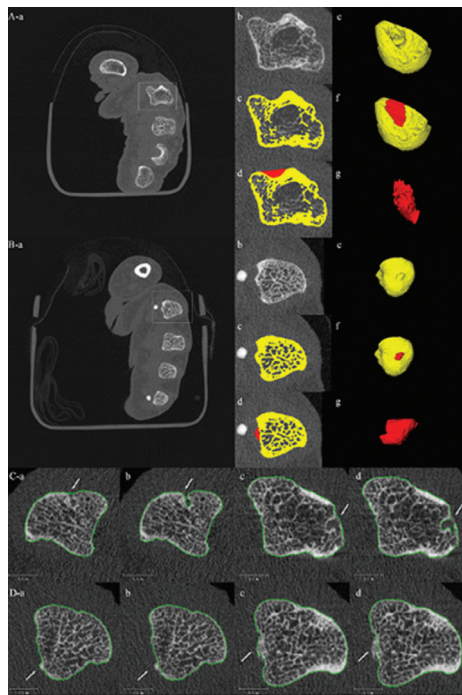


fraction [BV/TV] and Tb. thickness] was observed at the MCH compared to control. After excluding of enthesiophyte, a further deterioration in the Ct. compartment (vBMD, perimeter, thickness) in PsA patients was observed. Regression model in PsA and controls indicated that PsA was independently associated with an increased total volume of enthesiophytes per person. Regression model in PsA showed that CRP, older age and higher BMI were independently associated with an increase in the total volume of bone erosion. On the other hand, older age was independently associated with an increase in total volume of enthesiophyte per person.



Conclusions: Intra-articular trabecular bone loss and enthesial new bone formation was more prevalent in the MCH of patients with PsA.

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THURSDAY, 14 JUNE 2018

RA: such a pain, and beyond

OP0133

UNACCEPTABLE, REFRACTORY PAIN DESPITE INFLAMMATION CONTROL IN EARLY RHEUMATOID ARTHRITIS AND ITS RELATION TO TREATMENT STRATEGY: RESULTS FROM THE RANDOMISED CONTROLLED SWEFOT TRIAL

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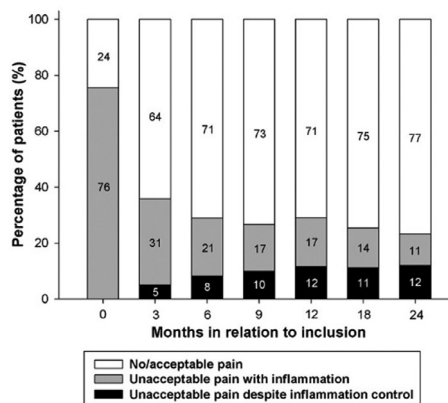
Background: Pain is a major concern of RA patients and earlier work has defined the level considered not acceptable by patients (unacceptable pain according to the patient acceptable symptom state (PASS)¹). While a lot of focus has been put on the occurrence and management of inflammatory pain, less is reported on refractory pain despite inflammation control, and its pattern in early RA.

Objectives: The aim of this study was to investigate the prevalence of unacceptable pain despite inflammation control during the first 2 years after treatment start in new-onset RA patient and to compare the impact of biological vs conventional combination therapy on the occurrence of this pain status.

Methods: The SWEFOT (SWedish FarmacOTherapy) trial was designed as a randomised, active-controlled, open-label study, enrolling early (<1 year) RA patients Oct 2002 to Dec 2005 After a 3 month run-in period on methotrexate (MTX), patients reaching DAS28 ≤ 3.2 continued monotherapy (n=147), while the others were randomised to addition of infliximab (IFX; n=128) or sulfasalazine +hydroxychloroquine (SSZ+HCQ; n=130). Results for disease activity and radiographic data were published earlier. Here, we used a measure of unacceptable pain despite inflammation control as outcome (combining VAS pain >40 mm¹⁰⁰ with CRP <10 mg/L² and ≤ 1 swollen joint (of 28)). When comparing the randomised arms, last observation carried forward in case of protocol breach was used, while for analyses of the whole material we used all data irrespective of protocol breach. Differences in prevalence were analysed by McNemar's test, while differences between patients randomised to IFX vs SSZ+HCQ as well as between EULAR response groups were estimated by logistic regression, adjusting for age, sex and VAS pain at baseline.

Results: In the whole material (including all 3 groups, n=405), the frequency of unacceptable pain despite inflammation control increased gradually from inclusion, reached 12% at 1 year (difference from inclusion; $p<0.001$), and then remained stable until the 2 year follow-up; at that point accounting for more than half of all unacceptable pain (figure 1). The frequency was unrelated to EULAR response from inclusion to the 2 year follow-up (11.4% of good responders vs 10.4% of non-responders, $p=0.95$). Furthermore, no difference in unacceptable pain despite inflammation control at 2 years was found between patients randomised to IFX vs SSZ+HCQ, (adjusted odds ratio 1.1 [95% CI: 0.5 to 2.4]; $p=0.75$).

