just over half of patient’s management of rheumatoid arthritis received “appropriate” care. We recommend that further studies be done to evaluate the appropriate care for RA patients around the time of arthroplasty to strengthen current guidelines. We also recommend introducing a standard pre-arthroplasty form for perioperative management including recommendations on care.

(156)
C1 – CC048

Prevalence of Metabolic Syndrome in Psoriasis and Psoriatic Arthritis

Jayakar J (1), Eder L (2), Thavaneswaran A (3), Shanmugarajah S (4), Gladman D (1)

University of Toronto, Ontario, Canada, (2,5) University of Toronto, Ontario, Canada

Objectives: Psoriasis (Ps) is an immune-mediated skin disease affecting 2-3% of the population, of whom about 30% develop Psoriatic Arthritis (PsA), an inflammatory arthritis. The metabolic syndrome (MetS) is a cluster of cardiometabolic risk factors that includes abdominal obesity, dyslipidemia, hyperglycemia and hypertension. It is known that Ps and PsA patients have an increased prevalence of cardiovascular disease. However, the prevalence of MetS in PsA and the differential cardiovascular risk between Ps and PsA are not established. The objective of this study was to determine if PsA patients have a higher prevalence of MetS compared to Ps patients because of higher inflammatory burden.

Methods: Patients with PsA are followed prospectively in the Toronto Western Hospital PsA clinic. Patients with Ps without arthritis have been included in an observational cohort since 2006. All patients undergo a clinical examination according to a standard protocol which includes assessment of the components of MetS. Descriptive statistics are used to describe the patients. Univariate analysis including t-tests for continuous variables and chi-squared tests for dichotomous variables was performed to compare MetS in Ps and PsA. Multivariate analysis using a stepwise logistic regression model was used to identify associations between potentially related variables and MetS.

Results: 167 patients with PsA (42.5% F/57.5% M, mean age 51.1 yrs, mean Ps duration 25.3 yrs, mean PsA duration 15.6 yrs, mean number of actively inflamed joints 5.6, mean PASI (psoriasis skin severity score) 4.1) and 98 Ps patients (43.9% F/56.1% M, mean age 50.3 yrs, mean Ps duration 18.4 yrs, mean PASI 5.8) were included. Prevalence of MetS was 36.3% in PsA, and 25.5% in Ps (p=0.0773). Multivariate analysis revealed that age, use of anti-TNF agents, and psoriasis skin severity scores (PASI) are associated with MetS, with odds ratios of 1.063 (p=0.0001), 2.455 (p=0.055), and 1.049 (p=0.033) respectively.

Conclusions: Our interim results provide the first report of the prevalence of MetS in PsA. Our results further show that MetS is not more prevalent among patients with PsA compared to Ps. However, a larger sample size may be necessary to detect a significant difference. It is notable that markers of severe disease activity, such as use of anti-TNF agents and high PASI scores, are associated with increased the development of MetS in patients with Ps with or without arthritis.

(127)
C1 – CC050

Psoriatic arthritis (PsA) in Canadian Clinical Practice: the PsA Assessment in Rheumatology (PAIR)

Gladman D (1), Chandran V (2), Thavaneswaran A(3), Zummer M (4)

(1-2) University of Toronto, Ontario, Canada, (3) Toronto Western Hospital, Ontario, Canada, (4) CH Maisonneuve-Rosemont, Quebec, Canada

Objectives: We aimed to determine disease severity and treatment of patients with PsA followed in rheumatology practice in Canada.

Methods: Rheumatologists were invited to participate in the Assessment in Rheumatology (AIR) PsA program through the Canadian Rheumatology Association. Rheumatologists were asked to complete a form for each patient addressing demographic questions, CASPAR criteria, medication use, current status including joint counts, presence of dactylitis, enthesitis, back involvement, patient (PGA) and physician (MDGA) global assessment, acute phase reactant, assessment of prognosis and plans for change of medication. Descriptive statistics are provided.

Results: From across Canada 22 rheumatologists, from 5 provinces submitted 2 consecutive PsA patients 145 males (62.2%), 88 females (37.8%), mean age of 53.2 (12.7) years, 88.4% having disease for >2 years. 80.7% fulfilled CAPSAR criteria (95% entered on peripheral arthritis, 15.9% on spondylitis and 34% on enthesitis). The majority fulfilled current psoriasis, 50 (21.7%) did not have current psoriasis but had previous psoriasis or a family history of psoriasis. 38% had nail lesions, 80% were rheumatoid factor positive, 48% had dactylitis, and 16% had fluffy periostitis. 30% had taken no DMARDs. Current (past) medications included 6.9% (22.9%) oral steroids, 7.3% intra-articular injections, 58% (25%) methotrexate, 12.0% (25.8%) sulfasalazine, 3.9% (10.3%) leflunomide, 6% (17.5%) anti-malarials, and 2.6% (6.9%) on gold/aurafin. 67 patients were taking biologics, the majority receiving etanercept. At the time of the visit, patients...
averaged 3 swollen joints, 4 tender joints, PGA 2.3, MDGA 1.9. 16% had dactylitis at the time of the visit with equal distribution in hands and feet. 11% of the patients had enthesitis, mainly at the Achilles tendon or both, Achilles and plantar fascia. Spinal involvement was documented in 13% of the patients. Most rheumatologists did not measure spinal metrics. Clinical joint damage was documented in 60% of the patients, active skin disease in 70% and nail lesions in 32%. Only 22% were rated as moderate to high disease activity while 52% were rated as low disease activity and 26% were deemed in remission. The decision was based on joint counts, PGA, MDGA and acute phase reactants. 27% of the patients were to have their medications changed based on the current visit, the majority for inadequate response to medications.

Conclusions: PsA patients seen in regular rheumatology practice fulfill CASPAR criteria, have active disease, and more than half have clinical damage. The majority have low activity or remission.

(098) C1-CC051

Patient-physician discordance of global disease assessment in psoriatic arthritis patients

Hamilton G, Tobin Y, Ardern R, Rahman P
Memorial University of Newfoundland, Newfoundland, Canada

Objectives: The visual analog scale (VAS- using a standard 0-10 range) is a common measure for global disease severity used by both patients and physicians. We assessed the concordance of psoriatic arthritis (PsA) patient scores compared with physician scores.

Methods: In our longitudinal study, 10 patients with active PsA completed the VAS assessing their global disease activity approximately every 4 weeks for up to 4 years. A physician's VAS was completed for every patient VAS completed. In addition, a count of both swollen and tender joints was completed for each visit, representing a standard scale of severity.

Results: Overall 237 assessments were analyzed, which showed VAS scoring for global disease by patients differed from the physician significantly; patients gave a higher level of severity than the physician (mean for patients = 7.0, mean for physician = 4.97, paired t-test = 3E-9). More specifically, 7 of the 10 patients gave values that were significantly higher than the physician's values. The physician's VAS values correlated more strongly with the swollen joint count than the patient's VAS values (physician vs. swollen r = 0.74, patient vs. swollen r = 0.36).

Conclusions: This study demonstrates a significant discordance of the VAS scores for global assessment for patients with PsA between the patients and their physician. The physician's VAS score values correlated more strongly with the swollen joint count than did the patients. For patients, it would appear there are other factors beyond their swollen joints contributing to their global disease measurement.

(099) C1-CC053

A Comparison of Methotrexate Use Amongst Dermatologists and Rheumatologists in Canada

Dupuis E, (1) Dutz J (2)
(1) University of British Columbia, BC, Canada, (2) Department of Dermatology and Skin Science, Skin C, BC

Objectives: Methotrexate (MTX) is commonly used by both dermatologists in the treatment of psoriasis and rheumatologists for psoriatic arthritis (PsA) and rheumatoid arthritis (RA). Treatment guidelines on use of MTX have recently been published in both specialties but current use patterns are largely unknown. This study set out to explore and compare the current preferences of MTX use amongst Canadian dermatologists and rheumatologists.

Methods: An online survey was made available to 414 Canadian dermatologists and 415 Canadian rheumatologists during a two-week period in September 2010. The 50 question survey explored MTX use in the treatment of psoriasis, PsA, and RA with topics ranging from administration route to biologics use. Influencing factors were also explored.

Results: 27.2% of rheumatologists and 16.4% of dermatologists responded to the survey. Psoriasis 80.0% of rheumatologists and 96.8% of dermatologists...
who treated psoriasis used oral tablets to initiate MTX therapy. When needed, 95.7% of rheumatologists and 49.2% of dermatologists would switch to parenteral MTX. When they switched, 98.0% of rheumatologists and 62.5% of dermatologists switched to subcutaneous (SC) injections. When using biologics with MTX, 75.6% of rheumatologists did not change the MTX dose, while 81.1% of dermatologists discontinued MTX. Psoriatic Arthritis (PsA) 82.0% of rheumatologists and 100% of dermatologists who treated PsA initiated MTX therapy with oral tablets. When needed, 100% of rheumatologists versus 68.8% of dermatologists would switch to parenteral MTX, specifically to SC injections (98.0% of rheumatologists, 81.8% of dermatologists). When using biologics, 70.4% of rheumatologists did not change MTX dose while 43.8% of dermatologists discontinued MTX.

Conclusions: The survey had an overall response rate of 21.5% (95% CI: 15.8% to 27.8%), so the results should be interpreted with this in mind. In treatment of psoriasis or PsA both specialties initiated MTX treatment with oral tablets. However, rheumatologists were more likely to switch to a parenteral route and use SC injections. While both specialties used biologics, they differed in how they bridged it from MTX. Rheumatologists would often not change the MTX dose after initiating a biologic whereas dermatologists would discontinue MTX, either immediately or through a taper. Rheumatologist’s use of MTX was largely similar for RA and PsA. Overall, this study showed that in the treatment of psoriasis and PsA, rheumatologists and dermatologists do not differ in their initial use of MTX. However, the specialties showed a notable difference in their preferences for how they proceed with MTX use.

**Assessment of Work Disability in Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis**

Rhee C, Rohelkar S

*University of Western Ontario, Ontario, Canada*

**Objectives:** Few studies compare work disability (WD) and loss of work productivity in patients with different forms of inflammatory arthritis (IA) presenting to one clinic. We measured prevalence of work disability and productivity loss in patients with rheumatoid arthritis (RA), psoriatic arthritis (PsA) and ankylosing spondylitis (AS). We also examined the relationship between WD and patient-reported measures of disease activity.

**Methods:** After obtaining IRB approval, data were collected from 1000 patients at the Rheumatology clinic. Patients were given a questionnaire asking about work status. WD was defined as the inability to work due to arthritis or early retirement due to arthritis. The package also contained the Work Limitations Questionnaire (WLQ), Health Assessment Questionnaire (HAQ), Patient Global Assessment of disease activity (PGA) and Functional Comorbidity Index (FCI). Relationships between the WLQ scores, demographic information, and the results of the HAQ, PGA and FCI were analyzed.

**Results:** 638 patients (316 RA, 59 PsA, 42 AS) completed the questionnaire packages, of which 289 completed the WLQ (136 RA, 33 PsA, 26 AS). The proportion of patients with WD due to arthritis was 12.7% (RA), 13.3% (PsA), and 16.7% (AS). The average WLQ score, or the average loss of the productivity in each condition, was 4.97%, 3.91% and 4.35% for RA, PsA and AS, respectively. Number of days lost per month due to arthritis was 0.92 (RA), 1.92 (PsA), and 0.44 (AS). Loss in work productivity was significantly correlated with HAQ scores (r = 0.593 RA, 0.521 PsA, 0.329 AS), PGA fatigue score (r = 0.425 RA, 0.553 PsA, 0.385 AS), PGA pain score (r = 0.484 for RA, 0.631 for PsA, 0.574 for AS), and PGA general health score (r = 0.604 RA, 0.588 PsA, 0.373 AS). Productivity loss was correlated with increasing number of comorbid conditions in RA (r = 0.348), but not in PsA or AS. Number of days or hours missed from work showed no correlation with HAQ, FCI, or PGA. Disease duration was not correlated with WLQ scores or absence from work.

**Conclusions:** WD occurred in 10.8%, 11.7% and 14.3% of patients with RA, PsA and AS. The average decrease in work productivity due to health was 12.7%, 13.3% and 16.7% (RA, PsA, AS). WLQ scores showed close associations with HAQ and PGA scores in IA conditions, but disease duration did not.

**Predictors of Radiographic Progression in Adalimumab-Treated Patients with Ankylosing Spondylitis**

Maksymowycz W (1), Van der Heijde D (2), Landewé R (3), Pangan A (4), Brown L (5), Lavie F (6)

(1) University of Alberta, AB, Canada, (2) Leiden University Medical Center, Leiden, Netherlands, (3) University Hospital Maastricht, Netherlands, (4-5) Abbott Laboratories, IL, US, (6) Abbott Laboratories, France

**Objectives:** To identify factors contributing to radiographic progression in Ankylosing Spondylitis (AS) patients treated with adalimumab (ADA).

**Methods:** The ATLAS randomized AS patients to treatment with ADA or placebo for a 24-week double-blind period, followed by an open-label extension with ADA. Two independent blinded readers scored X-rays obtained at baseline and year 2 using the mSASSS method. Dependent variables were: 1) change in mSASSS ≥2 and ≥4, and 2) development of new syndesmophytes. Independent variables were age, disease duration, baseline spinal mobility, baseline ASDAS, baseline mSASSS, and 2-year area under the curve (AUC) for CRP and ASDAS. Categorical variables included: HLA-B27, sex, peripheral synovitis at baseline (SJC=0), peripheral enthesis at baseline (MASES=0), presence of baseline syndesmophytes, and history of uveitis. Associations were tested univariately; significantly associated variables were entered as explanatory variables in a multivariate analysis.

**Results:** This analysis includes 275 subjects with 2 years of exposure to ADA; at baseline, subjects had mean disease duration of 10.8 years, mean ASDAS of 3.7, and mean mSASSS of 20.3; syndesmophytes were present in 85% of patients at baseline. Radiographic progression (∆mSASSS ≥2) was found in 61 subjects (22%), and severe radiographic progression (∆mSASSS ≥4) was observed in 22 subjects (8%). New syndesmophytes were found by either reader in 106 subjects (39%). Univariate analysis identified significant associations of age, mobility, and baseline bone damage with radiographic progression. For example, odds ratios (95% confidence intervals) for ∆mSASSS ≥2 were: age, 1.04 (1.009, 1.062); baseline syndesmophytes, 3.87 (1.126, 13.301); baseline mSASSS, 1.03 (1.011, 1.059); and baseline cervical rotation, 0.98 (0.968, 0.995). Linear regression revealed similar findings. Sex, HLA-B27, uveitis, peripheral synovitis or enthesis, disease duration, baseline ASDAS, and CRP levels were not predictive in any analysis. In multivariate analysis, only baseline mSASSS was consistently identified as a significant contributor to radiographic progression (∆mSASSS ≥2 and ≥4, OR [95% CI]: 1.02 [1.005, 1.036] and 1.02 [1.001, 1.046]) and only baseline syndesmophytes were predictive of the development of new syndesmophytes (OR [95%CI]: 7.63 [2.381, 24.476]).

**Conclusions:** Clinical measures of disease activity were not related to radiographic progression. Only the presence of radiographic damage at initiation of therapy was consistently associated with the formation of new syndesmophytes in adalimumab-treated AS patients. These results support previous studies demonstrating a disconnect between disease activity and bone formation in patients with long-standing AS, and suggest treatment initiation prior to syndesmophyte formation might be advantageous for decreasing structural damage.
Scleroderma prevalence in Alberta: A population-based assessment.

Barnabe C (1), Joseph L (2), Edworthy S(3), Belisle P (4), Svenson L (5), Labrecque J (6), HemmelgarnB (7), Barr S (8), Bernatsky S (9)

University of Calgary, Alberta, Canada, (4,6,9) Research Institute of the McGill University Health, Quebec, Canada, (10) Alberta Health and Wellness

Objectives: To estimate the prevalence of systemic sclerosis (SSc) using population-based administrative data, and to compare First Nation (FN) versus non-FN prevalence rates.

Methods: We ascertained SSc cases from provincial physician billing and hospitalization databases in Alberta (covering over 3.7 million individuals). Three case definitions were used: ≥1 billing codes by a rheumatologist; or ≥2 billing codes by any physician, ≥8 weeks apart but within 2 years; or a hospitalization diagnosis. The Alberta Health and Wellness registry file was used to determine FN status, as well as rural and urban residence (by postal code). To account for imperfect case ascertainment, we employed a hierarchical Bayesian latent regression model that accounted for possible between-test dependence conditional on disease status, and potential differences in case ascertainment sensitivity and specificity based on patient characteristics (age, sex, and rural-versus-urban residence). Cases were ascertained from 1994-2007, and prevalence estimates based on those who were still alive as of 2007.

