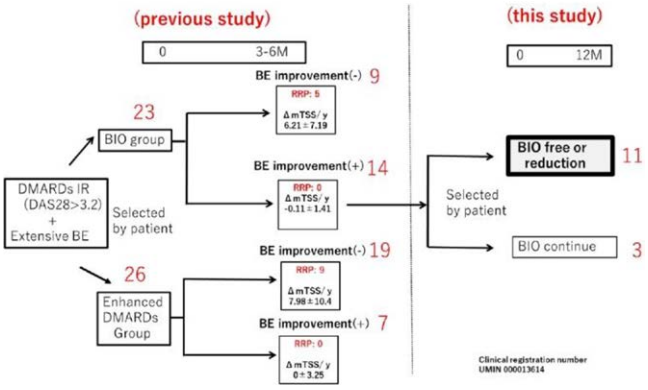
Figure 1 Study Protocol



Disclosure of Interests: None declared
DOI: 10.1136/annrheumdis-2020-eular.3187

AB0299

REAL-WORLD ASSESSMENT OF GP2015 (ETANERCEPT BIOSIMILAR, SDZ-ETN): AN INTERIM ANALYSIS OF DATA FROM THE SELF-INJECTION ASSESSMENT QUESTIONNAIRE IN PATIENTS WITH RHEUMATOID ARTHRITIS IN THE COMPACT STUDY

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Background: COMPACT is a non-interventional study to collect real-world evidence in European countries and Canada on effectiveness, safety and quality of life in rheumatoid arthritis (RA), ankylosing spondylitis or psoriatic arthritis patients (pts) treated with SDZ-ETN (GP2015), an approved etanercept biosimilar. The first effectiveness and safety data from the study have been reported earlier[1].
Objectives: This interim analysis assessed patient usage behaviour and feelings of self-administered injection in general and with the auto-injector device using the Self-Injection Assessment Questionnaire (SIAQ) at Week 12 in pts with RA.
Methods: Pts aged ≥18 years for whom treatment with SDZ ETN were initiated are being enrolled. The SIAQ, a patient questionnaire validated for pts with RA, was developed to assess overall pt experience with subcutaneous self-injection[2]. It assesses the perceived self-confidence on self-injection, potential barriers, as well as satisfaction with self-injection via device before the first self-injection (PRE module) and after dosing (POST module). The POST module used in COMPACT includes 21 items grouped into six hypothetical domains: "feelings about injection," "self-image," "self-confidence," "injection-site reactions," "ease of use of self-injection device (SD), and "satisfaction with self-injection." Descriptive statistics were used to summarise SIAQ POST module data. The results for "ease of use of SD" domain are reported here. The "ease of use of SD" was rated by pts on a 6-point scale: 1 (very difficult) to 6 (very easy).
Results: Of the 430 pts recruited, pts with RA represented the largest group (59.5%, n=256). Majority of pts with RA (77.7%) had comorbidities. Of the 256 pts with RA, 102 (40%) pts who used SD responded to the questionnaire. Majority of the pts found usage of the SD easy or very easy, for each of the domains assessed (Table). 49 % and 14% of the patients were "comfortable" and "very comfortable", respectively using the SD. A majority of patients reported to be bothered by pain at the injection site "not at all" or only "a little" (69.6%), and to be bothered by redness "not at all" or only "a little" (89.2%), respectively.

Table. Overall patient experience with usability of self-injection device at Week 12 (RA population)

Domain: Ease of use of self-injection device

Questions	Category, %						
	Very easy	Easy	Some what easy	Somewhat difficult	Difficult	Very difficult	N/A
Removal of Cap	36.3	34.3	16.7	4.9	3.9	2.0	2.0
To depress the device	34.3	42.2	13.7	2.9	2.0	2.9	2.0
To administer without any help	42.2	35.3	10.8	2.0	2.0	5.9	2.0
Use of self-injection device	38.2	37.3	11.8	3.9	2.9	3.9	2.0

Conclusion: The interim analysis results, although descriptive, show a clear trend for ease of use and good satisfaction with SDZ-ETN SD in pts with RA.