Conclusions: After 2 years of early active treatment in new-onset RA patient, a substantial portion had unacceptable pain despite inflammation control. This pain status was as common in EULAR good responders as in non-responders and no difference was found between patients randomised to IFX compared to SSZ+HCQ. These data are in line with insufficient effects of current treatment strategies to prevent development of inflammation-independent pain in a subgroup of patients, strongly warranting alternative treatment strategies in these patients.



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OP0134

MULTIFACTORIAL EXPLANATORY MODEL OF FATIGUE IN PATIENTS WITH RHEUMATOID ARTHRITIS: A PATH ANALYSIS

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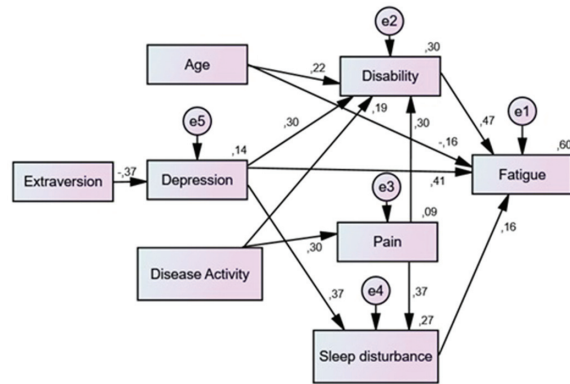
Background: Fatigue is one of the most prevalent and disabling symptoms among patients with Rheumatoid Arthritis (RA). However, it is also one of the most

neglected by health professionals. Much of this problem is due to health professionals' poor understanding of the etiology of fatigue and, also, the absence of effective strategies to prevent or treat it.

Objectives: This study aimed at developing a multidimensional explanatory model of fatigue in patients with RA as means to foster better understanding and care of this symptom.

Methods: This was an ancillary analysis of an observational, cross-sectional, single centre study. Patients completed a questionnaire that included demographic data and measures of sleep (0–10 Numeric Rating Scale (NRS)), pain (0–10 NRS), disability (HAQ), anxiety and depression (HADS), and personality (TIPI). Fatigue was assessed by the Functional Assessment of Chronic Illness Therapy – Fatigue (FACIT-F). Disease activity (DAS28-CRP3v) and haemoglobin levels were also assessed. Path analysis was performed to test and improve a hypothesised model for fatigue.

Results: In total, this analysis included 142 patients (83.1% females, mean (SD) age of 61.1 (11.7) years). The final path analysis model (figure 1) presented acceptable fit (Goodness of Fit Index, GFI=0.92; Comparative Fit Index, CFI=0.89; Root Mean Square Error of Approximation, RMSEA=0.10), and explained 60.0% of the variance of fatigue. Depression and disability had the greater direct influences upon fatigue ($\beta=0.412$; $p<0.001$ and $\beta=0.465$; $p<0.001$, respectively). Sleep disturbance also influenced directly fatigue but at a lower intensity ($\beta=0.157$; $p=0.007$). Disease activity and pain had only an indirect influence on fatigue through disability and sleep disturbance ($\beta=0.149$, $p=0.005$, and $\beta=0.199$, $p=0.005$, respectively). Age was negatively associated with fatigue ($\beta=-0.162$, $p=0.003$). Extroverted patients presented less depressive symptoms and, consecutively, less fatigue ($\beta=-0.224$, $p=0.002$).



Abstract OP0134 – Figure 1 Final path analysis model with standardised direct coefficients.

Goodness of fit index=0.92; Comparative fit index=0.89; Root mean square error of approximation=0.10.

All coefficients in the model presented $p<0.05$.

Conclusions: Depression, disability and sleep disturbance appear to be the main factors explaining fatigue in patients with RA. Disease activity and pain seem to play only a secondary role. These findings foster a shift in the paradigm of patient care towards a more holistic management of fatigue, integrating adjunctive therapies in association with measures driven solely towards abrogation of the inflammatory process.

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OP0135 FOETAL-NEONATAL AND MATERNAL OUTCOMES IN WOMEN WITH RHEUMATOID ARTHRITIS

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Background: Pregnancy involves adaptation to the immune system to prevent rejection of the foetus and this might have consequences on the activity of the rheumatoid arthritis (RA). Equally the aberrant immunity and disease activity of the RA might influence the pregnancy and foetal-neonatal outcomes.

Objectives: This study was designed to estimate the risk of adverse foetal-neonatal and maternal outcomes in pregnancies in women with RA.

Methods: We identified 2,350,339 singleton pregnancies using the Taiwan National Health Insurance database and birth registry between 2001 and 2012. Maternal history of RA, SLE, Sjögren's syndrome, systemic sclerosis, vasculitis and poly/dermatomyositis were ascertained; among them, 845 individuals had RA. Odds ratios (ORs) and 95% confidence intervals (CIs) for pregnancy outcomes were estimated using an adjusted generalised estimating equation model.