Results: Accounting for error inherent in both the billing and the hospitalization data, the estimated overall SSc prevalence in Alberta as of 2007, is 57.7 cases per 100,000 females (95% credible interval, CrI 51.3-65.3) and 9.8 cases per 100,000 males (95% CrI 7.2-13.6). Prevalence was higher for individuals aged>45, particularly in rural women (140.2 cases per 100,000, 95% CrI 118.7-166.3). Although the overall prevalence of SSc in FN was similar to that of non-FN, interesting trends were seen for a higher prevalence of SSc in women of FN status (64.6 cases per 100,000 males (95% CrI 43.4-94.0) compared to non-FN women (57.2 cases per 100,000, 95% CrI 50.4-65.3). This was particularly marked for females aged>45 living in rural areas, where the prevalence was 264.8 cases per 100,000 in FN (95% CrI 157.0-422.9) and 135.8 in non-FN (95%CrI 113.6-164.4). For females aged>45 living in urban areas, the prevalence was 207.3 cases per 100,000 in FN (95% CrI 95.0-391.7) and 124.6 in non-FN (95%CrI 113.6-164.4). The prevalence of SSc in subjects aged < 45 were similar in FN and non-FN groups, in both rural and urban areas.

Conclusions: We demonstrated differences in SSc prevalence according to age, sex, and region. Though the overall prevalence of SSc in Alberta was similar for FN and non-FN, we saw a trend towards more cases in FN females aged ≥45.

Expert Agreement of EULAR / EUSTAR Recommendations for the Management of Systemic Sclerosis

Walker K (1), Pope J (2)

(1) Trinity College, Dublin, Dublin, Ireland, ON, Canada, (2) University of Western Ontario, Ontario, Canada

Objectives: Recently, guidelines in the management of systemic sclerosis (SSc) by EULAR were published. This study was done to determine and compare agreement with these guidelines by SSc experts and identify differences in agreement between North American and European SSc experts.

Methods: A survey was generated using Survey Monkey, which included the 14 EULAR/EUSTAR recommendations. Members of the Sclerosis Clinical Trials Consortium (SCTC) and Canadian Scleroderma Research Group (CSRG) were asked to indicate how little or strongly they agreed with each recommendation on a 10-point scale, from 0 (not at all) to 9 (completely agree). The survey was sent to 117 participants three times.

Results: The response rate was 66 (56%). Mean North American agreement ranged from 5.2 to 8.9, with a range of 41% to 100% (as measured by the % with agreement of 7, 8 or 9). Mean European agreement ranged from 5.5 to 8.8 with a range of 39% to 100%. Agreement was highest with: ACEI use in SRC, monitoring BP for SSc patients using steroids, and PPI use for GERD in SSc. Lowest agreement was with methotrexate for treatment of SSc skin, and bosentan and iloprost for digital vasculopathy.
Experts from North America and Europe were significantly different in the strength of agreement with guidelines for digital vasculopathy and PAH. Europeans agreed 83% vs 58% of NA with iloprost for digital ulcers (p=0.001). North Americans agreed 95% vs 63% with intravenous epoprostenol for severe SSc PAH (p=0.006).

**Conclusions:** Most there was good agreement with the guidelines by experts. Perhaps agreement was low overall with some recommendations due to small treatment effect such as with Mtx treatment for SSc skin. However, agreement for digital vasculopathy may have differed due to variability in access to medications; as iloprost is not available in North America and bosentan is not approved for digital ulcer prevention in North America. Also some treatments for PAH are covered differently in various countries; which may have affected the European vs North American agreement with guidelines.

**C1-CC059**

**Treatment of Vascular Involvement in Systemic Sclerosis (SSc): What to use when first-line treatment fails - a consensus of SSc experts.**

Walker K (1), CSRG and SCTC T (2), Pope J (3)

(1) Trinity College, Dublin, Dublin, Ireland, ON, Canada, (2,3) University of Western Ontario

**Objectives:** Most published treatment in SSc is in first-line therapy such as ACE inhibitors (ACEi) for scleroderma renal crisis (SRC). There is a need for standardization in SSc management, particularly for treatment after failure of first-line therapy. We attempted to gain consensus among SSc experts for treatment and management of specific organ systems.

**Methods:** Members of the Scleroderma Clinical Trials Consortium (SCTC) and Canadian Scleroderma Research Group (CSRG) (n=117) were sent electronic surveys. The surveys asked both open-ended and multiple-choice type questions pertaining to various treatments, management and testing for the manifestations of SSc including vascular complications such SSc, Raynaud’s phenomenon (RP) and digital ulcers (DU). Each survey was sent 3 times. Those who responded to the first survey were invited to continue in the study for a total of 3 surveys. Results are in % who responded with each treatment option and only common choices are reported.

**Results:** SRC – Forty-seven % would routinely hospitalize a patient with mild SRC and 93% in more severe SRC. Regardless of severity, first-line therapy for SRC is an ACEI (97%). For mild SRC, second-line is either adding a calcium channel blocker (CCB) (37%) or angiotensin receptor blocker (ARB) (35%), third-line is a CCB (35%) and fourth-line an alpha-blocker (27%). For more severe SRC, second-line is adding a CCB (27%), third-line is either a CCB (28%) or ARB (27%) and fourth-line an alpha-blocker (20%). RP – For mild RP, first-line treatment is a CCB (92%), second-line a phosphodiesterase inhibitor (PDEi) (35%), third-line an ARB (32%) and fourth-line iloprost (23%). For more severe RP, second-line is either a PDEi (45%) or iloprost (32%), third-line is either a PDEi (45%) or iloprost (27%) and fourth-line is to try another CCB (32%). DU – For DU prevention (depending or previous DU history – mild or severe), first line is a CCB (73%), second line a PDEi (57% mild, 43% severe), third-line an endothelin receptor antagonist (ERA) (47% mild, 47% severe) and fourth-line iloprost (38% mild, 40% severe).

**Conclusions:** Physicians managing SSc are relatively comfortable with choosing a first-line treatment for the various manifestations of SSc. Discrepancies and variation in drug choice differ after failure or incomplete response to first-line treatment. However, many SSc experts chose similar treatment but some considered a specific drug to be a second choice and others third choice. This study can help clinicians decide how to treat more complicated vascular events in SSc.

**C1-CC060**

**Oral Health Related Quality of Life and Clinical Features in Systemic Sclerosis**

Gravel S (1), Baron M (2), Hudson M(3), Lo E (4), Gyger G (5), Canadian Scleroderma Research Group (6), Gornitsky M (7)

(1-5) SMBD Jewish General Hospital, Québec, Canada, (2-4,7) McGill University and Jewish General Hospital, QC, Canada

**Objectives:** Orofacial manifestations of systemic sclerosis (SSc), as well as xerostomia and caries, are thought to occur commonly. Nevertheless, few studies have systematically assessed their prevalence and impact on oral health related quality of life (OHRQol). The purpose of this study was to describe the orofacial abnormalities, caries and the impairment of OHRQol in SSc compared to controls.

**Methods:** All SSc patients were randomly recruited from 7 sites of the Canadian Scleroderma Research Group (CSRG) registry. Controls were non-SSc rheumatology patients from the same clinics. Patients and controls underwent a standardized dental examination that included a Diseased/Missing/Filled Teeth (DMFT) scoring, interincisal and oral aperture measurements and the Saxon test for saliva production. The OHRQol was measured using the Oral Health Impact Profile-49 (OHIP-49) questionnaire, which consists of 7 domains. Orofacial abnormalities and OHRQol were compared in a multivariate regression analysis between SSc patients and controls, adjusting for demographic characteristics, partial and full dentures, and study center.

**Results:** There were 151 SSc patients and 150 controls included in the study. SSc patients and controls were similar: mean age 56.5 and 57.9 years, 90.1% and 91.2% female, 52.1% and 61.7% with more than high school education and 9.7% and 13.4% current smokers, respectively. On average, oral aperture and interincisal distance in SSc patients were 18.7 mm (95%CI = 14.2-23.9) and 7.0 mm (95%CI = 5.2-8.8) smaller than controls, respectively. They had an average of 0.19 g (95%CI = -0.01-0.39) less saliva production per minute. SSc patients had more missing and filled teeth than controls, mainly in the maxillary and mandibular posterior quadrants (P< 0.05). The OHIP–49 total score was significantly higher in SSc patients than controls (mean increase: 1.88, P< 0.001), indicating worse OHRQol. OHIP–49 domains showing the greatest Impairment were functional limitation, psychological discomfort and physical disability (P< 0.002).

**Conclusions:** This study demonstrated that SSc patients have a significantly smaller oral opening and interincisal distance than controls, and there was a strong trend towards greater xerostomia. The OHIP–49 indicates that SSc patients have significantly worse OHRQol than controls. The results of this research will facilitate the development of future projects related to the prevention and treatment of orofacial manifestations of SSc, with the aim of reducing its impact on quality of life.

**C1-CC065**

**Can Body Mass Index Be Considered a Differentiating Factor when Diagnosing Systemic Sclerosis?**

Kate S, Yan A, Ilyas M

University of Alberta, Alberta, Canada
**Objective:** We previously reported Body Mass Index was lower in a retrospective cohort of long standing scleroderma patients compared to the overall population. It remains unknown if BMI could be a useful clue to diagnose a prospective cohort of rheumatology patients referred for initial assessment of possible systemic sclerosis.

**Methods:** In this single rheumatologic practice prospective study, we examined all patients referred for assessment of scleroderma over 5 years between 2005 and 2010 and who had a weight and height recorded from their first physician visit. Gender, final diagnosis, and BMI were recorded. Patients were then stratified and compared based on final diagnosis.

**Results:** 47 patients were referred for possible scleroderma, with 10 excluded as no BMI was recorded and 4 excluded without a final diagnosis recorded. Of the remaining 33, 20 were diagnosed with scleroderma (Scl+), 19 Females, with an average age of 51. Diagnoses of the other 13 (Median age: 60, Female) included: 6 primary Raynaud’s disease, 2 rheumatoid arthritis, 1 systemic lupus, 1 mechanical back pain, 1 rotator cuff tendinopathy, 1 diabetes, and 1 atherosclerosis. The average BMI was 23.7 kg/m² for the Scl+ group and 28.01 kg/m² for the Scl- group (p=0.038). Only 1 Scl+ patient had a BMI greater than 30, compared to 5/13 in the Scl- group (p=0.0248).

**Conclusions:** For the rheumatologist who is presented with a first time patient with a question of scleroderma, a higher BMI may be a useful differentiating factor. Further study is necessary with a larger cohort and more physician experience.

**The relationship between oral health and psychosocial outcomes in systemic sclerosis.**

Gyger G (1), Hudson M (2), Lo E (2), Gravel S (4), Gornitsky M (5), Baron M (6)

(1,2,4,5) McGill University and Jewish General Hospital, Quebec, Canada, (6) SMBD Jewish General Hospital, Quebec, Canada

**Objectives:** Orofacial manifestations of systemic sclerosis (SSc) are common and SSc is known to be strongly associated with worse psychosocial outcomes, including depression, health-related quality of life (HRQoL), function and fatigue. The purpose of our study was to evaluate the association between oral health and psychosocial outcomes in SSc patients.

**Methods:** In a cross-sectional study, SSc patients from the Canadian Scleroderma Research Group Registry, were randomly recruited from 7 centers. Oral health was assessed using the Oral Health Impact Profile (OHIP), a validated self-reported measure of dysfunction, discomfort and disability attributed to oral conditions. The OHIP is composed of 7 subscales (functional limitation, physical pain, psychological discomfort, physical disability, psychological disability, social disability and handicap). Each subscale is scored separately from 0 to 40 (with 0 representing better and 40 representing worse quality of life). An overall score, ranging from 0 to 40, can also be computed using a detailed algorithm. In this study, psychosocial outcomes of interest included: depression (measured using the Center for Epidemiologic Studies Depression questionnaire, range 0-60), HRQoL (measured using the Medical Outcome Trust Short Form 36 Physical and Mental summary scores, SF-36 PCS and MCS, range 0-100, mean = 50, standard deviation = 10), function (measured using the Health Assessment Questionnaire, HAQ, range 0-3) and fatigue (measured using the Vitality subscale of the SF-36). The associations of the OHIP and the outcomes of interest were estimated using hierarchical regression analyses, adjusting for age, gender, education, current smoking and disease duration.

**Results:** There were 151 patients in the study: mean age 56.5 years, 90.1% females, 52.1% with more than high school education, 9.7% current smokers and mean disease duration 13.8 years. Mean OHIP score was 8.67. Mean SF-36 PCS and MCS scores were 37 and 50, respectively. HAQ was 0.79, depression was 14 and fatigue was 45. In multivariate analyses controlling for sociodemographic variables and disease duration, the OHIP was an independent predictor of the SF-36 PCS (p<0.001), SF-36 MCS (p<0.001), HAQ (p<0.001), depression (p<0.001), and fatigue (p<0.001). The OHIP contributed 7 to 13% of the variance in the outcomes of interest.

**Conclusions:** This study demonstrates the significant impact of oral health on psychosocial outcomes in SSc. We recommend more attention and research on oral health in SSc patients.

**The efficacy of non-biologic disease-modifying antirheumatic drugs (DMARDs) in the treatment of pain in early versus late inflammatory joint disease (IJD): a systematic literature review**

Steiman A (1), Bykerk V (2), Thiessen-Philbrook H (2), Li L (4), Mosher D (5), Flanagan C (6), Harasou B (6), Besette L (4), Leclercq S (1), Thorne C (6), Pope J (11)

(1) University of Toronto, Ontario, Canada, (2) Mount Sinai Hospital, MA, United States, (11) London Health Sciences Centre, (1) University of Calgary, Alberta, Canada, (6) none, (2) University of Montreal, QC, Canada, (4) N/A, Quebec, Canada, (5) Southlake Regional Health Care, The Arthritis Prog, ON, Canada, (6) University of Western Ontario, Ontario, Canada

**Objectives:** Non-biologic DMARDs have been used in the management of IJD for decades. In recent years, the importance of prompt initiation of such treatment to prevent the development of joint erosions and resultant damage has become apparent, especially in the treatment of rheumatoid arthritis (RA). Another clinically important outcome is that of pain control. In this systematic literature review, we investigated the effect of commonly prescribed non-biologic DMARDs on pain in early and late IJD. Biologic DMARDs were not studied.

**Methods:** A systematic literature search was performed with Medline, Embase, Cochrane Central and Cochrane Database of Systematic Reviews, and abstracts from the 2008/2009 annual congress of the American College of Rheumatology. A manual search of the citation lists of retrieved publications was performed. Only randomized controlled trials were included in the analysis. Their quality was assessed with the Risk of Bias tool; those fulfilling a minimum of 3/5 criteria were included. Descriptive statistics were used in the metaanalysis.

**Results:** Of 9,860 articles identified, 29 (8 for ankylosing spondylitis (AS), 6 for psoriatic arthritis (PsA), 8 for early rheumatoid arthritis (ERA) and 7 for RA) were included for analysis (some had >1 DMARD arm). For each of AS and PsA, only one study reported average disease duration <5 years; the remainder studied established disease. In AS, 4 studies revealed VAS-pain improvement with sulfasalazine, while 4 studies revealed no VAS-pain improvement with DMARDs (2 studied sulfasalazine, 1 leflunomide, 1 methotrexate). In PsA, 5 studies (3 sulfasalazine, 2 gold) reported VAS-pain improvement, whereas 3 studies (1 each of methotrexate, methotrexate + cyclosporine, and gold) did not. In ERA and RA, use of all DMARDs and combinations thereof resulted in significant VAS-pain improvement excepting two studies of gold salts. Although there was heterogeneity, for studies that could be analyzed, the DMARD-associated mean VAS-pain decrement in ERA, RA, PsA and AS (using a 100 mm scale) was 29.3, 20.6, 16.9, and 12.8 (median 28.4, 21.4, 13.5 and 11.5), respectively. There was no difference in mean disease duration between studies reporting efficacy and those that did not in any disease category.

**Conclusions:** Sulfasalazine may be beneficial in improving pain in AS and PsA. All DMARDs appear to improve pain in early and established RA. The greatest VAS-pain decrement was in ERA patients, and the least in AS patients. Relative efficacy of DMARDs in pain control in early versus late IJD could not be addressed.
A Longitudinal Trivariate Model of Disease Activity Score, Physical Function and Radiographic Damage: Results from SONORA Study

Chen Maggie (1), Li Xiuying (2), Akhavan Pooneh (3), Bombardier Claire (4)

Objectives: Rheumatoid arthritis (RA) affects approximately 1% of adults in North America. Active disease leads to radiographic damage and poor physical function. There is no literature available on common predictors for these three important aspects, that is, disease activity score (DAS); physical function, which is health assessment questionnaire (HAQ) and radiographic damage (Sharp Score). The purpose of this study is to demonstrate the use of longitudinal trivariate model and address the issue of longitudinally relationship between DAS28, HAQ and Sharp score and identify the significant common predictors for three of them.

