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AB0650 BIOSIMILAR INFLIXIMAB EXPERIENCE IN SPONDYLOARTRITIS PATIENTS: TREASURE REAL LIFE RESULTS

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Background: Biosimilar infliximab (bio-INF) was approved for all indications of the reference product in several countries. It has been marketed since 2014 in Turkey and used in the same indications with its bio-originator.
Objectives: Herein, we aimed to analyse clinical features and the drug survival rates of spondyloarthritis patients who have recieved bio-INF.
Methods: This multicenter, prospective observational cohort study used the TReasure database in which web-based registration of rheumatoid arthritis and SpA patients are being performed in 13 centers across different regions of Turkey. Age, gender, and acute phase responses (erythrocyte sedimentation rate and C-reactive protein), HAQ scores, VAS patient global, VAS fatigue, VAS pain, VAS physician global, BASDAI, BASFI, ASDAS ESH and ASDAS CRP values, clinical findings of SpA patients, number of patients who has received bio-INF as first line therapy or after switch, treatments which are used before bio-INF, the reasons for switching bio-INF to another biologic DMARD and drug survival rates were retrospectively evaluated.
Results: A total number of 231 SpA (94 (40.7 %) female, 137 (59.3%) male, mean age 43±11 yrs) patients have received biosimilar infliximab in the database. Of the 231 patients 127 (55%) had received bio-INF as first line therapy, whereas 104 (46 (19.9%) 2nd choice, 58 (25.1%) 3rd choice) patients used switching after another biologic DMARD. Previously used biologic and synthetic DMARDs were adalimumab (28.6%), etanercept (22.5%), golimumab (9.1%), original infliximab (8.2%), secukinumab (13.4%), methotrexate (23.8%), leflunamid (10.4%), sulphasalazine (60.6%). The baseline and first visit (3. Months) diseases activity scores were shown in Table 1. Drug survival rates were 79.1 in 12. months, 65.5 in 24. months and 54.6 in 60. months. (Figure 1). The most common reasons for switching from biosimilar infliximab to another biologic DMARD is secondary (25(10.8%)), and primary ineffectiveness (22(9.5%)). Other reasons to discontinuation of treatment are psoriasis (5 (2.1%)), infusion reaction (3(1.2%)), allergic reaction (22(8.8 %)), chest pain (3(1.2%)), dyspnea (1 (0.4%)), vasculitis (1 (0.4%)) and patient or doctor wish (7 (3.4%)).
Conclusion: The results of this real life data provides evidence that biosimilar infliximab is an effective and safe treatment option with long term use in SpA patients. Drug survival rates of bio-INF is similar to its bio-originator.

Table 1. Disease activity scores

	Baseline visit	3.month	
	median (Q1-Q3)	median (Q1-Q3)	p
HAQ score	0,63 (0,4-1)	0,25 (0-1)	**<0,001**
BASDAI	6,2 (4,8-7)	2,8 (1-5)	**<0,001**
BASFI	5,05 (3,3-6)	2,1 (0,45-4)	**<0,001**
VAS Patient Global	70 (50-80)	30 (10-50)	**<0,001**
VAS Doctor Global	60 (40-70)	30 (20-40)	**<0,001**
VAS Pain	50 (3-80)	30 (10-50)	0,572
VAS fatigue	70 (50-80)	40 (10-65)	**<0,001**
ESR	24 (11-45)	11 (6-23)	**<0,001**
CRP	12,1 (4,4-30)	3,91 (2,19-9)	**<0,001**
ASDAS ESR	3,12 (2,51-4)	2,05 (1,39-3)	**<0,001**
ASDAS CRP	3,53 (2,86-4)	2,21 (1,5-3)	**<0,001**

*Wilcoxon Signed Rank Test

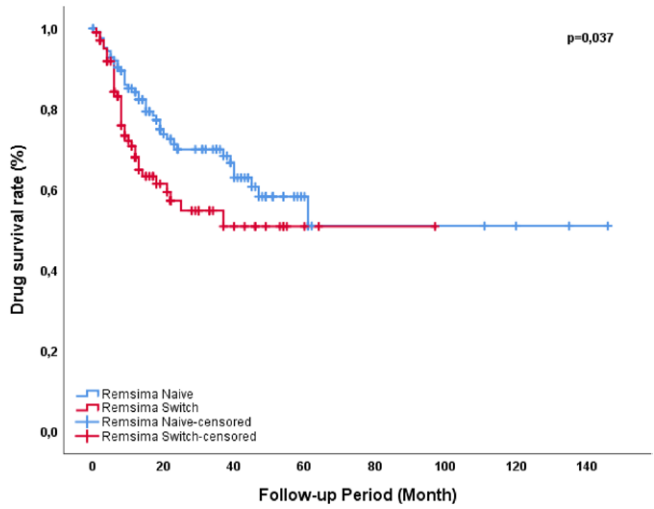

Figure 1. Drug survival rates

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AB0652 MACHINE LEARNING TO PREDICT EARLY TNF INHIBITOR USERS IN PATIENTS WITH ANKYLOSING SPONDYLITIS

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Background: Tumor necrosis factor (TNF) inhibitors are important drugs in treating patients with ankylosing spondylitis (AS). However, they are not used as a first-line treatment for AS. There is an insufficient treatment response to the first-line treatment, non-steroidal anti-inflammatory drugs (NSAIDs), in over 40% of patients. If we can predict who will need TNF inhibitors at an earlier phase, adequate treatment can be provided at an appropriate time and potential damages can be avoided. There is no precise predictive model at present. Recently, various machine learning methods show great performances in predictions using clinical data.
Objectives: We aim to generate an artificial neural network (ANN) model to predict early TNF inhibitor users in patients with ankylosing spondylitis.
Methods: The baseline demographic and laboratory data of patients who visited Samsung Medical Center rheumatology clinic from Dec. 2003 to Sep. 2018 were analyzed. Patients were divided into two groups: early TNF inhibitor users treated by TNF inhibitors within six months of their follow-up (early-TNF users), and the others (non-early-TNF users). Machine learning models were formulated to predict the early-TNF users using the baseline data. Additionally, feature importance analysis was performed to delineate significant baseline characteristics.
Results: The numbers of early-TNF and non-early-TNF users were 90 and 509, respectively. The best performing ANN model utilized 3 hidden layers with 50 hidden nodes each; its performance (area under curve (AUC) = 0.75) was superior to logistic regression model, support vector machine, and random forest model (AUC = 0.72, 0.65, and 0.71, respectively) in predicting early-TNF users. Feature importance analysis revealed erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), and height as the top significant baseline characteristics for predicting early-TNF users. Among these characteristics, height was revealed by machine learning models but not by conventional statistical techniques.
Conclusion: Our model displayed superior performance in predicting early TNF users compared with logistic regression and other machine learning models. Machine learning can be a vital tool in predicting treatment response in various rheumatologic diseases.