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POS0536

FILGOTINIB DEMONSTRATES CLINICAL EFFICACY IN RHEUMATOID ARTHRITIS INDEPENDENT OF SMOKING STATUS: A POST-HOC SUBGROUP ANALYSIS OF THREE PHASE 3 CLINICAL TRIALS

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Background: Filgotinib (FIL), an oral janus kinase 1 (JAK1) inhibitor, has been evaluated in three phase 3 clinical studies (FINCH 1-3) in adults with moderately-to-severely active rheumatoid arthritis (RA). Patients with RA who currently smoke (a predisposing factor for RA) have been reported to be less likely to respond to anti-TNF α treatment and more likely to discontinue or switch treatment.^{1,2,3} However, the impact of smoking on JAK1 efficacy in RA patients is unknown.

Objectives: A post-hoc sub-group analysis of FINCH patient (pt) data was performed in order to identify associations with smoking status.

Methods: Data from 3452 RA pts participating in the FINCH3 (MTX-naïve; NCT02886728), FINCH1 (MTX-IR; NCT02889796), or FINCH2 (bDMARD-IR; NCT02873936) clinical trials were included for analysis of clinical response at weeks 12 and 24. Logistic regression models were fitted to assess the effects of smoking status on categorical clinical endpoints (ACR20/50/70, CDAI $\leq$ 10, DAS28(CRP) $\leq$ 3.2 or $<$ 2.6). Adjustments were made for covariates selected based on previously published work¹ and listed in the Figure 1 caption. No adjustments of p-values were made for multiple testing.

Results: In the MTX-IR population (FINCH1), current (12% of enrolled patients) and former (13%) smokers treated with ADA+MTX had a lower week 12 ACR50 response rate compared to non-smokers (25% and 28% vs. 39%, nominal p = 0.095 and p=0.21, respectively). In contrast, the ACR 50 response at week 12 in FIL+MTX treated pts showed no association with smoking status. Former smokers had higher response rates than non-smokers in the MTX-IR (FINCH1) and MTX naïve (FINCH3) populations (Table 1). Direct comparison between non-smoking pts in the MTX-IR FIL200+MTX-arm and ADA+MTX-arm showed no significant difference in ACR50 response rate (46% vs. 39%, p=0.08). In contrast, former and current smokers showed significantly better week 12 ACR50 response rates under FIL200+MTX treatment compared to ADA+MTX patients (former smoker: 62% vs. 28%, p=0.0017, current smoker: 50% vs. 25%, p=0.016, Figure 1. Similar observations were made at both weeks 12 and 24 for other clinical endpoints, including ACR20/50/70, DAS28(CRP) $<$ 2.6 or $\leq$ 3.2, and CDAI $\leq$ 10 response criteria.

Table 1. Difference in adjusted ACR50 response rate compared to non-smokers for FINCH1/2/3.

		PBO+MTX [‡]	FIL100+MTX	FIL200+MTX
FINCH1	Current	-1%	+2.4%	+3.3%
	Former	-6%	+12%	+16% (*)
FINCH2 [†]	Current	0%	+13%	-9%
	Former	+9%	-7%	+4%
FINCH3	Current	0%	+1%	+4%
	Former	+4%	+20% (*)	+17% (*)

ACR50 response rate based on fully adjusted logistic regression model. [†]: FINCH2 patients received either MTX or csDMARD. [‡]FINCH3 had active comparator arm of MTX together with PBO to maintain blind. *: p < 0.05, **: p < 0.01, ***: p < 0.001

FINCH1: Week 12 ACR50 Responder Response rate by smoke status

Figure 1. FINCH1 adjusted Week 12 ACR50 response rate stratified by smoking status. ACR50 response rate based on fully adjusted logistic regression model. *: p < 0.05; **: p < 0.01; ***: p < 0.001. Former and current smokers that received FIL200mg + MTX showed a higher response rate compared to similar ADA+MTX patients.

Conclusion: This exploratory analysis showed that current and former smokers with RA who received ADA+MTX trended toward a lower response rate compared to non-smokers. In contrast, FIL+MTX was found to be similarly efficacious independent of smoking status within both the MTX-IR and MTX-naïve RA populations. Current or former smokers were more likely to respond to FIL200mg + MTX compared to ADA+MTX across a range of endpoints. Given the small number of current and former smokers enrolled in these studies, further studies of the efficacy of JAK inhibitors and the mechanism of reduced response to anti-TNFs in patients with a history of smoking are warranted.