Methods: 994 Patients diagnosed as having new onset RA (symptoms ≥3 but ≤12 months) by a board-certified rheumatologist were recruited from 98 rheumatology practices. Clinical, laboratory, X-ray and health questionnaire data were collected by the enrolling rheumatologist at baseline, year 1 and year 2. A trivariate longitudinal model of DAS28, HAQ and sharp score was constructed and estimated using pooled cross sections for two years period, adjusting the significant predictors from the univariate analysis at the same time allowing for the latent individual-level effect. Different covariance structures were tested for the assumptions among these three outcomes in the model.

Results: The mean age of patients was 53 years (SD, 14.8), with 72% female and 90% Caucasian. The mean RA symptom duration was 170 days (180). The DAS28, HAQ and Sharp score were 4.4(1.32), 1.0(0.73) and 5.01 (7.28) at baseline, 3.4(1.38), 0.82(0.71) and 6.19(8.73) at year 1, 3.2(1.34), 0.77(0.72) and 6.39(9.25) at year 2, respectively. Partial correlation adjusting for time point showed that DAS, HAQ and Sharp score are significantly correlated (all p-values < 0.001). The longitudinal trivariate model showed that only higher baseline DAS, HAQ or Sharp Score value (P<0.0001), higher 28 swollen joint count (P<0.0001), longer disease duration (P=0.002) and lower household income (P=0.015) were significant predictors from the univariate analysis.

Conclusions: This innovative method identified the significant common predictors for three outcomes which related to the different aspects of RA patients. This method can help us better understand the longitudinally complex relationship between different aspects from a broader view of the disease. These identified factors can help rheumatologists to identify the patients who are at greater risk of worsen disease, physical function and radiographic damage and make treatment decisions for RA patients at the early stage.

Progression Patterns of Radiographic Damage: Results from SONORA Study

Chen M (1), Li X (1), Akhavan P (3), Bombardier C (4)

Objectives: Identifying progression patterns and its characteristics for radiographic damage is important to understand early rheumatoid arthritis (RA).

Data from SONORA (study of new-onset rheumatoid arthritis) was analyzed to explore patterns of radiographic progression in early RA patients.

Methods: A total of 529 patients diagnosed as early RA (symptoms ≥3 and ≤12 months) and had hand radiographs at baseline, year 1 and 2 were included in this study. The radiographs were scored according to original Sharp method (range 0 to 280) in random order per patient. Radiographic progression was defined by a change of at least 3.5 in total Sharp score within a year. Four patterns of radiographic progression were identified; never progressed, progressed at year 1 only, progressed at year 2 only and progressed at both year 1 and year 2. Demographic and clinical characteristics were compared across these four patterns using ANOVA for continuous outcomes and Chi-square test for categorical outcomes.

Results: Among these four patterns, 86% subjects never had radiographic progression, 3.4% progressed in the first year only, 7.6% progressed in the second year only and 2.6% progressed in both year 1 and year 2. There were significant differences between the patterns, for swollen joint count, baseline HAQ score, sharp score, CRP and anti-CCP positive. Subjects who had no radiographic progression in two years were those who are younger, had less swollen joint counts, lower DAS score, lower sharp score, lower CRP, anti-CCP negative and RF negative at baseline.

Conclusions: Majority of the early RA subjects do not have radiographic progression within first two years of the disease. Very few subjects continuously progressed within 2-year period. Baseline sharp score is the best indicator of whether the subject will progress or not. Then it is baseline anti-CCP positive, CRP and swollen joint count. These identified indicators can help clinicians to identify the subjects who are at high risk of continuous radiographic progression.

A Canadian Survey Regarding Musculoskeletal Imaging for Rheumatology Residents

Humphrey-Murto S, Cicalo M, Diplimio G, Milman N, Sheikh A, Sutherland S

University of Ottawa, On, Canada

Objectives: Rheumatology residents must be proficient at interpreting musculoskeletal radiographs as stipulated by the Royal College of Physicians and Surgeons of Canada. It is unclear if, or how these skills are acquired. The purpose of this study was to survey Rheumatology program directors (PD) and residents (RR) regarding their perceived educational needs in radiology, types of training received, perceived adequacy of training, as well as acceptability of an online module.

Methods: All Canadian PD and RR were invited to participate in a voluntary online survey. The survey consisted of a total of 14 questions exploring the perceived importance of MSK radiology reading skills, present resident skill level, teaching methods, effectiveness, suggestions for improvement, need for web-based teaching tool and questions regarding its content. Results were reported as percentage of applicants selecting a response or the mean of applicant responses on a 5-point Likert scale.

Results: Completion rates were 12/14 (85.7%) for PD and 20/28 (71.4%) for RR. Over 85% of PD and RR felt that the ability to read plain MSK films was extremely important. The types of films that residents should be able to interpret (1 = no, 3 = neutral, 5 = yes) included plain film (5.0 PD and RR), CT scan (3.58 PD, 3.59 RR), MRI (3.25 PD, 3.7 RR), bone scan (3.25 PD, 3.35 RR) and ultrasound (3.08 PD, 3.89 RR). About half the PD (58.3%) and RR (50%) reported the confidence of residents as “a little confident” in their present ability to read films. The following percentage of those surveyed reported that present skill acquisition involved: formal didactic sessions (50% RR, 75% PD), learning by reviewing patient’s films (85% RR, 100% PD) and web-based material (10% RR, 16.7% PD). Very...
Does Moderate or Severe Knee Strain Affect the Progression of Radiographic Osteoarthritis?

Sayre E (1), Singer J (2), Thorne A (3), Wong H (4), Kopec J (5), Esdaile J (6), Guermazi A (7), Nicolaou S (8), Cibere J (9)

Objectives: Knee injuries increase progression of radiographic osteoarthritis (ROA). Such injuries include knee ligament, patella or meniscal trauma (“specific” injuries). Less physiologically quantifiable injuries can be called “strain”. The purpose of this study is to understand the effect of moderate and severe knee strain on ROA progression.

Methods: We recruited a population-based sample with knee pain “on most days of the month at any time in the past and any pain in the past 12 months”, aged 40 to 79 (weighted mean=57.6), stratified by age and sex, from Vancouver, Canada. Baseline was between 2002 and 2005, follow-up 2.5 to 5.6 years later (mean=3.3) (N=163). 54% were female. Average BMI was 26.1 (18.1-43.2). Study knee was the more symptomatic knee.

Analyses: We used radiographic measures of ROA from available films (1,5-6) Arthritis Research Centre of Can, BC, Canada, (2-4,8-9) University of British Columbia, BC, (9) Boston University, MA

Results: Of 220 mailed questionnaires (180 RA,40 SLE patients), 43 (24%) RA and 12 (30%) SLE patients returned their completed questionnaires. Thirty-eight (88%) RA and 10 (83%) SLE patients had been pregnant, where 15 (39%) RA and 5 (50%) SLE patients developed their disease prior to pregnancy. The number of miscarriages in RA patients and SLE patients during the first, second and third trimesters respectively was: 16 (17%), 2 (2%),0 and 4 (14%), 3 (10%) and 0. Eight (53%) RA and 1 (20%) SLE patient reported active disease during pregnancy. Eleven (73%) RA patients continued DMARD therapy, including 1 (2.6%) on methotrexate, 2 (5.3%) on sulfasalazine, 5 (13%) on anti-malarials, and 5 (67%) took prednisone during their pregnancy. None of the 5 SLE patients continued their medications or took prednisone during their pregnancy. Four (27%) RA patients decided to not pursue further pregnancies as a result of increased disease activity during pregnancy and/or postpartum. One SLE patient aborted her last pregnancy because of increased past disease activity and 1 SLE patient had a tubal ligation. Four (9%) RA and 1 (8%) SLE patient reported difficulties with becoming pregnant.

Conclusions: In this descriptive study, many RA and SLE patients had pregnancies predating their disease onset. SLE patients appeared more reluctant to continue therapy compared with RA patients. Despite literature supporting improved RA disease activity in pregnancy, half of the pregnant RA patients reported continued activity during pregnancy. The impact of SLE or RA disease activity on future pregnancies could not be reliably assessed due to low numbers. Comprehensive preconception discussions and close monitoring peripartum are required.

C2.0069

The prevalence of systemic lupus in Alberta: A population-based assessment.

Barnabe C (1), Joseph L (2), Edworthy S (3), Belisle P (4,6), Svenson L (5), Labrecque J (6), Hemmelgarn B (5), Barr S (8), Bernatsky S (6)

(1) University of Calgary, Alberta, Canada, (2,4,6) Research Institute of the McGill University Health, Quebec, Canada, (3) University of Calgary, (6) Alberta Health and Wellness
Adverse Obstetrical and Neonatal Outcomes in RA and SLE

Barbosa C (1), Faris P (2), Quan H (3)

(1,2) University of Calgary, Alberta, Canada, (3) Alberta Bone and Joint Institute

Objectives: Adverse obstetrical and neonatal outcomes have historically been documented in women with rheumatic disease. These outcomes may be improved in recent times where better rheumatic disease and prenatal management is available.

Methods: An administrative database (years 1998/9 to 2008/9) provided obstetrical hospitalization details for women with RA and SLE, and each identified case was matched with 4 controls based on maternal age and year of delivery. Conditional logistic regression was used to calculate the odds ratio (OR), with adjustments made for known confounders, for the following outcomes in patients compared to controls: pregnancy-related hypertension, cesarean section, premature births and neonates meeting criteria for small for gestational age (SGA). We also compared the hospital length of stay and proportion of neonates requiring special care unit admission.

Results: There were 38 singleton pregnancies in women with RA and 95 in women with SLE during the study period. The adjusted OR (aOR) for pregnancy-related hypertension in RA was 2.9 (95%CI 1.0-8.3; p=0.051) and in SLE 2.2 (95%CI 1.2-4.3; p=0.017). The aOR for cesarean section in RA was 2.3 (95%CI 0.9-6.3; p=0.097) and in SLE 2.8 (95%CI 1.5-5.1; p<0.01). The aOR for prematurity in RA was 2.7 (95%CI 1.0-7.0; p=0.043) and in SLE 6.6 (95%CI 3.5-12.3; p<0.001). The aOR for SGA in RA was 3.0 (95%CI 1.2-7.2; p=0.017) and in SLE 2.8 (95%CI 1.5-4.9; p<0.001).

Additionally, more women with SLE experienced postpartum infections compared to their controls (6.3% vs 1.3%; p=0.004). The maternal length of stay was longer for women with rheumatic disease (mean difference for RA 0.9 days (95%CI 0.4-1.5; p=0.003), for SLE 1.8 days (95%CI 1.1-2.6; p<0.001). More neonates born to mothers with RA or SLE required admission to the special care unit (RA 29% vs 11%; p<0.006; SLE 36% vs 13%; p<0.001).

Conclusions: Women with RA and SLE have increased odds of developing pregnancy-related hypertension, and a large proportion deliver by cesarean section. Neonates of women with rheumatic disease are more likely to be premature, and small for gestational age. These findings are in keeping with the historical literature, and do not appear to have improved over time. Additionally, women with SLE demonstrate a trend to an increased risk of postpartum infections, which has not been previously identified. Increased collaboration between rheumatologists and obstetric care providers is suggested to identify modifiable risk factors for these adverse outcomes.

Objectives: The Coping with Health, Injuries, and Problems (CHIP) Scale is a multidimensional self-report measure designed to assess four basic coping styles characteristically utilized by persons living with health problems. The coping dimensions measured include: distraction (a form of avoidance with actions and cognitions aimed at avoiding preoccupation with the health problem), palliative (self-help strategies to reduce the unpleasantness of the situation - making oneself comfortable, getting rest etc.), instrumental (active task-oriented strategies, such as seeking help and trying to learn more about the illness), and emotional preoccupation (focusing on the emotional impact of the health problem). The objective of this study was to assess the coping strategies used by women living with Systemic Lupus Erythematosus (SLE).

Methods: Demographics and SLE-Disease Activity Index (SLEDAI) were obtained from SLE females with no history of osteoporosis and cardiovascular disease enrolled in the Health Improvement and Prevention Program (HIPPP) study. Coping strategies were assessed using the CHIP scale consisting of 32-items (8 items per subscale; range 8-40 for each subscale). Distraction, palliative and instrumental coping are considered "task-oriented" and emotional preoccupation is considered an emotional strategy. Participants used a 5-point Likert scale (1=not at all to 5=very much) to indicate how much they engaged in a specific activity when encountering their particular health problem.

Results: The sample was composed of 269 female, 54.3% were Caucasians, 53.9% were married and 90.2% graduated from high school among which 60% had some post-secondary education. The average (SD) age of the

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Which Coping Strategies do Women Living with Systemic Lupus Erythematosus Utilize? 

Aghdassi E (1), Fortin P (2), Morrison S(3), Su J (4), Neville C (5), Hewitt S (6), Pope J (7), Da Costa D (8)

(1,2) The University Health Network, (3,4) Toronto Western Hospital, Ontario, Canada, (5) McGill University Health Center, Quebec, Canada, (6) St. Joseph’s Health Care, London, Ontario, Canada, (7) University of Western Ontario, Ontario, Canada

Objectives: The Coping with Health, Injuries, and Problems (CHIP) Scale is a multidimensional self-report measure designed to assess four basic coping styles characteristically utilized by persons living with health problems. The coping dimensions measured include: distraction (a form of avoidance with actions and cognitions aimed at avoiding preoccupation with the health problem), palliative (self-help strategies to reduce the unpleasantness of the situation - making oneself comfortable, getting rest etc.), instrumental (active task-oriented strategies, such as seeking help and trying to learn more about the illness), and emotional preoccupation (focusing on the emotional impact of the health problem). The objective of this study was to assess the coping strategies used by women living with Systemic Lupus Erythematosus (SLE).

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Results: The sample was composed of 269 female, 54.3% were Caucasians, 53.9% were married and 90.2% graduated from high school among which 60% had some post-secondary education. The average (SD) age of the
sample was 44.4 (13.1) years and the SLE duration was 11.5 (10.2) years. Patients had low SLEDAI score of 4.4 (4.5) at enrollment. The mean (SD) for each coping strategy were as follows: Distraction: 25.0(6.4); Pessimistic coping 23.0(4.8); Instrumental coping 29.1(5.7) and Emotional preoccupation: 19.7 (7.5). Emotional preoccupation and the use of distraction focused coping strategies were higher than the reported means for the general population (distraction: 19.2±6.1; emotional preoccupation: 16.3±6.2).

There were weak correlations between emotional- preoccupation coping and: age (r=-0.140; p=0.02), SLE duration (r=-0.173; P< 0.004) and SLE-DAI (r=-0.193, p<0.003).

Conclusions: Women with SLE in this study used various forms of coping strategies despite a relatively low disease activity and a number of co-morbid conditions. This instrument would be useful for Rheumatologists and allied health professional (i.e. nurses, psychologists) involved in lupus care to better understand the specific ways by which patients cope with their disease.

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Examination of Steroid Dose and Steroid-related Damage in an International Inception Cohort of Systemic Lupus Erythematosus Patients

Shi H (1), Anderson N (2), Ibanez D (3), Gladman D (4), Urowitz M (5)

(1) Toronto Western Hospital, Ontario, Canada, (2-5) University of Toronto, Ontario, Canada

Objectives: Corticosteroids (CS) remain the mainstay in the treatment of Systemic Lupus Erythematosus (SLE). It is known that cumulative CS dose is associated with damage; however the role of mean dose over time is not known. The purpose of this study is to determine the effect of dose dependent factors in the accrual of steroid related damage in SLE patients.

Methods: Patients with SLE from the multicentre SLICC–RAS inception cohort were followed prospectively for 5 years. Annual data collection includes clinical and laboratory features of SLE, past and current therapy, and the SLICC/ACR damage index (SDI). The occurrence of permanent damage, as measured by the SDI, was categorized as definitely related, possibly related, or independent of CS. Steroid courses over this period were captured and used to calculate accumulated dose and average daily dose. Multivariable stepwise logistic regression and Mantel-Haenszel chi-square tests were performed to identify significant associations between dose dependent variables and steroid-related permanent damage.

Results: Of the 342 patients in our analysis (295 female, mean±SD age of 35±13 years at enrolment), the median cumulative steroid dose increased from 0.49g to 13.2g from enrolment to 5 years follow-up. During the same period, the mean damage (SDI) increased from 0.15±0.50 to 0.97±1.33, of which 0.24±0.60 (25%) was definitely related to steroids. Damage associated with cumulative dosages are as follows: at 0 g total SDI was 0.50±0.84 of which 0.11±0.34 (19.4%) was definitely related CS, and at ≥ 40 g the total SDI was 1.77 ± 1.74 of which 1.00±1.15 (50%) was definitely related to CS. Damage associated with average daily doses are as follows: total SDI at 0 mg/day was 0.50±0.84 of which 0.11±0.34 (19.4%) was definitely related to CS, and at ≥ 20 mg/day the total SDI was 1.64±1.75 of which 0.54±0.96 (28.9%) was definitely related to CS.

