TÜBİTAK

Turkish Journal of Medical Sciences

http://journals.tubitak.gov.tr/medical/

Research Article

Turk J Med Sci
(2018) 48: 856-861

doi:10.3906/sag-1807-200

Methodology of a new inflammatory arthritis registry: TReasure

Umut KALYONCU[1], Etem Koray TAŞCILAR[2], Ali İhsan ERTENLİ[1], Hüseyin Ediz DALKILIÇ[3], Cemal BES[4], Orhan KÜÇÜKŞAHİN[5], Timuçin KAŞİFOĞLU[6], Nilüfer ALPAY KANITEZ[4], Hakan EMMUNGİL[7], Gezmis KİMYON[8], Nazife Şule YAŞAR BİLGE[6], Servet AKAR[9], Mehmet Pamir ATAGÜNDÜZ[10], Süleyman Serdar KOCA[11], Aşkın ATEŞ[12], Veli YAZISIZ[13], Ender TERZİOĞLU[13], Emine Duygu ERSÖZLÜ[14], Müge Aydın TUFAN[15], Muhammet ÇINAR[16], Rıdvan MERCAN[17], Ali ŞAHİN[18], Şükran ERTEN[19], Yavuz PEHLİVAN[3], Sedat YILMAZ[16], Ayşe Bahar KELEŞOĞLU DİNÇER, Önay GERÇİK[9], Belkıs Nihan COŞKUN[3], Burcu YAĞIZ[3], Sema KAYMAZ TAHRA[10], Aysun AKSOY[10], Ömer KARADAĞ[1], Levent KILIÇ[1,*], Sedat KİRAZ[1]

[1]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Hacettepe University, Ankara, Turkey
[2]Rheumatology Clinic, Okmeydanı Training and Research Hospital, İstanbul, Turkey
[3]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Uludağ University, Bursa, Turkey
[4]Rheumatology Clinic, Bakırköy Dr. Sadi Konuk Training and Research Hospital, İstanbul, Turkey
[5]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, İstinye University, İstanbul, Turkey
[6]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Eskişehir Osmangazi University, Eskişehir, Turkey
[7]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Trakya University, Edirne, Turkey
[8]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Mustafa Kemal University, Hatay, Turkey
[9]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, İzmir Kâtip Çelebi University, İzmir, Turkey
[10]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Marmara University, İstanbul, Turkey
[11]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Fırat University, Elazığ, Turkey
[12]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Ankara University, Ankara, Turkey
[13]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Akdeniz University, Antalya, Turkey
[14]Unit of Rheumatology, Adana Numune Training and Research Hospital, Adana, Turkey
[15]Unit of Rheumatology, Başkent University Adana Hospital, Adana, Turkey
[16]Division of Rheumatology, Department of Internal Medicine, Gülhane Faculty of Medicine, University of Health Sciences, Ankara, Turkey
[17]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Namık Kemal University, Tekirdağ, Turkey
[18]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Cumhuriyet University, Sivas, Turkey
[19]Division of Rheumatology, Department of Internal Medicine, Faculty of Medicine, Yıldırım Beyazıt University, Ankara, Turkey

Received: 21.07.2018 • **Accepted/Published Online:** 11.08.2018 • **Final Version:** 16.08.2018

Background/aim: The TReasure registry, created in 2017, is an observational multicenter cohort that includes inflammatory arthritis patients. This article reviews the methodology and objectives of the TReasure registry established to collect data from rheumatoid arthritis (RA) and spondyloarthritis (SpA) patients.

Methodology: Fifteen rheumatology centers in Turkey will contribute data to the TReasure database. The actual proprietor of the database is the Hacettepe Rheumatology Association (HRD) and Hacettepe Financial Enterprises. Pharmaceutical companies that operate in Turkey (in alphabetical or er), Abbvie, Amgen, BMS, Celltrion Healthcare, Novartis, Pfizer, Roche, and UCB, support the TReasure registry. TReasure is a web-based database to which users connect through a URL (https://www.trials-network.org/treasure) with their unique identifier and passwords provided for data entry and access. TReasure records demographic and clinical features, comorbidities, radiology and laboratory results, measures of disease activity, and treatment data.