References:
[1] Schmalzing M, et al. *Arthritis Rheumatol*. 2019;71 (suppl 10).
[2] Keininger D, et al. *Health Qual Life Outcomes*. 2011,13;9:2.

Disclosure of Interests: Herbert Kellner: None declared, Ayman Askari Speakers bureau: Eli Lilly, Pfizer, Thomas Kupka: None declared, Hilke Friccius-Quecke Employee of: Sandoz Hexal AG, Fabricio Furlan Employee of: Sandoz Hexal AG, Sohaib HACHAICHI Employee of: Sandoz Hexal AG, Marc Schmalzing Consultant of: Paid consultant for Hexal AG
DOI: 10.1136/annrheumdis-2020-eular.1776

AB0300

SEVERITY FACTORS IN RHEUMATOID ARTHRITIS AND SPONDYLOARTHRITIS IN NEWLY TREATED PATIENTS WITH BIOLOGICS: SURVEY OF THE BINAR REGISTRY

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Background: Rheumatoid arthritis (RA) and spondyloarthritis (SA) are two heterogeneous diseases but both being major causes of disability in our practice. Biologic treatments have changed miraculously the course of these diseases in the past two decades.
Objectives: To determine severity factors in RA and SA patient newly treated with biologics.
Methods: A survey using results of the Tunisian registry BINAR including ten rheumamtology centers was conducted. Adults of 18 years or more were included. Only those meeting the ACR/EULAR 2010 critera for RA or the ASAS 2009 criterea for SA and treated with biologics for 2 years or less were included.
Results: Two hundred and ninety-eight patientd were enrolled including 111 males and 187 females (sexe ratio H/F of 0.6. The mean age was 49.1 years ± 14.1. The mean disease duration was 6.7 years ± 3.5 for RA and 6.5 years ±3.6 for SA. All patients were prescribed biologics for poor response under NSAIDS or conventional DMARDS. Smoking was reported in 17.7% patients. High disease activity defined as a DAS 28 VS score>5,1 in RA and was reported in 36% of cases. HAQ>2 was present in 14.3%, erosive forms were reported in 73.1% of cases. Rheumatoid factor (RF) and anti cetrullinated peptide antibodies were highly positive (>3x normal rates) in 71,2% and 62.4% of cases respectively. As for AS, active disease was defined by ASDAS CRP or ASDAS VS>2,1 or BASDAI>4 and was reported in 39%, 39.8% and 56.9 % of cases respectively. The functional score BASFI>4 was reported in 54.5% of cases. On the whole, a coxitis was noted in 48.8% of cases and extra articular manifestations (EAM) were present in 59.3 % of cases. Statistical analysis for SA patients didn't show an association between active disease (ASDAS>2,1 and different parameters (genre (p=0.205), smoking (p=0.120), inflammation in biology (p=0.481), uveitis (p=0.241) and the presence of coxitis (p=0.375)). Nevertheless, RA patients with severe disease were more likely men (p= <0.001). Other features for RA patients showed no significant statistical difference (age (p= 0.253), inflammation on biology (p=0.963), positive RF (p=0.789), ACPA positive (p=0.258), présence de EAM (p=0.382), erosive forms (p=0.203) and HAQ≥2 (p =0.219).
Conclusion: It's important to determine clinical, biological and radiographic factors in RA and SA patients as well as activity scores in order to recognize patients potentially at risk of poor progression and for better therapeutic management and biologic treatment may have an influence on these factors.

References:
[1] Wagner E, Ammer K, Kolarz G, Krajnc I, Palkonyai E, Scherak O, et al. Predicting factors for severity of rheumatoid arthritis: a prospective multicenter cohort study of 172 patients over 3 years. Rheumatol Int. 1 sept 2007;27(11):1041-8.

Disclosure of Interests: None declared
DOI: 10.1136/annrheumdis-2020-eular.5669