Conclusions: SLE patients receiving CS therapy accrue damage due to disease and other therapy factors, as well as due to CS over time; however the relative contribution of damage due to CS remains the same over a five year period. Additional research is required to better determine the susceptibility of SLE patients to steroid damage due to dose over an increased duration of corticosteroid use.

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Treatment of Hypertension and Hypercholesterolemia is not Successful in the Majority of Patients with Systemic Lupus Erythematosus

Pek E (1), Gladman D (2), Ibanez D (3), Urowitz M (4)

(1) Toronto Western Hospital, Ontario, Canada, (2-4) University of Toronto, Ontario, Canada

Objectives: Patients with SLE demonstrate accelerated atherosclerosis and are at an increased risk of coronary artery disease. Previous quality improvement studies have demonstrated that increasing numbers of patients are being treated for hypertension, and hypercholesterolemia. The objective of this study was to determine whether the initiation of treatment with anti-hypertensive or lipid lowering medications led to successful control of these risk factors.

Methods: Patients from a large lupus cohort presenting within 1 year of SLE diagnosis and who received treatment with anti-hypertensive medications since 1985 and/or lipid lowering medications since 1995 were included. Success was defined as having met target blood pressure (BP), systolic BP ≤ 140 and diastolic BP ≤ 90 mmHg, serum total cholesterol (TC), TC ≤ 5.2 mmol/L or serum LDL, LDL ≤ 3.2 mmol/L during at least 90% of follow-up).

Results: 70% and 29% of patients with documented hypertension or hypercholesterolemia respectively were initiated on appropriate therapy. 107 patients were treated for hypertension (86% female, mean±SD age at treatment was 43.3±15.4, mean±SD disease duration at treatment was 2.6±4.2years) and 49 were treated for hypercholesterolemia (82% female, mean±SD age at treatment was 42.9±13.3, mean±SD disease duration at treatment was 3.2±3.6 years). Overall the adjusted mean systolic pressure decreased from 147.00±18.71 mmHg to 131.49±14.32 mmHg following treatment and the adjusted mean diastolic pressure decreased from 90.37±12.05 mmHg to 80.39±14.32 mmHg. However, only 36 of 104 patients (35%) met our criteria for successful treatment of hypertension. The adjusted mean total serum cholesterol decreased from 6.29±1.48 mmol/L to 4.76±1.01 mmol/L and 3.65 ± 1.29 to 2.56 ± 0.81 respectively. However, only 19 of 48 patients (40%) attained target total cholesterol levels while 25/40 (63%) attained target LDL levels during over 90% of follow-up.

Conclusions: Treatment of hypertension and hypercholesterolemia does not necessarily result in successful control of these risk factors in the majority of SLE patients. Further analysis will be important to discern the reasons for unsuccessful treatment and to compare CAD outcomes in patients who were successfully treated and those who were not.

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Smoking Significantly Increases Disease Activity in Systemic Lupus Erythematosus (SLE): Results from the 1000 Faces of Lupus Cohort

Nguyen Mai (1), McVagh John (2), Pope J (3), Silverman E (4), Fortin P (5), Smith C (6), Hitchon C (7), Zummer M (5), Hudson M (8), Bernatsky S (8), Clarke A (11), Pineau C (12), Urowitz M (13), Gladman D (14), Peschken C (15)

(1-2,7,15) University of Manitoba, Manitoba, Canada, (3-6) University of Western Ontario, Ontario, Canada, (11) The Hospital for Sick Children, University of
Objective: Smoking has been shown to increase SLE disease activity. However, smoking is also strongly associated with sociodemographic variables such as ethnicity, education and income, all of which also impact on SLE disease activity. We examined the relationship between smoking, sociodemographic variables, and disease activity in SLE patients.

Methods: Adult SLE prevalent and incident cases were enrolled in a prospective, multi-centre cohort. Sociodemographic variables, and data on health-related habits, diagnostic criteria, disease activity, autoantibodies, treatment, and damage were collected annually using standardized tools, and results were compared between smokers and non-smokers. Disease activity was evaluated using the Systemic Lupus Erythematosus Disease Activity Index (SLEDAI). We analyzed annual follow-up data over a 3 year period, testing for differences in disease activity between smokers and non-smokers in univariate analyses; significant variables from univariate analyses were included in multivariate regression models examining predictors of disease activity.

Results: A total of 1380 adult participants were enrolled from July 2005-May 2009. Two hundred forty-one (17%) were current smokers and 1139 were non-smokers (83%). There were no significant differences between smokers and non-smokers with respect to age (44 ± 0.9 years vs. 45 ± 0.9 years), gender (88% vs 91% female), disease duration (11 ± 0.6 years vs. 12 ± 0.3 years), age at diagnosis (31 ± 0.9 years vs. 31 ± 0.4 years), ACR classification criteria met (5.9 ± 0.1 vs. 6.0 ± 0.1), and SLICC/ACR damage index (SDI) (1.5 ± 0.1 vs. 1.6 ± 0.1). A higher proportion of Caucasians (19%) and Aboriginals (44%) were smokers compared to Asians (6%), and Afro-Caribbeans (9%), (p < 0.001). Thirty-seven percent of smokers had annual incomes > $50000 compared to 25% of non-smokers; 76% of smokers had annual incomes < $15000 compared to 12% of non-smokers; and 25% of smokers had annual incomes > $15000 compared to 12% of non-smokers; p=0.002. Smokers (76%) were less likely to have completed high school compared to non-smokers (87%), p<0.001. SLEDAI scores did not differ between smokers and non-smokers in univariate analysis over the 3 years compared to non-smokers(87%), p< 0.001, LV (MAP 108.3 ± 14.3mmHg, P=0.001; SDI: 43.8%, P=0.033), and AS patients (MAP 101.9 ± 13.9mmHg, P=0.001; SDI: 45.4%, P=0.001) compared to controls (MAP 91.6 ± 10.9mmHg, SDI: 14.3%). Only patients with LV had higher SLEDAI at the time of biopsy compared to controls (16.9±8.5 vs 10.5±6.2, P<0.003). Grade of LN, activity indices and proteinuria were similar between groups; however, chronicity indices on biopsy were significantly higher in all RVL subgroups compared to controls. GFR by MDRD was lower in LV (40.7 ± 33.0 mL/min/1.73m2, P=0.001), and AS patients (70.5 ± 33.3 mL/min/1.73m2, P=0.03) compared to controls (84.5 ± 26.6 mL/min/1.73m2). A subset of 133 patients with similar period of follow-up was then evaluated for associations between RVL and outcomes such as thrombotic events (TE), end-stage renal disease (ESRD), chronic kidney disease (CKD) and death. On univariate analysis, presence of RVL was significantly associated with TE (P=0.009). However, RVL was not independently predictive of the outcomes of interest on multivariate analysis.

Conclusions: RVL are common in SLE patients with LN and may be associated with thrombotic events but the presence of RVL on initial renal biopsy was not independently associated with increased TE, ESRD or mortality.

(160)
Cz-CO076

Outcomes of SLE Patients Cared for by Rheumatology or Nephrology

Cheung S, Beuker E, Katz S, Pannu N, Harley D, Yacyshyn E
University of Alberta, Alberta, Canada

Objective: To assess the outcome and management of lupus nephritis (LN) patients under the care of both rheumatologists and nephrologists (R+N), rheumatologists only (R), and nephrologists only (N).

Methods: LN patients (n=66), who met the ACR criteria or had a positive kidney biopsy for systemic lupus erythematosus (SLE), were studied. Clinical and laboratory data, as well as past and current medications and/or other treatments were assessed. Disease damage and disease activity were scored using the Systemic Lupus International Collaborating Clinics Damage Index (SLICC)/American College of Rheumatology (ACR) Damage Index (SDI) and SLE Disease Activity Index (SLEDAI), respectively. Focus was placed on the comparison between the R+N and the N group, as the assumption was made that these patients had similar renal manifestations.

Results: Of the 66 patients studied, 48 were R+N patients, 8 were R patients, and 10 were N patients. The mean SDI score of the R+N, R, and N groups were 1.96±(1.81), 2.25±(3.14), and 1.89±(2.93), respectively. The mean SLEDAI of all 3 groups in the same order were 4.55±(4.06), 2.71±(1.58), and 5.44±(5.08). The differences in the SDI and SLEDAI

(169)
Cz-CO075

Clinical Significance Of Renal Vascular Lesions (RVL) On Renal Biopsy In Lupus Nephritis

Barber C (1), Herzenberg A (2), Aghdassi E (3), Su J (4), Lou W (5), Qian G (6), Yip J (7), Nasr S (8), Thomas D (9), Wither J (10), Urowitz M (11), Gladman D (12), Reich H (13), Fortin P (14)
(1,2,3,11,12) University Health Network, Ontario, Canada, (4,5,11) The Ottawa Hospital, Ontario, Canada, (6,12) CH Maisonneuve-Rosemont, Quebec, Canada, (7,10) McGill University and Jewish General Hospital, Quebec, Canada, (8,12) McGill University Health Centre, Quebec, Canada, (9-11,12) University of Toronto, Ontario, Canada

Objective: To determine the clinical significance of Renal Vascular Lesions (RVL) detected in renal biopsies of patients with systemic lupus erythematosus (SLE).

Methods: Renal biopsies were scored according to the ISN/RPS revised 2004 criteria for Lupus Nephritis (LN). RVL were defined as: 1) thrombotic microangiopathy (TMA), 2) arterial fibrinoid necrosis (AFN), 3) lupus vasculopathy (LV), and 4) arterial sclerosis (AS). Demographic, renal, vascular outcomes, overall mortality, disease activity measured by SLE-disease activity index-2000 (SLEDAI-2K) and organ damage assessed by SLICC damage index (SDI) were evaluated.

Results: 207 biopsies from 164 patients were examined. TMA was seen in 13 patients (7.9%), 15 had LV (9.1%), 3 patients had TMA and LV, 93 (56.7%) had only AS, 0 patients had AFN and 40 patients with LN and no RVL (24.4%) were used as controls. Baseline demographics including age at SLE diagnosis, gender and ethnicity were similar between groups. At time of renal biopsy the mean arterial pressure and the percentage of patients with an SDI score ≥ 1 was higher in the TMA (MAP 110.6 ± 20.7mmHg, P=0.001; SDI: 55.6%, P=0.018), LV (MAP 108.3 ± 14.3mmHg, P=0.001; SDI: 43.8%, P=0.033), and AS patients (MAP 101.9 ± 13.9mmHg, P=0.001; SDI: 45.4%, P=0.001) compared to controls (MAP 91.6 ± 10.9mmHg, SDI: 14.3%). Only patients with LV had higher SLEDAI at the time of biopsy compared to controls (16.9±8.5 vs 10.5±6.2, P<0.003). Grade of LN, activity indices and proteinuria were similar between groups; however, chronicity indices on biopsy were significantly higher in all RVL subgroups compared to controls. GFR by MDRD was lower in LV (40.7 ± 33.0 mL/min/1.73m2, P=0.001), and AS patients (70.5 ± 33.3 mL/min/1.73m2, P=0.03) compared to controls (84.5 ± 26.6 mL/min/1.73m2). A subset of 133 patients with similar period of follow-up was then evaluated for associations between RVL and outcomes such as thrombotic events (TE), end-stage renal disease (ESRD), chronic kidney disease (CKD) and death. On univariate analysis, presence of RVL was significantly associated with TE (P=0.009). However, RVL was not independently predictive of the outcomes of interest on multivariate analysis.

Conclusions: RVL are common in SLE patients with LN and may be associated with thrombotic events but the presence of RVL on initial renal biopsy was not independently associated with increased TE, ESRD or mortality.
between all 3 groups were not found to be significant. Forty-two out of forty-eight R+N patients (87.5%) compared to 50% of N patients were on hydroxychloroquine (HCQ). Using the Fisher’s-Exact test, the differences in these two groups is significant (p value = 0.0153). All patients seen only by rheumatologists were on HCQ. Thirty-seven out of forty-eight R+N patients (77.1%) compared to 90% of N patients were on ACE inhibitors and/or angiotensin receptor blockers (ARB) (p value = 0.6700). The difference was not significant according to the Fisher’s-Exact test.

Conclusions: There is no difference in disease damage and disease activity among patients seen by both rheumatologists and nephrologists versus those seen by only one or the other subspecialist. However, the use of HCQ is more frequent in LN patients under the care of a rheumatologist in conjunction with a nephrologist. This has implications on the management and care of LN patients. Whether or not HCQ should become part of the standard of care of LN still requires more research. More studies need to be done to evaluate the effect of HCQ on renal outcomes, morbidity, and mortality. Education of both Rheumatologists in the use of ACE-i and ARB’s, and Nephrologists in the use of HCQ should be a priority.

(011)
C2-CC077

Prognostic factors for survival in systemic lupus erythematosus associated pulmonary arterial hypertension

Chow S, Chandran V, Fazelzad R, Johnson S

University of Toronto, ON, Canada

Objectives: Pulmonary hypertension (PH) is a rare but severe manifestation of systemic lupus erythematosus (SLE) that can ultimately result in death. The identification of factors that prognosticate survival in SLE-PH is necessary for appropriate monitoring, timing of therapies and lung transplantation. The primary objective of this study was to identify prognostic factors for survival in SLE-PH through review of the literature. We also evaluated the methodological quality of the prognostic studies.

Methods: A systematic review of the literature was performed to identify studies evaluating prognostic factors for survival in SLE-PH. Medline, EMBASE, CINAHL, and Cochrane Central Registry of Controlled Trials (inception – week 2 2010) were searched. A standardized abstraction form was used to extract prognostic factors by 2 independent reviewers. Methodologic quality was evaluated using a validated quality index.

Results: Twenty-three studies (retrospective cohort studies and case reports) from 375 citations were evaluated. Elevated mean pulmonary artery pressure, Raynaud’s phenomenon, thrombocytopenia, pleural effusion, infection, thrombosis, pregnancy, pulmonary vasculitis, and anti-cardiolipin antibodies were associated with decreased survival. Lupus disease activity, nephritis and CNS disease were not associated with survival. The sample sizes were small and methodological quality of the studies was variable.

Conclusions: Our study summarizes factors that may be associated with decreased survival in SLE-PH. The small sample sizes and variable methodological quality preclude definitive conclusions. This study provides the groundwork for further research using large cohorts.

(012)
C2-CC079

Systemic Lupus Erythematosus Disease Activity Index (SLEDAI-2K) Responder Index (SRI)-50: a Valid Index for Measuring Improvement in Disease Activity

Touma Z, Gladman D, Ibanez D, Urowitz M

University of Toronto, Ontario, Canada

Objectives: SRI-50 describes partial improvement, ≥50%, in disease activity between visits in lupus patients. We aim to determine whether SRI-50 would capture patients who have improved by ≥50% as determined by physician global assessment (PGA), construct validity of SRI-50 for assessing improvement in disease activity in SLE.

Methods: All patients attending the Lupus Clinic from September 2009 to December 2009 were enrolled in a prospective longitudinal study. Of the 298 patients enrolled 141 had a follow-up visit and were studied further. SLEDAI-2K and SRI-50 scores were determined initially and on a follow-up visit at 1-3 months. During the first visit a PGA was determined on a visual analog scale (VAS) line of 100 mm, with anchors of 0 ‘no disease activity’ and 10 for very active disease’. During the follow-up visit a PGA was determined on a 7-point Likert VAS; 7 much, 6 moderately, and 5 slightly improved, 4 unchanged, 3 slightly, 2 moderately, and 1 much worse. We defined a 50% improvement as PGA 26. An external clinician evaluated patients’ records and grouped them on follow-up visit into: improved, same and worse using standardized predefined definitions. The external
SLEDAI-2K Responder Index (SRI)-50: A Reliable Index for Measuring Improvement in Disease Activity

**Objectives:** To test the inter-rater and intra-rater reliability of the SRI-50, an index designed to measure ≥50% improvement in disease activity between visits in lupus patients.

**Methods:** This is a multicenter, cross-sectional study with raters from Canada, United Kingdom and Argentina. Patient profile scenarios were derived from “real” adult patients. Ten rheumatologists, from university and community hospitals, and postdoctoral rheumatology fellows participated. An SRI-50 data retrieval form was used. Rheumatologist scored SLEDAI-2K at the baseline visit and SRI-50 on follow-up visit, for the same patients on two occasions 2 weeks apart. Physician Global Assessment (PGA) was determined on a numerical scale at baseline visit and Likert Scale (LS) on follow-up visit. Inter-rater and intra-rater reliability was assessed using intraclass correlation coefficient (ICC) and kappa statistics whenever applicable.