Discussion: TReasure will provide us with various types of data, such as a cross-sectional view of the current nationwide status of the patients currently receiving these treatments, and retrospective data as much as allowed by the participating centers' records. Finally, a high-quality prospective dataset will be built over the ensuing years from patients with a new diagnosis of RA or SpA.

Key words: Rheumatoid arthritis, spondyloarthritis, disease-modifying antirheumatic drugs, registry, TReasure

* Correspondence: drleventkilic@yahoo.com

1. Introduction

Registry of clinical, laboratory, and treatment features of chronic diseases is a significant achievement of modern medicine gained through informatics. Inflammatory arthritis is one example of such chronic diseases. Information concerning the broad nature and progress of arthritis can be collected thanks to regular registry and follow-ups. Monitoring patients at regular intervals and systematic, structured, long-term observations contribute to improvement in patient care and achieving a high-level standard. Observing patients' and clinicians' treatment choices, effects of treatment, and, more to the point, possible harms may help alert the patients and clinicians at early stages. Registries in rheumatology started around the early 2000s. These registries were established in single centers or assumed international multicenter structures. Registries for inflammatory arthritis were established in England, France, Germany, Sweden, Denmark, Italy, the United States, and South America (1–8). By this means, as an outstanding example, we understood that proper implementation of latent tuberculosis treatment decreases the risk of tuberculosis reactivation (9).

The Hacettepe University Biologics Registry (HUR-BIO) has recorded patients on biologic disease-modifying antirheumatic drug (bDMARD) treatments as a single center since 2005 (10). As of March 2017, approximately 2200 spondyloarthritis (SpA) and 1400 rheumatoid arthritis (RA) patients on bDMARD treatments were registered in the HUR-BIO registry. Since single-center registries record their entries in a uniform manner, there is not a problem of missing data. On the other hand, there are some disadvantages, such as not being widespread throughout the country and not being able to monitor externally. For this reason, starting from March 2017, to embrace other rheumatology centers, the widening of the HUR-BIO database has been mapped out. This article reviews the methodology and objectives of the TReasure registry established to collect data from RA and SpA patients.

2. Methodology

2.1. Administrative, financial, and ethical matters

Fifteen rheumatology centers in Turkey will contribute data to the TReasure database. The actual proprietor of the database is the Hacettepe Rheumatology Association (HRD) and Hacettepe Financial Enterprises. Pharmaceutical companies that operate in Turkey (in alphabetical order), Abbvie, BMS, Celltrion Healthcare, Pfizer, Roche, and UCB, support the TReasure registry. TReasure is a web-based database to which users connect through a URL (https://www.trials-network.org/treasure) with their unique identifier and passwords provided for data entry and access. Each center can access previously contributed data from the patients under their follow-up. The coordinating center can monitor the entirety of the data from all centers. Omega Research Organization Training and Counseling Ltd. handles all required correspondence with ethics committees and external monitoring. Local ethics committee approval for the TReasure database was obtained in May 2017 from Hacettepe University (KA-17/058) and in October 2017 from the Ministry of Health of Turkey (93189304-14.03.01)

2.2. Features of the database

2.2.1. General features of TReasure

TReasure is intended as a prospective observational cohort with two major subcohorts for RA and SpA. Demographic information, birthdate, sex, contact information, educational status, and social security information are recorded for all RA and SpA patients deemed eligible.

2.2.2. Eligibility criteria for TReasure

At the time of manuscript preparation, TReasure started recording RA and SpA patients. Currently the database records prevalent patients on conventional synthetic DMARD (csDMARD), bDMARD, and targeted synthetic DMARD (tsDMARD) treatments. After the study kick-off we plan to record all patients starting tsDMARD or bDMARD treatments. We also plan to record patients that are prevalent users of tsDMARDs and bDMARDs attending outpatient clinic visits. For every 10 patients using a tsDMARD or bDMARD, 3 patients using csDMARDs will be registered in the system. Written informed consent will be obtained from all participants before cohort entry.