Results: Pregnancies in women with RA were associated with an OR (95% CI) of 1.65 (1.37–1.98) for low birthweight (<2500 g) (n=114), 1.41 (1.128–1.68) for prematurity (<37 week) (n=124), and 1.62 (1.36–1.92) for small for gestational age (n=132). Maternal outcomes in pregnancies of women with RA were just associated with an OR (95% CI) of 1.34 (1.06–1.68) for preterm labour (n=74). Women with RA did not have an increased risk of post-partum death, cardiovascular complications, surgical complications, and the other systemic organ dysfunction.

Abstract OP0135 – Table 1

Foetal-neonatal outcomes in pregnancies of women with RA, SLE, Sjögren's syndrome, systemic sclerosis, vasculitis and poly/dermatomyositis different AIRDs.

	RA	SLE	Sjögren's syndrome	Systemic sclerosis	Vasculitis	Poly/ Dermatomyositis
Stillbirth	1.55 (0.99-2.58)	3.43 (2.71-4.33)*	1.29 (0.54-3.11)	1.56 (0.22-11.1)	N/A	1.21 (0.17-8.57)
explained stillbirth	1.06 (0.15-7.56)	3.48 (0.07-3.48)	N/A	N/A	N/A	N/A
unexplained stillbirth	1.69 (0.95-2.71)	3.75 (2.97-4.75)*	1.44 (0.60-3.46)	1.73 (0.24-12.3)	N/A	1.34 (0.19-9.49)
Low birth weight (<2500 g)	1.65 (1.37-1.98)*	3.26 (2.99-3.55)*	2.00 (1.54-2.61)*	2.46 (1.40-4.32)*	0.71 (0.18-2.86)	2.22 (1.34-3.69)*
Prematurity (<37 week)	1.41 (1.18-1.68)*	2.34 (2.14-2.56)*	1.30 (0.97-1.75)	2.34 (1.39-3.95)*	1.14 (0.43-3.05)	1.71 (1.02-2.90)*
Small for gestational age	1.62 (1.36-1.92)*	2.43 (2.21-2.66)*	1.93 (1.50-2.48)*	2.11 (1.22-3.63)*	0.53 (0.14-2.10)	1.51 (0.88-2.60)
Large for gestational age	0.51 (0.39-0.67)	0.34 (0.27-0.42)	0.50 (0.33-0.77)	0.15 (0.02-1.03)	0.64 (0.21-1.98)	0.76 (0.36-1.60)
Apgar score 1 min (<7)	0.94 (0.62-1.43)	3.02 (2.58-3.56)*	2.45 (1.63-3.72)*	1.93 (0.82-5.97)	1.11 (0.16-7.91)	3.82 (1.92-7.69)*
Apgar score 5 min (<7)	0.17 (0.02-1.21)	2.57 (1.83-3.61)*	0.97 (0.24-3.89)	5.68 (1.45-22.3)*	N/A	1.83 (0.26-13.0)
Foetal distress	1.21 (0.93-1.57)	1.33 (1.13-1.56)*	1.81 (1.29-2.55)*	2.49 (1.25-4.95)*	N/A	1.95 (1.02-3.75)*
Foetal abnormalities, any	1.15 (0.89-1.50)	1.25 (1.06-1.48)*	1.29 (0.89-1.87)	1.45 (0.60-3.48)	0.80 (0.20-3.18)	1.24 (0.56-2.77)
Central nervous system malformations	1.71 (0.85-3.43)	1.39 (0.84-2.33)	2.14 (0.80-5.71)	N/A	N/A	N/A
Chromosomal abnormalities	1.34 (0.64-2.81)	0.63 (0.30-1.33)	N/A	N/A	N/A	N/A
Decreased foetal movements	0.59 (0.31-1.14)	0.86 (0.59-1.24)	0.41 (0.13-1.27)	0.92 (0.13-6.51)	0.96 (0.14-6.83)	0.59 (0.08-4.18)
Other/unspecified abnormalities	1.51 (1.06-2.17)*	1.36 (1.06-1.75)*	2.61 (1.73-3.96)*	1.42 (0.35-5.67)	N/A	2.64 (1.10-6.33)*

*Adjusted for age, sex, Charlson comorbidity index, urbanization, income, occupation, birth year, maternal nationality
 Abbreviation: AIRDs, autoimmune rheumatic diseases; RA, rheumatoid arthritis; N/A, not applicable; SLE, systemic lupus erythematosus.
 *p<0.05

Conclusions: Pregnancies in women with RA were at a higher risk for multiple adverse foetal-neonatal outcomes, especially low birthweight (<2500 g), prematurity (<37 week), and small for gestational age. Maternal outcomes showed that just preterm labour was more common in women with RA. Women with RA should not be discouraged to seek pregnancy based on the disease alone.

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