**Results:** Forty patient profiles were created. 55% were Caucasian, 22% black, 5% Asian and 18% others. Age at diagnosis 30.4 ± 12.7, age at the visit 38.0 ± 13.5 years, disease duration 7.6 ± 8.1 years and SDI 1.05 ± 1.45. All 24 descriptors of SLEDAI-2K were represented. The ICC performed on 80 patient profiles for inter-rater ranged from 1.00 for SLEDAI-2K and SRI-50 to 0.96 for PGA. The ICC for SLEDAI-2K, SRI-50 and PGA ranged from 1.00 to 0.86. Substantial agreement was determined for inter-rater LS with a kappa statistic of 0.57.

**Conclusions:** The SRI-50 is reliable to assess ≥50% improvement in lupus disease activity. The use of the SRI-50 data retrieval form is essential to ensure the optimal performance of SRI-50. SRI-50 can be used by both rheumatologists and trainees and performs equally well in trained as well as untrained rheumatologists.
Methods: 35 patients with moderate disease activity (SLEDAI-2K ≥10) seen at a single centre over 3 months were enrolled. Both questionnaires were co-administered at the same visit. Cumulative damage was determined by Systemic Lupus International Collaborating Clinics/ACR Damage Index (SDI). We performed a descriptive analysis of the mean scores for all domains and compared comparable domains in both questionnaires. For the 4 non-comparable domains of the LupusQoL we determined the correlation between each domain with the Physical Component Score (PCS) and the Mental Component Score (MCS) of the SF-36. We determined the correlations between LupusQoL and SF-36 with SLEDAI-2K and SDI scores. We compared LupusQoL and SF-36 scores in patients with and without damage.

Results: Among the 35 patients (female 29 /male 6), 40% were Caucasian, 31% Black, 1% Asian, and 17% other. The mean age at SLE diagnosis was 25.0±10.9 years. At study visit the mean age was 35.1±10.7 and disease duration 10.1±6.4 years, SLEDAI-2K 10.31±5.36 and SDI 1.06±1.20. Both questionnaires assessed quality of life as low among patients. There was no statistically significant difference between comparable domains in both questionnaires. For the 4 non-comparable domains of the LupusQoL, there was a correlation between Body Image and MCS-SF-36 r=0.73, Planning and MCS-SF-36 r=0.63, Intimate Relationships and PCS-SF-36 r=0.59, and Burden to Others and MCS-SF-36 r=0.34 (all p were significant). Neither questionnaire correlated with disease activity nor with cumulative damage. When comparing the domains in patients with damage to patients without damage, there was a statistically significant difference compared with the SF-36 scores (Physical Functioning p=0.03 and PCS p=0.046) but not LupusQoL scores. In both cases, the scores were lower in patients with damage. No relationship could be identified between LupusQoL and fibromyalgia since there were only 2 patients with fibromyalgia.

Conclusions: Quality of life as determined by LupusQoL and SF-36 questionnaires is significantly compromised in lupus patients with moderate disease activity, but does not correlate with disease activity or damage. These findings confirm that the quality of life is an independent outcome measure in the assessment of lupus. There is no superiority of LupusQoL over SF-36 in assessing lupus patients’ quality of life. The responsiveness of LupusQoL needs to be evaluated in patients with moderate to severe disease activity.

Results of a Needs Assessment for Canadian Systemic Lupus Erythematosus Guidelines: A New CANIOS Initiative

Keeling, S

University of Alberta, Alberta, Canada

Objectives: The Canadian Network for Improved Outcomes in Systemic Lupus Erythematosus (CANIOS) is planning on developing Canadian Guidelines for the diagnosis and/or management of systemic lupus erythematosus (SLE). These guidelines would (1) have a Canadian-based focus on SLE treatment to help governing bodies approve future agents and (2) provide Canadian Rheumatologists with the best-evidence in the management of these complicated patients to improve standard-of-care. The main objective of this study was to conduct a needs assessment of Canadian rheumatologists to identify the utility of such guidelines in the diagnosis and/or management of SLE.

Methods: A systematic review of the literature was conducted in order to identify existing guidelines and review their content. A draft survey monkey questionnaire was devised to determine the level of interest and need of the Canadian rheumatology community for such guidelines. The draft questionnaire was reviewed by 2 CaNIOS subcommittees and co-chair of the CRA Therapeutics Subcommittee. The final 10-question survey was sent by email to the CRA membership and responses collected over a 2.5 week period at the end of September/early October 2010.

Results: Of the 133 CRA members who responded to the questionnaire, 88.6% (n=117) were adult and 11.4% (n=15) were pediatric rheumatologists, while 66.4% (n=87) had academic/university practices compared to 33.6% (n=44) with community practices. The majority of respondents saw a total of “1-3 SLE patients” per week (38.6% (n=51)) and “1-3 new SLE patients” per month (40.9% (n=54)). The most common SLE manifestations seen in clinic included arthritis (54.7% (n=70)) and cutaneous (38.5% (n=50)) followed by nephritis (31.6% (n=43)). 84 respondents (63.2%) felt that the guidelines would be helpful to their practice, with the “management of lupus nephritis” ranked highest followed by the “management of pregnancy in SLE” and “existing therapeutics in SLE”.

Conclusions: In Canada, SLE patients constitute a significant percentage of adult and pediatric rheumatology practice. A need does exist for the development of SLE guidelines, with specific interest in lupus nephritis and pregnancy. Distinction between adult and pediatric SLE populations will be important. Future directions include focusing the goals of SLE guidelines and establishing a working-group to pursue this task.

Prolonged serologically active clinically quiescent (SACQ) systemic lupus erythematosus (SLE): novel predictors of flare?

Steiman A (1), Urowitz M (2), Wither J(3), Ibanez D (4), Li T (5), Gladman D (6)

1-4. University of Toronto, Ontario, Canada, 1. The University Health Network

Objectives: Anti-double stranded DNA antibodies (anti-dsDNA) and complement levels can predict SLE flare. Some patients, however, are clinically quiescent despite persistent serologic activity (i.e., elevated anti-dsDNA and/or hypocomplementemia). Past studies reveal that 60% of such SACQ patients flare, but do so only after average 182 weeks. In these patients changes in anti-dsDNA and/or C3/C4 levels measured at routine clinic visits did not predict disease flare. Some studies suggest that anti-chromatin (-nucleosome) antibodies are more sensitive than anti-dsDNA to detect active SLE, and that time to first flare after a SACQ period significantly correlates with their presence. We investigated whether levels of anti-dsDNA and -chromatin isolates, measured during a prolonged SACQ period, differed in patients who remained SACQ versus those who flared.

Methods: Archived serum samples of patients with a prolonged SACQ period, stored at -80°C, were retrieved and divided by disease activity during SACQ period vs during flare. Serum levels of IgM, IgA, total IgG, and IgG1-4 anti-dsDNA and anti-chromatin antibodies were measured by ELISA. H1-stripped chromatin was prepared from the human cell line, MOLT4. ELISA plates were coated overnight with dsDNA (40 μg/ml) and chromatin (8 μg/ml) diluted in PBS at 4°C. Serum was diluted 1/100 for IgM, IgA, and IgG, or 1/50 for IgG1-4. SACQ was defined as at least a two year sustained period with SLEDAI-2K of 2 or 4 from serologic activity only, during which patients could be taking antimalarials, but not steroids or immunosuppressives. Flare was defined as any clinical disease activity. Non-parametric statistics were used.

Results: Thirty-eight samples corresponding to a prolonged SACQ period (from 23 patients) were analyzed. 15/38 (39%) samples corresponded to patients who flared. Anti-chromatin total IgG levels were lower in SACQ patients who flared than in those who remained SACQ (0.36±0.277 vs 0.83±0.700, p<0.007; normal < 0.147), however there was no difference between these groups when IgG was broken down by subtype, IgM and IgA were comparable between groups. Anti-dsDNA IgA (but not IgM or IgG) was lower in patients who flared compared to those who remained quiescent.
SACQ \(0.028 \pm 0.025 \text{ vs } 0.081 \pm 0.095, p = 0.018\). When only the most recent sample from each SACQ patient was analyzed (9/23 (39%) of whom flared), there was no difference between anti-chromatin or anti-dsDNA iso-type levels between patients who flared and those who remained SACQ.

**Conclusions:** In this pilot study neither anti-chromatin nor anti-dsDNA antibodies predicted flare in patients with a prolonged SACQ period. Alternate biomarkers must be sought.

**References:**

(126)
C2-CO085

**Case Based Learning in Pediatric Rheumatology - An Effective Method for Teaching the Medical Expert Role**

Jurencak R, Roth J

**Children’s Hospital of Eastern Ontario, ON, Canada**

**Objectives:** To design, implement and evaluate a Case-based Learning (CBL) module focused on rheumatic disorders.

**Methods:** Course structure: 4 weekly sessions, each of 30 minutes duration, were implemented into each 4-week rheumatology rotation of pediatric residents. Course participants: pediatric residents. Case database: A case-scenario database was established from which cases were chosen to reflect the spectrum of clinical problems encountered by the resident in the past seven days. All cases are open-ended and allow for discussion, modification and adjustment of the clinical scenario as necessary. Each case was emailed to the residents several days in advance to allow for adequate preparation. Evaluation: Each resident completed an anonymous detailed evaluation questionnaire of the teaching module at the end of their rotation. The questionnaire consisted of 5-point Likert scale questions (1 = strongly disagree, 5 = strongly agree) as well as open ended questions.

**Results:** 24 CBL sessions were evaluated by 6 residents (each attended 4 sessions). The course was highly valued among the residents and consistently rated as very beneficial for thought organization, application of knowledge and learning organization (mean Likert scale score = 5). The residents felt the course improved their clinical reasoning skills as well as problem solving skills (mean Likert scale score 5 for each domain). The trainees appreciated the extra time and space specifically dedicated to this teaching unit as well as the opportunity to study each case in advance.

**Conclusions:** Our study illustrates the usefulness of CBL in teaching of pediatric rheumatology. In our experience, CBL greatly contributes to resident’s understanding of complex rheumatic disorders in pediatric population such as systemic lupus erythematosus, inflammatory myopathies and vasculitides which ultimately leads to improvement of residents’ analytic skills in a clinical setting and their role as Medical Expert.

**References:**

(139)
C2-CO086

**Identifying Patients who are Arthroplasty Candidates within a Medically-based Osteoarthritis Education and Treatment Program**

Bain L, Denning L, Mierdel S, Thorne C

Southlake Regional Health Centre, Ont, Canada

**Objectives:** To identify patients who are enrolled in an osteoarthritis education and treatment program for medical management who currently meet criteria and are good candidates for arthroplasty surgery.

**Methods:** To determine the current tools through literature review and expert consultation to assist with paper triage process To develop a pilot paper and clinical algorithm for triage and identification To support additional options for those patients who are triaged as arthroplasty candidates but don’t meet surgical criteria To evaluate the pilot project (clinical outcomes, metrics and patient education) in order to determine next steps for future recommendations.

**Results:** Environmental scan showed that currently there was no clear cut paper algorithm readily available in the arthritis literature to identify patients who were candidates for an arthroplasty procedure. New tools were in the works but not ready for threshold to be identified. A TAP paper algorithm was developed for testing that included the WOMAC, PASSO, HOOS/HOOS-PS, KOOS/KOOS-PS, VAS, ICOAP©. An individual TAP physical assessment process was developed to triage patients to determine if criteria were met for a surgical consult. Pilot process was successful in identifying patients enrolled in a medical education and treatment program who were arthroplasty candidates. Those triaged, who did not meet inclusion criteria for surgery had other musculo skeletal issues that were brought to the forefront due to the triage process.

**Conclusions:** Patients referred to OA program are for the most part appropriate for these classes. A proportion of patients improved by the end of the classes, others on their way to improvement. Some patients had barriers to improvement in OA program because of other musculo skeletal issues that needed to be addressed on an individual basis. Many patients had appointments for consultation with orthopeds and were being followed even though they did not have dates for arthroplasty. Further piloting is needed on a larger scale to confirm and consolidate the algorithm developed.

**References:**

(74)
C2-CO087

**A Simulation Model of Medication Use and Impact among Persons with Osteoarthritis in Canada**


**Objectives:** The objective of this research was to build a drug treatment module for POHEM-OA, a population-based computer model of osteoarthritis (OA). POHEM-OA is a microsimulation model in which aggregate results for the adult population of Canada are obtained by simulating “life histories” of about 25 million individuals, one at a time.

**Methods:** Model parameters have been derived from analyses of administrative data in BC (prescription drug use), national population surveys (over-the-counter use), and a comprehensive review of the literature (benefits and adverse effects of medication). POHEM-OA simulates the use of 4 types of medication (acetaminophen, NSAIDs, COX-2 inhibitors and opioids) as a function of age, sex, OA, and health level, measured by the Health Utilities Index 3 (HUI3). HUI3 is an 8-domain health index that includes pain. The model also simulates the benefits of medication in terms of its positive impact on HUI3 (estimated from data on pain reduction), as well as adverse effects of drugs and their negative impact on HUI3 and survival.

**Results:** Probabilities of use for each type of medication have been estimated for 390 subgroups defined by age, sex, OA diagnosis, OA duration, surgical treatment, and HUI3 category. These probabilities ranged from 0.01 to 0.77 for acetaminophen, 0.03 – 0.93 for NSAIDs, 0.001 – 0.28 for Coxibs, and 0.0002 – 0.67 for opioids. For example, the highest users of coxibs were men, > 50 years of age, < 2 years after joint replacement surgery. HUI3 levels had a strong effect on the use of opioids and coxibs and moderate-to-weak effect on the use of acetaminophen and NSAIDs. Average relative pain reductions (0-100 scale) ranged from 28% for acetaminophen to 38% for NSAIDs and coxibs and 40% for opioids. Excess risks of
Quality of Life Before and After Joint Replacement Surgery

Kopec J (1), Rahman M (2)

(1) University of British Columbia, BC, Canada, (2) Arthritis Research Centre of Canada, BC, Canada

Objectives: The purpose of this study was to describe the level of health-related quality of life (HRQL) among persons with osteoarthritis prior to and following joint replacement surgery (JRS).

Methods: We used administrative data from the British Columbia Linked Health Database (BCLHD) 1986–2007 linked by a unique identifier to the BC component of the Canadian Community Health Survey (CCHS, 2001, 2003, and 2005). The BCLHD includes diagnostic codes for all visits to doctors and hospital admissions and procedure codes for patients undergoing surgery. Health-related quality of life was measured in all cycles of the CCHS using the Health Utilities Index 3 (HUI3). We compared the median and mean HUI3 levels for persons grouped according to the time between their JRS and CCHS interview.

Results: There were 25,638 individuals in the linked dataset. Of those, 223 patients with OA had a date of JRS after the date of the CCHS interview. The median HUI3 was 0.78 (mean=0.71, SD=0.27, min=0.12, max=1.0). When patients were grouped according to time from JRS to CCHS interview, the median (mean) HUI3 were as follows: time < 2 years (N=49), median HUI3=0.91 (mean=0.82); time 2-3 years (N=35), 0.86 (0.79); time 3-4 years (N=31), 0.91 (0.71); time 1-2 years (N=48), 0.67 (0.67); time < 1 year (N=70), 0.66 (0.62). We have identified 340 cases assessed in the CCHS after their JRS. When they were grouped according to time between their JRS and CCHS interview, the median (mean) HUI3 were as follows: time < 2 years (N=21), 0.91 (0.71); time 1-2 years (N=48), 0.67 (0.67); time < 1 year (N=49), median HUI3=0.91 (mean=0.82); time 3-4 years (N=35), 0.86 (0.79); time 2-3 years (N=21), 0.91 (0.71); time 1-2 years (N=48), 0.67 (0.67); time < 1 year (N=70), 0.66 (0.62). We have identified 340 cases assessed in the CCHS after their JRS.

Conclusions: Linking administrative and survey data provides an alternative method for assessing the long-term trajectory of HRQL before and after JRS. These data suggest a strong decline in average quality of life starting about 2-3 years before surgery. HUI3 after JRS is higher than < 2 years prior to surgery and stable for up to 15 years after surgery, but does not achieve levels comparable to those 4-5 years before surgery. Individual variation in HUI3 in these patients is very large.

Bone Health in Patients with Interstitial Lung Disease

Subramanian G, Papneja T, Yacyshyn E

University of Alberta, AB, Canada

Objectives: Osteoporosis is a common condition in patients with end-stage lung disease, but little attention has been given to bone disease in patients with interstitial lung disease (ILD). The purpose of this study is to perform a systematic review of the literature to determine: (1) the prevalence of low bone mineral density (BMD) in patients with ILD, (2) identify correlates of osteoporosis/osteopenia in this special group of patients, (3) effects of treatment of low BMD in patients with ILD.