2.2.3. Diagnosis

Two sets of classification criteria will be applied for RA diagnosis. These are the 1987 American Colleague of Rheumatology (ACR) criteria (11] and the 2010 European League Against Rheumatology (EULAR)/ACR classification criteria (12). Otherwise the clinical diagnosis of the rheumatologist will also be accepted. With respect to SpA diagnoses, patients fulfilling the modified New York criteria are eligible (13); for axial SpA, the 2009 EULAR axial SpA classification criteria (14) as well as the peripheral SpA classification criteria (15) are eligible. Classification criteria for psoriatic arthritis (CASPAR) criteria will be utilized to validate psoriatic arthritis (PsA) diagnoses (16). For patients with enteropathic arthritis, evidence for a diagnosis of Crohn's disease or ulcerative colitis will be sought in addition to peripheral joint involvement or axial involvement.

2.2.4. Comorbidities

TReasure records a prespecified set of comorbid diseases for both RA and SpA patients. Namely, these are hypertension (date of diagnosis, current drugs), diabetes mellitus (date of diagnosis, current drugs, current status of microvascular complications), osteoporosis (results of bone densitometry

and osteoporosis drugs), dyslipidemia (date of diagnosis, lipid-lowering medications, lipid profile), kidney disease (creatinine and estimated glomerular filtration rate (GFR)), chronic pulmonary disease (COPD and asthma), thyroid diseases, cardiovascular disease (myocardial infarction, congestive heart failure, valvular disease, diagnoses, and treatments), presence of thromboembolic disease and sites of involvement, peptic ulceration and gastrointestinal bleeding, chronic liver disease, type and date of cancer, presence of amyloidosis, neurologic conditions (dementia, cerebrovascular accident), presence of acquired immune deficiency syndrome (AIDS), and previous surgery. A baseline Charlson Comorbidity Index score will be calculated for each patient and updated longitudinally as additional comorbidity occurs (17).

2.2.5. Rheumatoid arthritis extraarticular involvement

TReasure records prevalent and new extraarticular involvement in patients with RA. For interstitial lung disease, date of onset and diagnosis, physical examination findings, score of labored breathing (Borg scale), spirometry results, and findings from chest radiography and computed tomography imaging are recorded (18). Other extraarticular findings that will specifically be sought include skin ulceration and subcutaneous nodules, neurologic deficits (entrapment neuropathy, atlantoaxial involvement, peripheral nervous system involvement, central nervous system involvement), Felty's syndrome, scleritis, Sjögren's syndrome, and hematologic abnormalities.

2.2.6. Spondyloarthritis examination and extraarticular involvement

TReasure records the presence of inflammatory back pain (as per Calin, ASAS, and Berlin criteria) (19–21), enthesitis (as specified in the Leeds Enthesis Index (LEI)) (22), peripheral arthritis, and dactylitis. In addition, extraarticular involvement such as uveitis (date of first attack, number of attacks, presence of permanent damage, site and extent of involvement), inflammatory bowel disease (Crohn's disease, ulcerative colitis, and indeterminate colitis), psoriasis (affected skin area, nail involvement), and presence of familial Mediterranean fever (FMF) (clinical symptoms, response to colchicine treatment, MEFV mutation) are also recorded. Family history of SpA, psoriasis, and FMF will also be included.

2.2.7. Radiology and laboratory results

TReasure records the presence of erosions in hand and feet radiographs. Participating centers also perform and record the results of an ultrasound scan of the wrist and the 2nd metacarpophalangeal and 5th metacarpophalangeal joints for patients who are to initiate bDMARD or tsDMARD treatments. Highest values of RF and anticyclic citrullinated peptide (anti-CCP) values from first diagnosis up until registration are recorded.

Centers record the degree of sacroiliitis in pelvic X-ray, presence of syndesmophytes in the spinal column, reduction in hip joint space (none, mild, medium, severe, in need of prosthesis), findings from sacroiliac MRI scans (active and chronic changes indicating sacroiliitis), and results of human leucocyte antigen (HLA)-B27 tests for patients with AS.