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POS0537

TRENDS AND PREDICTORS OF INPATIENT MORTALITY IN PATIENTS WITH CLOSTRIDIODES DIFFICILE INFECTION AMONG THOSE WITH AND WITHOUT RHEUMATOID ARTHRITIS: A NATIONWIDE ANALYSIS

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Background: People with rheumatoid arthritis (RA) have a higher risk of serious infections. The most common nosocomial infection in the United States (US) is *Clostridioides difficile* infection (CDI) and yet, little is known regarding the impact of comorbid RA on outcomes in persons hospitalized with CDI.

Objectives: To evaluate the trends over time and predictors of inpatient mortality in hospitalized patients with CDI comparing those with and without RA.

Methods: We used the National Inpatient Sample (NIS) database, the largest available all-payer database of inpatient hospitalizations in the US. Patients aged

≥18 years admitted with CDI from 2006-2018 were included. Patients with RA were identified using the International Classification of Diseases (ICD) 9 and 10 codes. Categorical variables between CDI patients with and without RA were compared using Chi-squared test. Temporal trends of hospitalization charges, length of stay (LOS) and inpatient mortality were assessed using the Cochran Armitage test. Predictors of inpatient mortality were assessed using multivariable logistic regression adjusting for: age ≥65, sex, race, presence of RA, and Elixhauser comorbidity index.

Results: There were 4,396,945 hospitalizations with a discharge diagnosis of CDI in the study period, of which 111,336 (2.5%) had a coexisting diagnosis of RA. Over the study period, the proportion of CDI patients with a diagnosis of RA increased from 1.7% in 2006 to 3.3% in 2018 with a statistically significant trend of rise (p trend <0.001). There were significantly more females in the RA group (78.2%) than without RA (57.5%), p <0.001. RA group was significantly younger (68.0 vs 70.7, P <0.001). Races were similar between the groups.

The inflation-adjusted average charge for hospitalization for CDI without RA was significantly higher than for CDI with RA (\$95,863 vs \$73,025, p <0.001). There was an increasing trend in inflation-adjusted average charge for hospitalization for both CDI without RA (\$76,966 in 2006 to \$104,552 in 2018, p <0.001) and CDI with RA (\$55,689 in 2006 to \$77,295 in 2018, p <0.001). Patients with or without RA had the same median length of stay (LOS) of 7 days. But when trended over time, for patients without RA, the median LOS decreased from 8 days in 2006-08 to 6 days in 2016-18 whereas for patients with RA, the median LOS fluctuated between 6 and 7 days over the course of study period.

CDI patients without RA had a significantly higher mortality over the study period than those with RA (7.8% vs 6.1%, p <0.001). Among non-RA CDI patients, mortality decreased from 9.3% in 2006 to 6.3% in 2018 (p trend <0.001). Hospitalizations of people with CDI and comorbid RA showed an overall decreasing trend (p trend <0.001).

The multivariable analyses found age ≥65 was associated with increased inpatient mortality (adjusted odds ratio [aOR], 1.77, 95% confidence interval [CI], 1.73-1.80), whereas a diagnosis of RA was associated with a decreased mortality (aOR 0.86, 95% CI, 0.81-0.91) (Table 1).

Table 1. Predictors of inpatient mortality

	aOR	95% C.I. for aOR		P-value
		Lower	Upper	
Age ≥ 65	1.765	1.730	1.801	<0.001
Hospitalization years				
-Years 2006-2011	Ref			
-Years 2011-2014	0.707	0.693	0.721	<0.001
-Years 2015-2018	0.582	0.569	0.594	<0.001
Elixhauser Comorbidity Index	1.056	1.055	1.056	<0.001
Rheumatoid Arthritis	0.859	0.810	0.911	<0.001
Female	0.870	0.855	0.885	<0.001
Race				
-White	Ref			
-African American	1.071	1.044	1.099	<0.001
-Hispanic	1.144	1.108	1.180	<0.001
-Asian/Pacific Islander	1.267	1.200	1.337	<0.001
-Native American	1.022	0.910	1.147	0.716
-Other races	1.263	1.201	1.329	<0.001

aOR = Adjusted Odds Ratio; C.I. = confidence interval

Conclusion: In this nationwide study, among hospitalized patients with CDI, those with comorbid RA had significantly decreased odds of inpatient mortality than those without RA. Further studies are needed to understand this association.