Methods: We reviewed the literature for all English language publications from 1950–September 2010 in Pubmed, EMBASE, MEDLINE, and Cochrane database of systematic reviews. The articles were screened on title, abstract and full-text. In addition, reference lists were searched by hand. Trials evaluating prevalence, predictors and treatment of osteopenia/osteoporosis in patients with ILD were included. Data extraction was carried out by first reviewer and verified by a second reviewer.

Results: The prevalence of low bone mineral density varied 62–70% with 5–43% ILD patients having osteoporosis. Only one study compared the observed prevalence of osteoporosis and osteopenia in ILD patients to the expected prevalence in a normal population matched for age, gender, and race. ILD patients had similar observed rates of low BMD as the matched healthy controls, with the exception of a higher proportion of ILD men with lower BMD at the lumbar spine. Correlate of osteoporosis in ILD is mainly body mass index, although causality has not been proven. Effects of treatment of osteoporosis have not been investigated in ILD patients specifically.

Conclusions: There is lack of high-quality data evaluating the prevalence and predictors of osteoporosis in ILD patients exclusively. In addition, prospective comparative studies assessing the effects of treatment of osteoporosis in ILD patients only are warranted.

Optimal Therapy for Osteoporosis in Respiratory Patients: A Systematic Review

Subramanian G, Papneja T, Yacyshyn E

University of Alberta, AB, Canada

Objectives: Osteoporosis is a common problem in patients with chronic respiratory failure of various origins. The purpose of this review is to assemble the currently available high-quality treatment data for treatment of osteoporosis in patients with respiratory illnesses such as cystic fibrosis (CF), chronic obstructive pulmonary disease (COPD) on chronic steroid therapy, and post-lung transplant.

Methods: MEDLINE, EMBASE, and Cochrane trials registers were systematically searched to identify randomized controlled trials comparing drug therapy for osteoporosis in patients with CF, COPD on chronic steroid therapy, and post-lung transplant. In addition, reference lists were searched by hand. The articles were screened on title, abstract and full-text. Selected studies were scored using the Jadad score. The primary outcome was bone mineral density (BMD) changes. Data extraction was carried out by first reviewer and verified by a second reviewer.

Results: Four studies in patients with CF, eleven studies in patients on chronic steroid therapy and three studies in patients with lung transplant were included. There are no clinical trials evaluating effects of treatment of osteoporosis in samples consisting of COPD patients exclusively. Efficacy of oral and intravenous bisphosphonates in increasing BMD has been
Physician As The Hub

sample sizes are needed in these patient populations to guide osteoporosis treatment recommendations are based on the effects on the surrogate outcomes have not been powered to look at fractures as an end-point, so bisphosphonates in patients with CF, chronic steroid therapy and post-organ transplant. Teriparatide can be used for patients with osteoporosis on chronic steroid therapy who have failed bisphosphonates. These studies have not been powered to look at fractures as an end-point, so large sample sizes are needed in these patient populations to guide osteoporosis clinical care for them.

(029)
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Treating Osteoporosis After A Fragility Fracture: The Family Physician As The Hub

Beaulieu M (1), Gosselin S (2), Gaboury F (3), Vanasse A (4), Cabana F (5), Boire G (6)

(1-4) CSSS-IUGS Sherbrooke, Quebec, Canada, (5) Université de Sherbrooke, (6) Centre hospitalier universitaire de Sherbrooke, Quebec, Canada

Objectives: To describe the implication of Family Physicians (FPs) in the management of osteoporosis revealed by a fragility fracture.

Methods: The impact and costs of fractures is straining the health system. A better collaboration between specialists and FPs should improve the evaluation and treatment of affected patients. Since January 2007, the OPTIMUS initiative is an attempt to reach that objective in the Estrie area of the Province of Quebec. With OPTIMUS, rates of appropriate treatment of osteoporosis at one year in previously untreated patients more than double (53% vs 20%). In OPTIMUS, FPs remain responsible for investigation and treatment of their patients after identification of a bone fragility fracture. A coordinator based in orthopedists' outpatient clinics identifies fragility fractures in patients older than 50 yo., informs them about bone fragility and its link to osteoporosis, and spurs them to contact their FPs to get treated; the importance of persistence on treatment is reinforced during phone follow ups. Initially and when patients remain untreated upon follow up, the coordinator sends a letter to the patient’s FP about the occurrence of the fracture, its predictive value for future fractures, and the need for investigation and treatment. This represents a personalized form of continuous medical education for FPs, in the hope that FPs become leaders in the prevention of fragility fractures. To evaluate the perception of FPs about OPTIMUS, we performed a mail survey targeting FPs reached at least once by OPTIMUS.

Results: The survey was sent to a total of 212 FPs. One hundred and nine (51.4%) answered. Of these, 97 (89%) agreed that a fragility fracture is an indication for treatment of osteoporosis; 56 (51%) agreed that OPTIMUS had helped them take charge of osteoporosis; and 105 (96.3%) were Satisfied or Very Satisfied of the OPTIMUS initiative.

Conclusions: Because of this high level of acceptance, we propose to put into place a more elaborate intervention including a full prevention program that will be managed by nurse coordinators in 16 FP Groups (GMF); these 16 Groups include 178 of the 360 FPs of the area. The FPs practicing in GMF are also involved in teaching to colleagues, residents and medical students; we expect an exponential effect on the practice of FPs over the years. We believe this enhanced intervention will improve the quality of life and autonomy of the patients while decreasing their rate of fractures.

(015)
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Arthritis In Celiac Disease Patients Does Not Respond Significantly To Gluten Free Diet Celiac Disease Arthropathy Study- A Single Centre Canadian Perspective

Iqbal T (1), Zaidi M (2), Wells G (3), Karsh J (4)

(1) The Queensway Carleton Hospital, Ontario, Canada, (2) The Northern Ontario School Of Medicine, Laurentia, Ontario, Canada, (3) University Of Ottawa Heart Institute, Ontario, Canada, (4) The Ottawa Hospital - Riverside Campus, Ontario, Canada

Objectives: The purpose of our study was to determine the prevalence of arthritis in a Canadian population of Celiac disease patients and to ascertain whether a gluten free diet improves the symptoms of arthritis associated with Celiac disease.

Methods: This prospective, questionnaire based, cross-sectional cohort study was designed to evaluate the presence or absence of arthritis (primary outcome) simultaneously in both Celiac and non-Celiac disease cohorts. 1770 questionnaires in a ratio of 1:2 were sent to patients with Celiac disease and healthy age and sex matched volunteer non-Celiac disease controls respectively.

Results: 356/590 (60.33%) patients with celiac disease responded to the invitation to participate in this study. 443 (75%) respondents (median age 58 years) were female; 60.5% with Celiac disease and 39.5% with non-Celiac disease. Celiac disease diagnosis (median duration 7 years) was endoscopically confirmed in 78.6% patients Overall, a doctor diagnosed arthritis in 223 (37.8%) patients; (65.5% GP & 22.9% rheumatologists). 131 cases of arthritis were reported in Celiac disease patients and 92 in non-Celiac disease patients. Osteoarthritis (89 vs. 59, p=0.93) was the most common diagnosis reported by Celiac disease patients, while rheumatoid arthritis (23 vs. 16, p=0.017) and psoriatic arthritis (5 vs. 1, p=0.60) were more commonly reported in non-Celiac disease patients. 4 patients with Celiac disease had Sacroiliitis and 2 patients had Ankylosing Spondylitis. Celiac disease group patients with diarrhea (66%) and anemia (53%) improved on gluten free diet. Only 51 (14.5%) patients with Celiac disease reported improvement in arthritis symptoms with gluten free diet compared to 121 (34%) patients reported no improvement. Univariate logistic regression analysis showed s high school education (OR 4.13, p=0.003), age ≥ 60 yrs (OR 4.6, p=0.001), and osteoporosis (OR 2.78, p= <0.001) to be significantly associated with report of arthritis in celiac disease patients, the latter two being still significant on multivariate logistic regression analysis. Being on gluten free diet and smoking did not significantly reduce or increase the incidence of arthritis in Celiac disease patients respectively. Autoimmune thyroiditis (10.6% vs. 0.4%), insulin dependent diabetes mellitus (2.2% vs. 1.7%), SLE (1.1% vs. 0), and psoriasis (12.9% vs. 5.5%) occurred more frequently in celiac disease patients.

Conclusions: There was no increase in inflammatory arthritis (Rheumatoid arthritis and Psoriatic arthritis) in Celiac disease patients. Being on gluten free diet did not result in significant improvement in arthritis symptoms, compared to improvement in anemia and diarrhea in celiac disease patients.

(073)
C2-CC093

Advanced Clinician Practitioner in Arthritis Care (ACPAC) Program-Trained Therapists in Ontario: Impact on System Integration and Change

Reumatol Clin. 2011;7 Suppl.1 163
Objectives: The Advanced Clinician Practitioner in Arthritis Care (ACPAC) program is an innovative, clinical and academic, interprofessional education program for licensed physical and occupational therapists. The program focuses on assessment, diagnosis, triage and independent management of selected musculoskeletal and arthritis-related disorders. This study aimed to evaluate the performance of ACPAC program-trained extended role practitioners with respect to health care delivery using System Integration and Change (SIC) indicators. The research objectives were to measure: 1) the role utilization of the ACPAC program-trained practitioner, 2) access to ACPAC program-trained practitioners in Ontario, and 3) integration with internal/external services and other services/resources.

Methods: ACPAC program-trained practitioners (n=30) were recruited from 15 healthcare institutions across the province of Ontario. These included urban, rural, academic, non-academic, adult and paediatric settings. ACPAC program-trained practitioners completed a longitudinal survey at the end of each fiscal quarter in 2009. Data were collected using Survey-Monkey©. SIC indicators and related questionnaire items were developed by: teleconference brainstorming, ranking and pilot testing with ACPAC program graduates; input from stakeholders (healthcare administrators and patients of these extended role practitioners). Descriptive statistics were used to summarize the data.

Results: The response rate varied from 83-93% over the fiscal quarters. Most respondents were working in an extended practice role (range 84-93%). The mean wait time to see an ACPAC program-trained practitioner varied from 14 to 22 days. These practitioners provided a wide range of services to patients in the 2009 fiscal year: referring 3946 patients to internal or external services, 1867 patients to medical doctors (general practitioners or specialists), and 3262 patients to educational resources. Most ACPAC graduates (75%) reported acting under the auspices of medical directives to support their extended practice role. Most respondents ordered X-rays (82%), lab tests (64%) and diagnostic ultrasounds (54%). 70% reported recommending medication/dosage changes and 4% made these changes independently. 89% reported recommending joint injections and 88% were performing them.

Conclusions: ACPAC program-trained practitioners were working in extended practice roles performing tasks that have the potential to improve access to care for patients with arthritis. Future evaluations will monitor the evolution of these new roles and assess their impact on patient outcomes. This new human health resource may be an effective strategy to address the evolution of these new roles and assess their impact on patient outcomes.

Do we care about vitamin D intake in our inpatient population? A quality assurance study

Sabbagh Z
University of Saskatchewan, SK, Canada

Objectives: To determine whether vitamin D status and/or advice for supplements were offered to patients admitted to Clinical Teaching Unit (CTU).

Methods: We randomly selected charts of 80 patients aged 50 or older who were admitted to CTU between January 1st, 2009 and January 1st, 2010. We excluded those with chronic kidney disease, hypercalcaemia, advanced malignancy or other terminal illness. Our primary outcome was the percentage of patients advised to take a vitamin D supplement (any dose) at discharge. We postulated that at least 75% of eligible patients should be advised to take supplementary vitamin D at discharge. Secondary outcomes included the percentage of patients taking supplements on admission, and the percentage of patients in whom serum 25-hydroxycholecalciferol (25-OHCC) was measured.

Results: Seventeen (21%) were taking vitamin D supplements on admission (mean dose 837.5±265.5). More women than men took supplements: 32.3% vs. 10.0% (p< 0.05). At discharge, only 10 further subjects were advised to take vitamin D. At both pre-admission and at discharge, all supplement users reported vitamin D intake of at or above the 400 IU/day. No patients received follow-up advice regarding vitamin D use or had 25-OHCC concentrations recorded.

Conclusions: To our knowledge, there is no study to evaluate vitamin D intake in inpatient population. Our study reveals a major deficiency in recommending advice for vitamin D supplementation in CTU patients. We recommend that a checked box be added to the discharge summary confirming that appropriate advice was offered.
Evaluation of Patient Satisfaction at the Sunnybrook Health Sciences Centre Rheumatology Outpatient Clinic

Shu J (1), Veinot P (2), Tavares R (3), Boyle J (4), Bell M (5)

(1) University of Western Ontario, ON, Canada, (2) Sunnybrook Health Sciences Centre, Ontario, Canada, (3) McMaster University, Ontario, Canada, (4) The Arthritis Society

Objectives: The purpose of this study was to evaluate and quantify overall patient satisfaction at the Sunnybrook Health Sciences Centre (SHSC) rheumatology outpatient clinic using the Leeds Satisfaction Questionnaire (LSQ), a validated and reliable tool designed specifically for a study of the follow-up of rheumatology patients. Differences in satisfaction scores between various aspects of care and amongst the four rheumatologists participating in this study were also assessed.

Methods: 329 LSQ questionnaires were collected July 2007 to June 2008. All patients attending a follow-up rheumatology appointment who were capable, over 18 years, and able to comprehend English were given the voluntary option of completing a LSQ anonymously. A total of 321 questionnaires were included in the study. Data was exported from a Microsoft Access 7 database to SAS for statistical analysis. Descriptive statistics (i.e. mean, median, standard deviation) were used to analyze the scores of the patient satisfaction questionnaires while the Kruskal-Wallis and one-way ANOVA tests were used to compare scores between rheumatologists.

Results: The satisfaction of patients at the SHSC with the care they received was generally positive and comparable with previous studies using the LSQ. The mean score across all providers was 4.08 on a Likert scale of 1 to 5 (SD = 0.49). There were statistically significant differences between the overall satisfaction of the 4 rheumatologists participating in this study (p < 0.05). Patients identified technical quality and competence as the area they were most satisfied with (4.44, SD = 0.47), whereas access to service and continuity of care received the lowest satisfaction score (3.77, SD = 0.68).

Conclusions: Patient satisfaction has been previously found to influence whether one seeks medical advice, treatment compliance, and the longitudinal relationship with a practitioner. Hence, in order to improve future delivery of care to patients with rheumatic disease, patient satisfaction with current care should be assessed to identify specific aspects of care that could potentially serve as target areas for reflection and improvement. This study is a pioneer example of evaluating patient satisfaction in a Canadian rheumatology outpatient setting and presents other rheumatologists with a potentially valuable tool to assess patient satisfaction in their practices. Furthermore, patient satisfaction with access to and continuity of care were found to be weaknesses in this study, which may suggest a future area of quality improvement.

Objectives: To capture practitioner and stakeholder satisfaction with the roles of Advanced Clinician Practitioner in Arthritis Care (ACPAC) program-trained physical therapists (PTs) and occupational therapists (OTs).

Methods: ACPAC program graduates and their colleagues were recruited from 15 institutions across the province of Ontario. Participants included program graduates, nurse practitioners, physicians, unit managers and program directors. Patients’ perspectives have been captured in a separate study. Program graduates participated in focus groups and their clinical colleagues and administrators participated in individual interviews. Interviews and focus groups were digitally audio-recorded for verbatim transcription. Transcripts were verified and entered into HyperResearch software for textual data analysis. Transcripts were coded for anticipated and emergent themes using the method of constant comparison including searches for disconfirming evidence. Focus groups, interviews and analyses were conducted by a qualitative researcher.

Results: Graduates (n=20) valued their ACPAC training and the advent of their extended practice roles (where achieved), seeing them as positive opportunities for career advancement. Those enjoying extended practice roles felt they were improving communication and continuity of care, improving access to care in under-served communities, providing timely and appropriate referrals and earlier recognition of potentially serious problems. Barriers to role utilization included lack of dedicated funding and administrative recognition through title, remuneration and medical directives and the unwillingness of others to understand or accommodate extended practice roles within their practice structure. Colleagues of ACPAC graduates (n=18) generally highly valued graduates’ roles. They felt that graduates were innovative, communicative, provided enhanced provision of care in under-served areas, allowed physicians to see more patients and greatly enhanced education for patients regarding their disease process, treatment and recovery. Administrators expressed concern about the cost-effectiveness and sustainability of extended practice roles for graduates within the current system. A lack of hands-on therapists if graduates move into extended practice roles was also a concern. At the system-level, it was felt that ACPAC graduates could reduce patient wait times, improve access to rheumatologists, reduce long-term disability, and provide a better approach to chronic disease management for an aging population.

Conclusions: Administrators, clinical colleagues and program graduates themselves value their capabilities and perceive that they improve patient care on many levels; however, barriers to role utilization at the team, institution and system levels pose challenges for the sustainability of extended practice roles. Future work needs to focus on ways to break down these barriers and maximize role utilization for the benefit of patients with arthritis.