2.2.8. Measures of disease activity

A battery of RA core domain items are recorded in TReasure in order to longitudinally follow disease activity. Namely, these are tender and swollen joint counts in 66 and 68 joints respectively, the Health Assessment Questionnaire Disability Index (HAQ-DI) (23), patient global assessment of overall disease activity-visual analog scale (VAS) (0–100 mm), pain-VAS (0–100 mm), physician global assessment of overall disease activity-VAS (0–100 mm), fatigue-VAS (0–100 mm), and morning stiffness (duration in minutes and severity). Acute phase response markers, erythrocyte sedimentation rate (ESR) (mm/h), and C-reactive protein (CRP) (mg/dL) are also recorded. Using these core domain items, the following composite disease activity measures are calculated: Disease Activity Score (DAS)-28-ESR and/or DAS-28-CRP (24), Simplified Disease Activity Index (SDAI), and Clinical Disease Activity Index (CDAI) (25).

The battery is different for patients with SpA. It includes back pain-VAS (0–100 mm), peripheral pain/swollen joint-VAS (0–100 mm), count of fingers with dactylitis, morning stiffness (duration in minutes and severity), overall pain-VAS (0–100 mm), physician global assessment -VAS (0–100 mm), patient global assessment VAS (0–100 mm), fatigue-VAS (0–100 mm), and swollen and tender joint counts as in RA. Acute phase reactants, ESR (mm/h), and CRP (mg/dL) are recorded. Featured composite outcome/activity indices are the Bath Ankylosing Spondylitis Activity Index (BASDAI) (26), Bath Ankylosing Spondylitis Functional Index (BASFI) (27), HAQ-DI (25), ASAS disease activity scale as ASDAS-ESR (28) and ASDAS-CRP (28), EQ-5D (29), LEI (22), and ASAS life quality index (30). For PsA patients an additional small battery consisting of PsAID-12 (31) and PSI (32) is assessed.

2.2.9. Treatment data

TReasure utilizes a similar data entry procedure for all treatments in RA and SpA. All csDMARDs have a dose, route of administration, start and end dates, and reason for cessation if treatment is stopped. For nonsteroid antiinflammatory drugs (NSAIDs), the compound, daily average dose, and weekly frequency of use are noted. Dosage and duration of glucocorticoids are also recorded. Among bDMARDs, all products licensed in Turkey, namely abatacept, adalimumab, anakinra, canakinumab, certolizumab, etanercept, golimumab, infliximab, rituximab, secukinumab, tocilizumab, and ustekinumab,

are noted. Currently the only licensed tsDMARD in Turkey is tofacitinib.

2.2.10. Visit data

As per the social security reimbursement regulations for bDMARDs or tsDMARDs in Turkey, patients receiving any of these medications must be examined/evaluated by their providers every 3 months and new treatment prescribed if need be. For this reason, our prospect is to record patients' visits every 3 months. However, since the database reflects real life, data will be entered as encounters occur. Each visit record will include the currently received csDMARD, tsDMARD, and bDMARD so that treatment switches, cessations, and initiations can be easily tracked with good temporal resolution.

In the event that the attending clinician decides to stop bDMARD or tsDMARD treatment, the reason for treatment cessation will be recorded. These reasons are categorized as inefficiency, decision to conceive, physician's request, adverse events, and others. In the case of inefficiency, data about the type of inefficiency, primary or secondary, will be recorded. Adverse events are categorized as injection site reactions, infusion reactions, infections (life-threatening, requiring hospitalization, requiring parenteral treatment with antibiotic/antiviral/antifungal drugs, or prolonging hospital admission), psoriasis, systemic lupus or lupus-like events, uveitis, reactivation tuberculosis, neurologic events, cancer, abnormal liver function tests, leukopenia, thrombocytopenia, anemia, gastrointestinal adverse events, and others.

2.3. Studies in progress

At the time of manuscript preparation, 24 observational study proposals were submitted to the TReasure administration; 21 of these were from the collaborating centers and three were from the pharmaceutical industry. A descriptive account of demographic and clinical information of patients receiving csDMARD, tsDMARD, and bDMARD treatments is currently underway. This exercise, in addition to describing the overall TReasure cohort, will also include the current disease activity status with each drug/combination, drug survival, and differences in baseline characteristics of individuals receiving various treatments.