Figure 1.

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POS0538

RELATIONSHIP BETWEEN HINDFOOT DEFORMITIES AND ULTRASOUND TENOSYNOVITIS IN RHEUMATOID ARTHRITIS

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Background: Rheumatoid arthritis (RA) is an inflammatory disease that frequently affects the joints and soft tissues of the feet. Tibialis posterior tenosynovitis has a reported prevalence between 13 and 64% in RA. The condition is associated with a progressive flat foot deformity and significant gait disability. However, few studies have investigated the relationship between foot deformities and the involvement of tendons. Recently, ultrasonography (US) has been reported as the gold standard for the investigation of tendons.

Objectives: This study aimed to assess the relationship between hindfoot deformities and US tenosynovitis in RA.

Methods: We conducted a cross-sectional study including patients with RA (ACR/EULAR 2010). Demographic data and disease parameters were collected. For each patient, a podoscope examination of both feet was performed by a rheumatologist. A radiologist experienced in musculoskeletal imaging performed a US examination using a Philips HD11 device with a high-frequency linear transducer. The assessed lesions were synovitis of the tibiotalar, talonavicular, and subtalar joints, and tenosynovitis of tibialis anterior (TA), extensor hallucis longus (EHL), extensor digitorum longus (EDL), tibialis posterior (TP), flexor digitorum longus (FDL), flexor hallucis longus (FHL), fibularis brevis (FB) and fibularis longus (FL) tendons. The presence or absence of synovitis and tenosynovitis was recorded, and the composite synovitis score (power doppler/grayscale ultrasound (PDUS)) was measured for each joint. The US score of each patient was defined by the sum of the composite scores of the joints studied (0-30). A p-value <0.05 was considered significant.

Results: Sixty-two feet were examined in 31 RA patients (25 women and six men) with a mean age of 54.8±10.8 years old [32-70]. The mean disease duration was 8.5±7.2 years [1-37]. Rheumatoid Factor (RF) and Anti-Citrullinated Peptides Antibodies (ACPA) were positive in respectively 61.3% and 83.8% of cases. The mean DAS28 ESR was 3.8±1.5 [0.6-7].

Podoscope examination revealed pes planus valgus (PPV) in 55.6% of cases and pes cavus varus (PCV) in 18.5% of cases. US showed tibiotalar synovitis in 59.3% of cases, talonavicular synovitis in 64.8% of cases, and subtalar synovitis in 46.3% of cases. In the anterior compartment, tenosynovitis of TA was noted in 5.6% of cases, of EHL in 1.9% of cases, and EDL in 9.3% of cases. In the medial compartment, tenosynovitis of TP was found in 22.2% of cases, of FDL in 5.6% of cases, and FHL in 0% of cases. In the lateral compartment, tenosynovitis of FB and FL was found in 25% and 11.1% of cases respectively.

An association between PPV and synovitis of the tibiotalar joint (p <0.001) and the subtalar joint (p =0.007) was found. An association was also noted with FL tenosynovitis (p =0.045) but not with the other assessed tendons.

No association was noted between PCV and synovitis or tenosynovitis of the assessed structures.

Conclusion: PPV was frequent among RA patients. This condition was associated with tibiotalar and subtalar synovitis and FL tenosynovitis. It is important to detect and correct foot deformities in order to ensure optimal control of the disease.

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POS0539

PAIN IS AN INDEPENDENT ASSOCIATED FACTOR ON FUNCTIONAL LIMITATION IN CHINESE PATIENTS WITH EARLY RHEUMATOID ARTHRITIS

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Background: Rheumatoid arthritis (RA) is a leading cause of extremity disability in Chinese female population according to 2006 national survey. However, less epidemiological data about functional limitation in Chinese RA patients have been published.

Objectives: To investigate the prevalence, characteristics and associated factors of functional limitation in Chinese RA patients.

Methods: Consecutive patients with RA were recruited. The demographic and clinical data were collected including indicators of disease activity, functional assessment and radiographic assessment. According to Health Assessment