Perceptions of Advanced Clinician Practitioner in Arthritis Care (ACPAC) program-trained Practitioners: Roles and Role Utilization within the Ontario Healthcare System

Warmington K (1), Kennedy C (2), Lunden K (3), Rozmovits L (4), Lineker S (5), Shupak R (6), Schneider R (7)

(1-3,6) St. Michael’s Hospital, Ontario, Canada, (4) Linda Rozmovits Qualitative Research, (5) The Arthritis Society, Ontario, Canada, (7) The Hospital for Sick Children, University of Toronto, Ontario, Canada

Objectives: To systematically investigate the quality and reporting of studies about the validity of administrative claims databases for ascertaining diagnoses of rheumatic diseases (RD).

Methods: A comprehensive search strategy was applied to MEDLINE and EMBASE to capture validation studies published between 1990 and 2010. All studies that adopted medical records or patient self-report
measures as the gold standard to validate administrative data were selected for inclusion. Data were abstracted using modified versions of the STARD and QUADAS tools. Two reviewers evaluated all studies. Results are reported using frequencies.

**Results:** A total of 21 validation studies were identified. Two-thirds used US administrative data, 19.0% used UK/European data, and the remaining 14.3% used Canadian data. The most common diagnosis was Rheumatoid Arthritis (57.1%). Osteoarthritis, Spondyloarthopathies, Gout, SLE, fibromyalgia, and unspecified arthritis were less commonly investigated. 85.7% validated linked databases (inpatient, outpatient and/or pharmacy data). Diagnostic codes were most frequently validated using medical records (81.0%). Gold standard definitions included clinical classification criteria, diagnoses documented in medical records and patient-reported data. Most studies (74%) sampled patients by identifying diagnostic codes prior to data collection. The most common sampling strategy involved sampling all patients (57.1%), followed by systematic sampling (38.1%). All studies described inclusion criteria and three-quarters reported using an a priori data collection tool. However, only 19.0% of studies performed an a priori sample size calculation. Excluding the four studies that used patient self-reported diagnosis as the gold standard, 29.4% of studies reported readers of the gold standard to be blinded to the results of the classification by administrative data. Most studies (76.2%) reported clinical/demographic characteristics of the study population, but only 38.1% described misclassified patients. While 81.0% of studies reported methods for calculating diagnostic accuracy, only 28.6% reported four or more estimates of diagnostic accuracy. Only 52.4% of studies reported the prevalence of disease in the target population.

**Conclusions:** Considering the diversity of administrative databases worldwide, the number of published validation studies is small. The quality of the studies and completeness of the reporting of study details varied considerably. Studies to evaluate the validity of administrative database ascertainment of RD in Canada are needed.

**Efficacy and Safety of Cannabinoids for Pain in Musculoskeletal Diseases: a Systematic Review and Meta-analysis.**

Kung T (1), Hochman J (2), Sun Y (3), Bessette L (4), Harouei B (5), Pope J (6), Bykerr V (7)

(1-2) University of Toronto, Ontario Canada, (3) University Health Network, Ontario, Canada, (4) N/A, Quebec, Canada, (5) University of Montreal, QC, Canada, (6) University of Western Ontario, Ontario, Canada, (7) Mount Sinai Hospital, Ontario, Canada

**Objectives:** To evaluate the efficacy and safety of Cannabinoids compared to placebo in adults with musculoskeletal disease.

**Methods:** We performed a systematic review comparing cannabinoids to placebo for the treatment of pain in patients with musculoskeletal (MSK) diseases. Trials were identified in MEDLINE, EMBASE, the Cochrane Library and ACR/EULAR meeting abstracts for 2008-2009. The primary outcome for efficacy was the mean difference in comparable numerical pain outcomes: pain Visual Analogue Scale (VAS) and Numerical Rating Scales (NRS). Primary outcomes for toxicity were serious adverse events (SAEs) and withdrawals due to adverse events. Secondary outcomes for toxicity were 3 specified adverse events (AEs): drowsiness, confusion or euphoria.

**Results:** A total of 4 randomized trials (218 patients) from 2450 citations investigated use of cannabinoids vs. placebo in MSK diseases. Although a much broader definition of MSK disease was entertained, only trials in rheumatoid arthritis (RA), back pain and fibromyalgia (FM) were retrieved. Where comparable data were not available, authors were contacted to obtain original data. For efficacy, the mean difference (10-pt scale) favoured cannabinoid treatment for pain over placebo (mean difference -1.47, 95% C.I. -2.01,-0.94) which is above the minimal important difference. Side effects were rare with no between group differences but analyses were underpowered. With respect to the secondary outcomes, AEs were statistically significantly different and more common in cannabinoids as compared to placebo for drowsiness (OR 4.05, 95% C.I. 0.43,4.01, Power=0.08) or euphoria (OR 4.05, 95% C.I. 0.24,67.39, Power=0.16). Side effects were rare with no between group differences but analyses were underpowered. With respect to the secondary outcomes, AEs were statistically significantly different and more common in cannabinoids as compared to placebo for drowsiness (OR 4.05, 95% C.I. 1.82, 9.00) and confusion (OR 5.48, 95% C.I. 1.91, 15.73), translating to numbers needed to harm (NNH) of 4 and 9 respectively.

**Conclusions:** Cannabinoids appear to be efficacious for treatment of pain in the musculoskeletal diseases RA, FM and back pain. The statistically significant improvement in pain scores corresponded to a modest clinical difference in these few studies (only one in RA) against placebo. Informa- tion is still lacking with respect to the most important toxicity outcomes designated as SAEs and those leading to withdrawal of medication. However, substantial numbers of patients may experience bothersome adverse events such as confusion and drowsiness. Given preliminary efficacy data but incomplete data on toxicity, further studies with cannabinoids in MSK disease are warranted, particularly against active comparators.
An Evaluation of Autoimmune Antibody Testing Patterns in a Canadian Health Region and an Evaluation of a Laboratory Algorithm Aimed at Reducing Unnecessary Testing

Man A (1), Shojania K (2), Phoon C (2), Pal J (2), Hudoba de Badyn M (3), David P (3), Lacaille D (7)

(1,3,4) University of British Columbia, BC, Canada, (5-6) Vancouver Coastal Health, BC, Canada, (7) Arthritis Research Centre of Canada, British Columbia, Canada

Objectives: ANA, ENA, and anti-dsDNA antibodies are being requested at increasing rates in the Vancouver Coastal Health (VCH) region. We attempted to identify areas for improvement in the utilization of these tests by examining ordering patterns retrospectively at the VCH laboratories. We also measured the potential cost benefit of establishing a new laboratory algorithm aimed at reducing unnecessary testing.

Methods: Laboratory data for ANA, ENA, and anti-dsDNA test requests received at VCH laboratories over a three year period (January 2007–December 2009) were reviewed and the following data were extracted: number of tests, dates, results, and ordering physician specialties. Based on the evaluation of this data and a relevant literature review, a laboratory algorithm was constructed and applied retrospectively to laboratory data from inpatients at Vancouver General Hospital from January to December 2009. An analysis of potential cost reduction was performed limited to evaluating costs of laboratory tests.

Results: 18,475 ANA, 10,656 ENA, and 5,170 anti-dsDNA tests were performed over the three year period. 8.5% of the ANA tests were repeats within the VCH laboratories, and of these, 1198/1551 (77%) were ordered after a previously negative result. Of the repeated ANA tests, 1.5% changed from <1:80 to ≥ 1:160 over the three year period. Over half of the ENA and anti-dsDNA tests were ordered simultaneously with ANA, indicating their possible use as screening tests. 15%, 16.8% and 13.3% of ANA, ENA and anti-dsDNA tests, respectively, were positive. A laboratory algorithm was constructed where ENA and anti-dsDNA tests would be automatically cancelled if ANA was negative in the same sample, and automatically cancelled if ANA was positive. Of the repeated ANA tests, 1.5% changed from <1:80 to ≥ 1:160 over the three year period. Of the repeated ANA tests, 1.5% changed from <1:80 to ≥ 1:160 over the three year period. Overall, there is mixed evidence for the short- and long-term effectiveness for interventions incorporating psycho-educational techniques on variables such as self-efficacy, arthritis self-management, psychological well-being, social support, couples’ communication, and physical function. All six interventions with positive health outcomes for the person with arthritis included skills-training specifically targeted to a partner, whereas two of the four interventions with no positive effects did not offer skills-training to partners. A number of limitations were identified, such as small sample sizes, limited long-term follow-up, and self-selection bias (e.g., satisfied couples in long-term relationships).

Conclusions: This systematic review has highlighted the potential role for family or partner-based psycho-educational interventions to promote health outcomes and/or the management of arthritis. More research is required to determine if specific couples might benefit more from inclusion in psycho-educational programs and if, and under what conditions, long-term positive effects are maintained.

Demographics of Seniors Attending a Rheumatology Clinic

Davis P, Juby A

University of Alberta, Alberta, Canada

Objectives: An increasingly aging population is impacting healthcare delivery in subspeciality areas of medicine outside of geriatrics including rheumatology. Geriatric patients can be challenging due to comorbidities and polypharmacy. This study was undertaken to assess the impact and demographics of seniors attending a rheumatology clinic and data compared to a younger cohort.

Methods: A retrospective chart review was undertaken on all patients attending a subspecialty rheumatology clinic in 2008. All patients were screened and triaged for inflammatory arthritis or multisystem connective tissue diseases before attending the clinic. Patients with degenerative arthritis were excluded.

Results: The search yielded 10 articles that met the inclusion criteria (including one that was a long-term follow-up of an included study). The intervention studies focused on OA of the knee/lower extremity (n=6), rheumatoid arthritis (n=3), and systemic lupus erythematosus (n=1). Interventions used a variety of techniques including cognitive behavioural therapy, disease self-management or skills training in social support, communication, problem solving, and/or pain coping; and educational information. The duration of interventions varied from one session with monthly telephone counselling for 6 months (n=1) to weekly meetings for six to 12 weeks (n=9). Overall, there is mixed evidence for the short- and long-term effectiveness for interventions incorporating psycho-educational techniques on variables such as self-efficacy, arthritis self-management, psychological well-being, social support, couples’ communication, and physical function.

Conclusions: Autoantibody tests for rheumatic diseases are being ordered in excess of what is clinically useful. Education is needed to reduce the frequency of ANA tests and to encourage more efficient use of ENA and anti-dsDNA tests. Our proposed laboratory algorithm would reduce laboratory test costs. To effectively impact ordering practices without negative impact on patient care, implementation of the algorithm should be accompanied by appropriate educational information for ordering physicians.
Focus Group to Review a Pilot Education Program for Inflammatory Myositis

Dey A, Flakstad L, Cotton K, Keeling St
University of Alberta, Alberta, Canada

Objectives: The main objective of this study was to review a pilot education program for patients with inflammatory myositis through the use of a patient focus group. The hypothesis was that an education program for inflammatory myositis would improve patient understanding of their condition, efficacy and quality of life.

Methods: Edmonton area rheumatologists were invited to refer their inflammatory myositis patients to participate in a pilot education program and a follow-up focus group. Inclusion criteria included a rheumatologist's diagnosis of either "polymyositis" or "dermatomyositis" and age over 17 years. The main exclusion criteria included inability to speak English and severe disease that would limit participation. Of the nine patients referred to the program, six attended the education program and five agreed to participate in the focus group. The focus group was conducted over 2 hours and was recorded by video camera. A list of pre-specified questions to review the education program was created after conducting a literature search to identify optimal focus group methodology. The rheumatologist (SOK), physiotherapist (LF), and occupational therapist (KC) did not attend the focus group session that was arranged and conducted by the medical student (AD) in order to avoid influencing the responses.

Results: Three main areas of interest emerged from this focus group. (1) Patients felt that disease information provided by this program would serve them better if delivered closer to the time of diagnosis. (2) The patients felt that instruction on how to exercise more effectively was extremely valuable. (3) Continued contact between patients in a support group format after the program was finished ranked highly. Areas for program improvement included: i) increased use of electronic resources such as a website; ii) the inclusion of information on nutrition; and iii) the individualization of exercise programs. Further discussion of the impact of disease on "return to work" was also requested by participants.

Conclusions: The focus group reviewing a pilot education program for inflammatory myositis revealed that such programs are extremely important in improving patient quality of life. This work suggests that education enhances disease management strategies over standard-of-care and may have long-term impact on patient outcomes. Patients were assessed one month prior to the program for objective measures of disease activity and quality of life measures and follow-up data will be available upon reassessment of these patients in November 2010.

(176)
C2–C104

Rheumatology Learning Needs Among Physicians in Kenya

Colmegna I (1), Bartlett S (2), Oyoo O (3)
(1-2) McGill University, Quebec, Canada, (3) University of Nairobi, Kenya

Objectives: The goal of this project was to identify the rheumatological learning needs of primary care physicians and interns in East Africa. Data will be used to inform the development of educational programs to enhance skills to recognize, diagnose and treat patients with musculoskeletal conditions in this region.

Methods: A survey was conducted among physicians attending the Kenya Association of Physicians 2010 Annual Scientific Conference. Areas queried included age, gender, specialty, number of years of practice, weekly patient load, former rheumatology education and duration, most common rheumatic conditions encountered, confidence performing a MSK exam and arthrocentesis, relevance of improving MSK skills and ways to do so.

Results: Participants included 36 (52%) community practicing physicians (CPP) and 33 (48%) residents from 6 cities in Kenya. Most (97%) were GPs or internists. CPP were mostly male (71%) with a mean age of 45.1 ± 9.2 yrs; 52% of residents were male, with a mean age of 30.9 ± 2.5 yrs. CPP and residents reported seeing a median of 80 patients per week. Among CPP, 64% reported that one every ten patients they see has a MSK complaint, compared with 24% of residents (p=.007). Back pain was ranked as the most common condition encountered (64%), followed by OA (47%), RA (19%), gout (11%) and septic arthritis (8%). Almost all physicians (97%) reported receiving some training in rheumatology; however, most (67%) received a total of <2 weeks of instruction. Almost all (91%) reported greater confidence conducting a cardiovascular vs. MSK exam. 34% of CPP vs. 6% of residents reported injecting joints at least 1/month; 11% of CPP and 30% of residents reported not doing injections (p = .001). Only 20% of CPP (but 0% of residents) "always felt confident" injecting joints (p=.01), though notably only in knees. Nearly all (88%) agreed it is "very relevant" to improve their skills in the evaluation and treatment of rheumatic conditions. To improve skills, 82% indicated a preference for face-to-face courses, followed by online tutorials (9%) and printed materials (6%).

Conclusions: Access to rheumatologists is severely limited in Eastern Africa. While internists see many patients with MSK complaints, their training in rheumatological evaluation, diagnosis and treatment remains minimal. Training CPP specific skills to identify and treat patients with musculoskeletal disorders can help improve health and reduce disparities in East African Countries.

(183)
C2–C106

Risk of developing Myocardial Infarction among Uveitis patients

Objectives: The main objective of this study was to review the inflammatory myositis report by a group of patients seen in November 2010.

Conclusions: The focus group reviewing a pilot education program for inflammatory myositis revealed that such programs are extremely important in improving patient quality of life. This work suggests that education enhances disease management strategies over standard-of-care and may have long-term impact on patient outcomes. Patients were assessed one month prior to the program for objective measures of disease activity and quality of life measures and follow-up data will be available upon reassessment of these patients in November 2010.
Teledicine as a Tool Assisting Therapists to Deliver Arthritis Care in Remote/Rural Communities

Linke S, Marcon M, Murdock J, MacQueen S, McGall D, Brown B, Herrington J
The Arthritis Society, Ontario, Canada

Objectives: Teledicine technology is in widespread use and therapists working in rural and remote communities are in a position to improve access to arthritis care through the use of this technology. This presentation will describe how therapists use telemedicine to enhance the integration of arthritis care in remote/rural communities.

Methods: Physical and occupational therapists working for a community rehabilitation program 1 developed a training protocol and trained telemedicine coordinators and nurse practitioners to be the ‘hands’ of the therapists and assess patients with arthritis remotely.

Results: Therapists reported that they have been able to expand the number of communities and patients they served, at a reduced cost in terms of travel time and mileage expense. They reported other benefits including less stress with winter driving, less wear on their vehicles, more efficient use of time, and fewer patient ‘no shows’. They also identified potential benefits for patients including more timely access to care, less client travel and reduced costs of receiving care. Challenges were also identified including difficulties with scheduling and the need for extra people to assist with the technology.

Conclusions: Telemedicine technology was free, efficient and easy to use, offering benefits to therapists delivering arthritis care in remote and rural locations. The potential benefits to patients, other health professionals, rheumatologists and the health care system need to be assessed further.