One major topic of studies in progress is the association between patient characteristics and treatment response. Two such studies will explore separately for RA and SpA the response to various treatments by comorbidity load as defined by the items of Charlson Comorbidity Index. A number of studies will explore extraarticular RA cases such as interstitial lung disease (ILD), clinical features, and influence on treatment selection, as well as the relation between various treatments and ILD progression/prognosis, and secondary Sjögren's syndrome and its relationship with RA clinical course and treatment response. csDMARD prescription for axial spondyloarthritis is not uncommon in Turkey. Extrapolating from studies on RA, one of the collaborating groups aims to study the effect of csDMARD use on bDMARD efficacy and drug survival in SpA patients. Another participating center launched a descriptive study of enteropathic arthritis patients and their response to new-generation treatments, a topic at large unexplored in large-scale studies.

Another major topic is the treatment of inflammatory arthritis subpopulations. One such study will describe the SpA subpopulation with uveitis and explore the risk factors and course. Another study will compare and contrast RA and SpA patients with diabetes in order to understand whether and how the clinical course and treatment response in this subpopulation is altered. Although RA is a disease of the middle aged, late-onset disease has a distinct clinical course. One study will explore the characteristics and treatment response in geriatric patients, including both late-onset RA and early-onset patients in the geriatric age category.

Harms is also a major topic of study proposals submitted to the TReasure administration. A number of studies will explore severe infections, tuberculosis, risk of thromboembolic complications, the risk of and measures for protection against viral hepatitis reactivation, and demyelinating disorders after treatment with tsDMARDs and bDMARDs. One study will explore the risk of paradoxical treatment responses with bDMARDs such as granulomatous inflammation or psoriasis-like skin changes. Finally, a descriptive study will focus on treatment selection and response in SpA patients with a recent history of cancer.

3. Discussion

The TReasure registry, created in 2017, is an observational cohort that includes inflammatory arthritis patients using csDMARD, bDMARD, and tsDMARD treatments. It involves 15 centers that see patients on a regular basis in Turkey and currently about 5000 patients are receiving bDMARD and tsDMARD treatments in these centers regularly. The registry includes patients receiving csDMARDs as well as patients receiving bDMARD or tsDMARD treatments. All patients receiving any bDMARD or tsDMARD treatment enter the registry. TReasure will provide us with various types of data. First, patients with prevalent bDMARD or tsDMARD treatment newly registered by the participating centers can be expected to provide a cross-sectional view of the current nationwide status of the patients currently receiving these treatments. For instance, the clinical features of patients who have uveitis and risk factors that might be related to it can be obtained cross-sectionally. Secondly, these prevalent patients will also provide retrospective data as much as allowed by the participating centers' records.

Finally, as patients with a new diagnosis of RA or SpA initiating csDMARD treatment and patients with new bDMARD or tsDMARD treatment enter the TReasure database, a high-quality prospective dataset will be built over the ensuing years. Using these prospective data, for example, we will have an opportunity to describe varying treatment responses with different treatment modalities in geriatric patients or understand the risks of severe infections, cancers, or neurologic complications of new treatment modalities over the long term. Another prospect is to take advantage of the single-payer healthcare system in Turkey by linking the TReasure database data with social security billing information and population records in order to study long-term hard outcomes such as joint surgery, cardiovascular events, and overall mortality. Such linkages could provide invaluable information with very good accuracy, much less effort, and more efficiency as compared to a prospective database built for such purposes. Finally, a well-structured prospective database could be a very useful resource to find and recruit patients for randomized controlled trials for new treatments or even perform opportunistic trials to test new treatment strategies. We intend to share our observations in national and international periodicals and conferences.