MU2SCLES online: Musculoskeletal Multi-professional Simulated Collaborative Learning E-nitiativeS online

University of Saskatchewan, Saskatchewan, Canada

Objectives: Musculoskeletal (MSK) medicine exemplifies the benefits of collaborative interprofessional care. By incorporating an interprofessional approach into the foundation years of medical education, one can predict that it will not only encourage more collaborative patient care but that it will be established as ‘standard of care’. Currently, the allocation of teaching time in medical school devoted to MSK-related conditions is disproportionate to the burden of disease in society. As such, there is a need for creative, persistent and standardized MSK educational resources in the undergraduate curriculum.

Methods: A dynamic, self-study MSK learning resource was developed with the aid of various medical disciplines and allied health care professionals in Saskatoon. Actual patient cases are selected in accordance to both commonality of the problem in Saskatchewan and urgency of management to identify a minimum level of competency for managing patients with musculoskeletal problems. With the aid of the Bone Joint Decade Undergraduate Curriculum Group (BJDUCG) recommendations and Medical Council of Canada (MCC) objectives, all possible knowledge, skills, and attitudes that may be relevant to MSK conditions are prioritized. Integration of a Saskatchewan-developed pharmaceutical resource, RxFiles, and online discussion boards are additional features. Pre and post-case quizzes are integrated to reinforce key learning issues.

Results: “MU2SCLES online” complements the lecture component of the University of Saskatchewan undergraduate MSK curriculum. By providing evidence-based teaching, optimal learning can occur while developing an appreciation for the fundamental role of intra and interprofessional collaboration. The pre-clinical learner will gain a greater understanding of the diagnosis and management of MSK conditions through simulated cases, across a variety of clinical settings. Students have the opportunity to familiarize themselves with the clinical use of the evidence-based drug therapy guide RxFiles. Links to external resources encourage self-directed learning and optimal utilization of established, validated online resources.

Conclusions: “MU2SCLES online” provides a standardized, interactive learning experience to a large number of students over a wide geographical area. The flexibility of this resource allows students to gain experience across the various disciplines involved in MSK medicine, ensuring the opportunity for equal exposure to all students. As a relatively low-cost educational tool, e-learning fits in with the distributed nature of today’s learning society. By using an intra and interprofessional, case-based approach, “MU2SCLES online” enhances the learning of musculoskeletal medicine and promotes professional collaboration. Future partnerships through the Canadian Healthcare Education Commons (CHEC) enable sharing of this unique Saskatchewan resource.
Effect of Odanacatib on Bone Density and Bone Turnover Markers in Postmenopausal Women with Low Bone Mineral Density: Year 4 Results

Leung A, Petrovic R, DaSilva C, Rosenberg E, Santora A, Lombardi A

Merck & Co., Inc, NJ, USA

Objectives: The selective cathepsin K inhibitor odanacatib (ODN) reduced bone resorption markers and progressively increased bone mineral density (BMD) during 3 years of treatment in a Phase 2b study. This study was extended for 2 additional years to further assess ODN efficacy and long-term safety.

Methods: In the 2-year base study, postmenopausal women with BMD T-scores between -2.0 and -3.5 at the lumbar spine, femoral neck, trochanter or total hip received placebo or ODN at 3, 10, 25 or 50 mg weekly. In Year 3, participants were re-randomized to ODN 50 mg weekly or placebo. In Years 4/5, women who received placebo or 3 mg ODN in Years 1/2 and placebo in Year 3 were switched to 50 mg ODN for Years 4/5; all others continued with their Year 3 regimen. 141 women entered the extension, and 133 completed 4 years. Endpoints were BMD at the lumbar spine (primary), total hip and hip subregions, and 1/3 radius; levels of biochemical bone turnover markers; and assessments of safety.

Results: Overall, 100 women received 50 mg ODN during Year 4 and 41 received placebo. Continuous treatment with 50 mg ODN for 4 years induced significant BMD increases from baseline at the spine (10.7%), total hip (8.3%), femoral neck (8.9%), and trochanter (10.3%) and maintained BMD (-0.1%) at the 1/3 radius; BMD changes from Year 3 were 2.8% (spine), 2.5% (total hip), 3.9% (femoral neck), and 2.9% (trochanter). Serum CTx remained low at Year 4 (~4%), whereas BSAP was relatively unchanged (~2%) from baseline. Women who received active treatment for 2 years and switched to placebo for 2 years experienced bone loss, with BMD near baseline for most sites and decreased by 4.5% at the 1/3 radius at the end of Year 4. Levels of bone turnover markers in women who discontinued active treatment after 2 years rose in the first month off-treatment, but all levels returned to baseline by the end of Year 4. ODN was generally well tolerated.

Conclusions: 4 years of ODN treatment increased lumbar spine and hip BMD and was generally well tolerated in postmenopausal women with low bone mass. Bone formation markers remained relatively unaffected. Discontinuation of ODN after 2 years of treatment was promptly followed by resolution of effects on bone turnover and density such that BMD and bone biomarker levels at Year 4 were at or near baseline.

GAVE Unmasked by Alprostadil for Digital Ulceration in a Scleroderma Patient

Omair M (1), Johnson S (2)

Mount Sinai Hospital, Ontario, Canada, (2) University of Toronto

Case Report: Objective. Prostaglandins are commonly used in the treatment of systemic sclerosis (SSc)-associated digital ulceration. Similarly, gastro-intestinal (GI) bleeding secondary to vasculopathic lesions in the GI tract is a recognized complication in SSc. We highlight an infrequent but clinically important occurrence in a common practice – gastric antral vascular ectasia (GAVE) unmasked by alprostadil therapy for severe digital ulceration. Case. A 54 year old female with limited SSc based on sclerodactyly, calcinosis, telangectasia, esophageal dysmotility, Raynaud’s phenomenon and anti-centromere antibody presented with a refractory ulcer in the right 3rd digit. She was treated with nifedipine, losartan, topical nitroglycerin, aspirin and pentoxifylline with inadequate response. She was admitted to hospital for intravenous (IV) alprostadil. The ulcer size and pain improved. On day 3 of the infusion, she developed hematemesis and a significant decline in hemoglobin. Endoscopy revealed severe esophagitis, esophageal ulceration and appearance of the stomach consistent with GAVE. A previous endoscopy in February 2008 did not show any of these findings. She was treated with blood transfusion, pantoprazole and discontinuation of alprostadil. The bleeding stopped and her hemoglobin stabilized. Discussion. Prostaglandins produce inhibition of platelet aggregation, vasodilatation and smooth muscle proliferation through a G-protein coupled receptor linked to adenylate cyclase; and promote fibrinolysis by reducing plasma concentrations of tissue-type plasminogen activator and plasminogen activator inhibitor-1. Long-term therapy reduces the level of factor VIII and Von Willebrand factor causing further inhibition of the coagulation cascade. GAVE is a rare but important cause of anemia in SSc patients with a prevalence of 2%-5.7%. The endoscopic pattern of GAVE is classically described as erythematous streaks on the longitudinal rugal folds traversing the antrum and converging on the pylorus. As these streaks resemble the stripes on the outside rind of a watermelon, this condition is also known as “watermelon stomach.” Biopsy specimens demonstrate mucosal dilated capillaries containing fibrin thrombi, reactive epithelial changes, and fibromuscular hyperplasia of the lamina propria. The time of presentation is usually variable, presenting early in the diffuse and late in the limited subtypes; and may be affected by other factors like use of non-steroidal anti-inflammatory agents, steroids and proton pump inhibitors. Conclusion. Alprostadil may precipitate bleeding from high-risk vascular lesions in the GI tract of SSc patients through its vasodilatory effects, inhibition of platelet aggregation, and promotion of fibrinolysis. Identification of high risk patients, close monitoring for occult blood loss and early intervention is recommended.

A 50 Year Old Woman with Fever, Hemoptysis and Rash

Sabbagh Z, Taylor-Gjevre R

University of Saskatchewan, Saskatchewan, Canada

Case Report: BACKGROUND: Churg Strauss Syndrome (CSS) is an eosinophil-associated small vessel vasculitis. Its incidence is 2.4-4 per million which makes it one of the rarest of the systemic vasculitides. ANCA, both PR3 and MPO, have been detected with variable frequencies in patients with CSS and is more associated with cutaneous, neurological and pulmonary involvement. CASE: We present a 50 year-old woman with a history of asthma and rhinitis who was admitted because of fever, hemoptysis, recurrent ear infections, sinusitis, weight loss, and purpuric rash. She reported swelling in her elbows and knees as well as tingling and numbness in her feet. In addition, leukocytosis, eosinophilia, elevation of CRP and ESR were observed. She developed rapid renal failure with serum creatinine of 189, proteinuria of 0.7 g/day and RBC casts. Moreover, ANCA/ PR3 was positive. Chest radiograph and computed tomography showed patchy air-space consolidation in both lung fields. Echocardiogram was normal. Skin biopsy depicted lymphocytic vasculitis with eosinophils. Given the clinical picture, laboratory data and pathologic findings, our patient fulfilled the ACR criteria for diagnosis of CSS. Following the skin biopsies, therapy with methylprednisolone and cyclophosphamide was initiated.
Eosinophilia, fever, hemoptysis, and weakness improved dramatically in the first 24 hr. CONCLUSION: Our patient is a rare ANCA/PR3 positive CSS with involvement of the lung, skin, kidney, and nervous system. The presence of ANCA/PR3 may contribute in severity of her renal impairment. These manifestations in a patient with asthma and eosinophilia should alert the clinician to the possibility of CSS. Immunosuppressive therapy with steroids and cyclophosphamide is beneficial.

Relapsing Polychondritis Associated with Hepatitis C Virus Infection

Hemmati I (1), Yoshida E (2), Shojania K (3)

(1) Department of Medicine, UBC, B.C., Canada, (2) Division of Gastroenterology, UBC, B.C., Canada, (3) University of British Columbia, BC, Canada

Case Report: Objective: Review of relapsing polychondritis (RP) and its association to hepatitis C virus (HCV) infection. Method Used: A case of RP associated with HCV infection in a 59-year-old male is reported. The English medical literature was reviewed for RP and its association with HCV infection. Results Obtained: RP is a rare autoimmune and multisystem disorder of unknown etiology in which the cartilaginous and related tissues are the primary targets of inflammation. HCV infection is a more common systemic illness with known hepatic and extrahepatic manifestations. Although RP is associated with other diseases in about 35% of cases, only one case of RP, HCV and mixed cryoglobulinemia has been reported. We report a case of RP associated with HCV infection. Treatment with pegylated interferon and ribavirin resulted in sustained virologic response and remission of treatment resistant RP with azathioprine. Brief Conclusion: We report a case of RP and associated HCV infection. Although treatment of HCV infection resulted in remission of RP, it is unknown if there is a causal relationship between HCV infection and RP.

Amyloidosis and GCA/PMR: Case report of a rare association

Legault K (1), Shoff A (2), Crowther M (3), Khalidi N (4)

(1,2) McMaster University, Ontario, Canada, (3) St. Joseph’s Healthcare Hamilton

Case Report: Objective: AA amyloidosis is caused by extracellular deposition of fibrils that are composed of fragments of the acute-phase reactant serum amyloid A (SAA) protein. It is associated with several rheumatological conditions, most notably rheumatoid arthritis, juvenile idiopathic arthritis, ankylosing spondylitis, and systemic lupus erythematosus. GCA and or PMR have not been commonly associated, with only nine cases previously reported in the literature. We present a case of secondary amyloidosis presenting as nephrotic syndrome that developed in a patient who was previously diagnosed with GCA/PMR. In contrast to the majority of the cases previously reported, our patient did not have clinical evidence of uncontrolled rheumatologic disease activity at the time of presentation with amyloidosis, with the exception of persistently elevated ESR. To further clarify this complex clinical area we elected to survey the published literature with respect to the association between amyloidosis and GCA/PMR. Methods: We systematically reviewed the published literature and summarized previous cases of AA amyloidosis in GCA/PMR, including treatment options. Results: We identified a total of 9 cases in 7 reports. All except one of the patients reported presented with the nephrotic syndrome and renal dysfunction leading to a diagnosis of amyloidosis. Most of the patients died as a result of progressive renal insufficiency. However two patients were treated with colchicine with subsequent stabilization of creatinine and proteinuria. In our patient, treatment with colchicine was initiated with subsequent evidence of stabilization of renal disease. Conclusion: Our case highlights the need for consideration for the development of amyloidosis in patients with GCA/PMR presenting with renal insufficiency even if their rheumatologic disease is quiescent. Although evidence is limited our results suggest a course of colchicine may be beneficial in ameliorating renal insufficiency.

Multiple Pulmonary Nodules Suspicious for Pulmonary Metastases: a Diagnosis Unmasked by Diffuse Alveolar Hemorrhage

Jeffery J, Hergott C, Gjevre J

University of Saskatchewan, Saskatchewan, Canada

Case Report: While Wegener’s granulomatosis is a rare cause of thoracic pathology, it is important to be aware of the various clinical and radiographic manifestations. We describe a case of Wegener’s granulomatosis initially manifesting as multiple pulmonary nodules presumed to be metastases. A 58-year-old female was seen in the outpatient respiratory clinic at the University of Saskatchewan for the workup of multiple pulmonary nodules recently found on a chest CT performed to evaluate dyspnea. Prior to visiting the clinic she was notified of the CT findings and their potential for pulmonary metastases. A chest x-ray (CXR) and pulmonary function tests (PFTs) were completed the morning of her appointment and available to the physician at the time of initial consultation. A striking result found among normal pulmonary flows and volumes was a DLCO (diffusing capacity of the lung for carbon monoxide) of 136%, suspicious for alveolar blood. The CXR revealed a large area of airspace consolidation within the right mid lung field; a striking change from a CXR done a month prior. Consultation revealed a four-day history of moderate hemoptysis, fatigue, generalized joint discomfort and a ten-pound weight loss with a low-grade fever over the preceding month. Blood work showed a twelve-point reduction in hemoglobin and urinalysis was positive for blood with few dysmorphic red cells and moderate protein. The patient was admitted to the pulmonary service for the work-up of a pulmonary-renal syndrome. Bronchoscopy with bronchouleolar lavage was consistent with diffuse alveolar hemorrhage (DAH) and was negative for organisms and malignant cells. Investigations revealed a positive p-ANCA with a high titre MPO-ANCA. Toxicity and medication-induced etiology was ruled out and she was started on methyl-prednisolone. Limited findings on renal biopsy and a consistently normal creatinine ruled out significant renal involvement. The patient was diagnosed with Wegener’s granulomatosis and treated with daily, oral cyclophosphamide and prednisone. Her DAH drastically improved over a week and her hemoglobin stabilized and gradually improved. Six months following the diagnosis, the patient is clinically in remission on oral cyclophosphamide and prednisone. Physicians are taught to consider uncommon manifestations of common diseases over common manifestations of uncommon diseases. Wegener’s granulomatosis presents a diagnostic challenge to the physician due to its rarity and diverse clinical manifestations. Pulmonary nodules are common CT findings, thus physicians should have a broad differential while interpreting clinical data.
Panniculitis/Fasciitis due to a Drug-Induced Neutrophilic Dermatosis: A case report

Dostrovsky N, Harish S, Verhovsek M, Salana S, Khalidi N
McMaster University, ON, Canada, McMaster

Case Report: Objectives: 1. To describe a case of a neutrophilic dermatosis presenting with panniculitis/fasciitis of the feet 2. To review the musculoskeletal manifestations of neutrophilic dermatoses A 56 year old man presented for evaluation with a one year history of progressive pain and swelling in his feet. The pain and swelling began after he started granulocyte-colony stimulating factor (G-CSF) for idiopathic neutropenia. Other symptoms included fatigue, hoarseness of voice and recurrent bullous skin lesions. On examination, there was diffuse swelling and tenderness over the plantar aspects of both feet. Laboratory investigations were significant for elevated ESR (96mm/hr) and CRP (49.7mg/L). C3 and C4, ANA, p and c ANCA, RF and anti-CCP were all negative. Ultrasound and MRI of his feet showed swelling and hyperemia consistent with panniculitis as well as some fasciitis, but there was no evidence of synovitis, myositis or abscesses. Ultrasound-guided percutaneous biopsy of the inflamed plantar fat was performed. This demonstrated heavy inflammatory infiltration of the tissue including with neutrophils in keeping with a panniculitis/fasciitis. The patient was started on 30mg/day of prednisone and the pain and swelling in his feet dramatically improved. His hoarseness of voice, fatigue and skin lesions also resolved. Additionally, his neutropenia improved and he no longer requires G-CSF. Musculoskeletal involvement, notably arthritis and arthralgia, is a relatively common manifestation of neutrophilic dermatoses such as Sweet’s syndrome. However, this case is unusual in that the primary presenting feature was panniculitis and fasciitis. This case exemplifies the contributions of clinical, radiological and histological assessments in making the appropriate diagnosis and guiding further management.