References

1. Askling J, Baecklund E, Granath F, Geborek P, Fored M, Backlin C, Bertilsson L, Cöster L, Jacobsson LT, Lindblad S et al. Anti-tumour necrosis factor therapy in rheumatoid arthritis and risk of malignant lymphomas: relative risks and time trends in the Swedish Biologics Register. Ann Rheum Dis 2009; 68: 648-653.
2. Lapadula G, Ferraccioli G, Ferri C, Punzi L, Trotta F. GISEA: An Italian biological agents registry in rheumatology. Reumatismo 2011; 63: 155-164.
3. Mariette X, Gottenberg JE, Ravaud P, Combe B. Registries in rheumatoid arthritis and autoimmune diseases: data from the French registries. Rheumatology (Oxford) 2011; 50: 222-229.
4. Strangfeld A, Eveslage M, Schneider M, Bergerhausen HJ, Klopsch T, Zink A, Listing J. Treatment benefit or survival of the fittest: what drives the time-dependent decrease in serious infection rates under TNF inhibition and what does this imply for the individual patient? Ann Rheum Dis 2011; 70: 1914-1920.
5. de la Vega M, da Silveira de Carvalho HM, Ventura Rios L, Goycochea Robles MV, Casado GC. The importance of rheumatology biologic registries in Latin America. Rheumatol Int 2013; 33: 827-835.
6. Ibfelt EH, Jensen DV, Hetland ML. The Danish nationwide clinical register for patients with rheumatoid arthritis: DANBIO. Clin Epidemiol 2016; 8: 737-742.
7. Mercer LK, Galloway JB, Lunt M, Davies R, Low AL, Dixon WG, Watson KD; BSRBR Control Centre Consortium, Symmons DP, Hyrich KL. Risk of lymphoma in patients exposed to antitumour necrosis factor therapy: results from the British Society for Rheumatology Biologics Register for Rheumatoid Arthritis. Ann Rheum Dis 2017; 76: 497-503.
8. Strand V, Miller P, Williams SA, Saunders K, Grant S, Kremer J. Discontinuation of biologic therapy in rheumatoid arthritis: analysis from the Corrona RA Registry. Rheumatol Ther 2017; 4: 489-502.
9. Ruderman EM. Overview of safety of non-biologic and biologic DMARDs. Rheumatology (Oxford) 2012; 51 (Suppl. 6): vi37-43.
10. Erden A, Kılıç L, Karadağ Ö, Akdoğan A, Bilgen ŞA, Kıraz S, Ertenli İ, Kalyoncu U. Ankilozan spondilit hastalarında golimumab kullanımı: HÜR-BİO/Spondiloartrit gerçek yaşam deneyimi. RAED Dergisi 2015; 7: 6-9 (in Turkish).
11. Arnett FC, Edworthy SM, Bloch DA, McShane DJ, Fries JF, Cooper NS, Healey LA, Kaplan SR, Liang MH, Luthra HS et al. The American Rheumatism Association 1987 revised criteria for the classification of rheumatoid arthritis. Arthritis Rheum 1988; 31: 315-324.
12. Aletaha D, Neogi T, Silman AJ, Funovits J, Felson DT, Bingham CO 3rd, Birnbaum NS, Burmester GR, Bykerk VP, Cohen MD et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European League Against Rheumatism collaborative initiative. Arthritis Rheum 2010; 62: 2569-2581.
13. van der Linden S, Valkenburg HA, Cats A. Evaluation of diagnostic criteria for ankylosing spondylitis. A proposal for modification of the New York criteria. Arthritis Rheum 1984; 27: 361-368.
14. Rudwaleit M, van der Heijde D, Landewé R, Listing J, Akkoc N, Brandt J, Braun J, Chou CT, Collantes-Estevez E, Dougados M et al. The development of Assessment of SpondyloArthritis International Society classification criteria for axial spondyloarthritis (Part II): validation and final selection. Ann Rheum Dis 2009; 68: 777-783.
15. Rudwaleit M, van der Heijde D, Landewé R, Akkoc N, Brandt J, Chou CT, Dougados M, Huang F, Gu J, Kirazli Y et al. The Assessment of SpondyloArthritis International Society classification criteria for peripheral spondyloarthritis and for spondyloarthritis in general. Ann Rheum Dis 2011; 70: 25-31.
16. Taylor W, Gladman D, Helliwell P, Marchesoni A, Mease P, Mielants H. Classification criteria for psoriatic arthritis: development of new criteria from a large international study. Arthritis Rheum 2006; 54: 2665-2673.
17. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. J Chronic Dis 1987; 40: 373-383.

18. Borg GA. Psychophysical bases of perceived exertion. Med Sci Sports Exerc 1982; 14: 377-381.

19. Calin A, Porta J, Fries JF, Schurman DJ. Clinical history as a screening test for ankylosing spondylitis. JAMA 1977; 237: 2613-2614.

20. Rudwaleit M, Metter A, Listing J, Sieper J, Braun J. Inflammatory back pain in ankylosing spondylitis: a reassessment of the clinical history for application as classification and diagnostic criteria. Arthritis Rheum 2006; 54: 569-578.

21. Sieper J, van der Heijde D, Landewé R, Brandt J, Burgos-Vagas R, Collantes-Estevez E, Dijkmans B, Dougados M, Khan MA, Leirisalo-Repo M et al. New criteria for inflammatory back pain in patients with chronic back pain: a real patient exercise by experts from the Assessment of SpondyloArthritis International Society (ASAS). Ann Rheum Dis 2009; 68: 784-788.

22. Healy PJ, Helliwell PS. Measuring clinical enthesitis in psoriatic arthritis: assessment of existing measures and development of an instrument specific to psoriatic arthritis. Arthritis Rheum 2008; 59: 686-691.

23. Bruce B, Fries JF. The Stanford Health Assessment Questionnaire: a review of its history, issues, progress, and documentation. J Rheumatol 2003; 30: 167-178.

24. Prevoo ML, van't Hof MA, Kuper HH, van Leeuwen MA, van de Putte LB, van Riel PL. Modified disease activity scores that include twenty-eight-joint counts. Development and validation in a prospective longitudinal study of patients with rheumatoid arthritis. Arthritis Rheum 1995; 38: 44-48.

25. Aletaha D, Nell VP, Stamm T, Uffmann M, Pflugbeil S, Machold K, Smolen JS. Acute phase reactants add little to composite disease activity indices for rheumatoid arthritis: validation of a clinical activity score. Arthritis Res Ther 2005; 7: 796-806.

26. Calin A, Nakache JP, Gueguen A, Zeidler H, Mielants H, Dougados M. Defining disease activity in ankylosing spondylitis: is a combination of variables (Bath Ankylosing Spondylitis Disease Activity Index) an appropriate instrument? Rheumatology (Oxford) 1999; 38: 878-882.

27. Calin A, Garrett S, Whitelock H, Kennedy LG, O'Hea J, Mallorie P, Jenkinson T. A new approach to defining functional ability in ankylosing spondylitis: the development of the Bath Ankylosing Spondylitis Functional Index. J Rheumatol 1994; 21: 2281-2285.

28. Lukas C, Landewé R, Sieper J, Dougados M, Davis J, Braun J, van der Linden S, van der Heijde D; Assessment of SpondyloArthritis International Society. Development of an ASAS-endorsed disease activity score (ASDAS) in patients with ankylosing spondylitis. Ann Rheum Dis 2009; 68: 18-24.

29. Hurst NP, Kind P, Ruta D, Hunter M, Stubbings A. Measuring health-related quality of life in rheumatoid arthritis: validity, responsiveness and reliability of EuroQol (EQ-5D). Br J Rheumatol 1997; 36: 551-559.

30. Kiltz U, van der Heijde D, Boonen A, Cieza A, Stucki G, Khan MA, Maksymowych WP, Marzo-Ortega H, Reveille J, Stebbings S et al. Development of a health index in patients with ankylosing spondylitis (ASAS HI): final result of a global initiative based on the ICF guided by ASAS. Ann Rheum Dis 2015; 74: 830-835.

31. Salaffi F, Di Carlo M, Carotti M, Farah S, Gutierrez M. The Psoriatic Arthritis Impact of Disease 12-item questionnaire: equivalence, reliability, validity, and feasibility of the touch-screen administration versus the paper-and-pencil version. Ther Clin Risk Manag 2016; 12: 631-642.

32. Fredriksson T, Pettersson U. Severe psoriasis--oral therapy with a new retinoid. Dermatologica 1978; 157: 238-244.