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AB1149

POOR RESPONSE TO HEPATITIS B VACCINATION IN RHEUMATIC PATIENTS TREATED WITH BIOLOGIC THERAPY – IMPLICATIONS FOR CLINICAL PRACTICE

V. C. Romão^{1,2}, P. Ávila-Ribeiro^{1,2}, M. J. Gonçalves^{1,2}, A. R. Cruz-Machado^{1,2}, A. Guerreiro², V. Teixeira^{1,2}, A. Valido^{1,2}, J. Silva-Dinis^{1,2}, E. Vieira-Sousa^{1,2}, M. J. Saavedra^{1,2}, E. Leite³, R. Tato Marinho⁴, J. E. Fonseca^{1,2}. ¹Hospital Santa Maria, CHULN, Rheumatology Department, Lisbon, Portugal; ²Instituto de Medicina Molecular, Faculdade de Medicina, Universidade de Lisboa, Rheumatology Research Unit, Lisbon, Portugal; ³Hospital Santa Maria, CHULN, Occupational Medicine Department, Lisbon, Portugal; ⁴Hospital Santa Maria, CHULN, Gastroenterology and Hepatology Department, Lisbon, Portugal

Background: Hepatitis B virus (HBV) vaccination is recommended for rheumatic patients starting biologic therapy. There is some evidence that HBV vaccination is effective in patients under conventional disease modifying anti-rheumatic drugs (DMARDs), but it is currently unclear whether this also applies to biologics.

Objectives: To assess the efficacy and safety of HBV vaccination in patients with rheumatic diseases treated with biologics.

Methods: We included patients with any inflammatory rheumatic diseases treated with any biologic, who were negative for anti-HBs and anti-HBc and had never been vaccinated for HBV. Engerix B® was administered at 0, 1 and 6 months and anti-HBs was re-assessed ≥1 month after last dose. Response was defined as anti-HBs >10IU/L and compared against healthy controls (HC) undergoing Occupational Health immunization. Disease flare was evaluated before and until at least 1 month post-vaccination. We recorded serious adverse events (SAE) and immune-related disorders not previously present.

Results: We included 67 patients, most treated with TNF inhibitors (TNFi), and 70 HC (Table 1). Most patients were taking concomitant DMARDs (69%) and were in remission/low disease activity (59%). Only 20 patients (30%) had a positive response to vaccination, in comparison to 68 HC (97%, $p < 0.001$). Mean post-vaccination anti-HBs titre was significantly lower in responding patients than HC (569 ± 772 vs 1316 ± 811 IU/L, $p < 0.001$). Responders diagnoses were RA ($n=8$ [25%]), PsA ($n=7$ [39%]), AS ($n=4$ [33%]) and IBD-associated SpA ($n=1$ [100%]). Response was seen in 19/53 patients treated with TNFi (36%), but only 1/14 (7%) of patients treated with non-TNFi ($p=0.037$). Importantly, some responders had to temporarily interrupt biologic therapy due to other intercurrents for at least one administration. No clinical or demographic variables were associated with response, including age and disease activity. Fourteen patients (21%) experienced disease flares, of which 7 were mild and did not require therapy adjustment; 3 patients required minor treatment/dose adjustments; 4 patients had secondary failures that led to switches. There were 3 SAE (acute diverticulitis; abdominal infection; atrial fibrillation and urinary infection) 1-4 months after 1st/2nd dose, deemed not to be related to vaccination. One RA patient on infliximab had bilateral uveitis 2 months after the 1st vaccine dose, which resolved with topical therapy.

Table 1. Baseline characteristics of study participants.

	Patients (n=67)	Controls (n=70)	p
Age (years)	56 ± 9	46 ± 9	<0.001
Female (%)	40 (60)	62 (89)	<0.001
Diagnosis (%)			
RA	32 (48)		
PsA / AS	18 (27) / 13 (19)		
Other	4 (6)		
Disease duration (years)	17 ± 10		
Biologic (%)			
TNF-inhibitor	53 (79)		
Tocilizumab / Abatacept	6 (9) / 1 (1)		
Rituximab / Belimumab	2 (3) / 4 (6)		
Anakinra	1 (1)		
Conventional DMARDs (%)			
MTX / LEF	39 (58) / 1 (1)		
SSZ / Other	6 (9) / 3 (4)		
None	21 (31)		
Prednisolone (%) / Dose (mg)	29 (43) / 5.6 ± 2.1		
DAS28	3.1 ± 1.4		
ASDAS	2.2 ± 1.4		

Conclusion: In this study, HBV vaccination response was poor and lower in rheumatic patients treated with biologic therapy than in healthy adults. Vaccination was overall safe but there were 4 severe flares and 3 SAE that lead to treatment switch/interruption, although causal association is difficult to establish. Our data reinforce the recommendation for HBV vaccination prior to starting biologic therapy, possibly even as soon as the diagnosis is established. Alternative HBV vaccination strategies should be investigated in patients already treated with biologics.

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AB1150

ECONOMIC IMPACT ASSOCIATED TO BIOLOGICAL THERAPY / SYNTHETIC FAME OPTIMIZATION IN A COHORT OF PATIENTS WITH CHRONIC INFLAMMATORY RHEUMATIC DISEASES TREATED BY OBJECTIVES.

P. Castro¹, A. Onteniente². ¹Glorieta Francisco de las Cabezas, Rheumatology, Madrid, Spain; ²Calle del General Aranzaz, Pharmacy, Madrid, Spain

Background: Therapeutic decision-making for biologic-therapies/ synthetic FAME (BT/SD) dose optimization, should be based on optimal disease activity results according to a treatment strategy by objectives. The goal of BT optimization is to guarantee long-term effectiveness and safety, maximising economic savings

Objectives: To evaluate BT optimization patterns in patients with rheumatic diseases (RD) and associated economic savings.

Methods: An observational and prospective study, which included a cohort of patients with rheumatoid arthritis (RA), spondyloarthropathies (SA) and psoriatic arthritis (PsA) treated with BT from January 2014 to December 2019. BT optimization, achieved by reducing or prolonging the interval at least one dose, was indicated when patients have more than 6 months of treatment and are in clinical remission (DAS28 <2.6 for RA and PsA, and BASDAI <2 for SA) or minimal clinical activity (DAS28 <3.2 for RA and PsA, and BASDAI <4 for SA).

Variables were described as frequencies and means. Diagnosis, BT (abatacept, adalimumab, apremilast, baricitinib, certolizumab, etanercept, golimumab, ixekizumab, secukinumab, tocilizumab, tofacitinib, and ustekinumab), dose regimens, total treatment duration, time on BT optimization (TO) and treatment costs were collected. Cost savings were calculated per patient by comparing optimization treatment costs to conventional treatment and globally by comparing real cost to theoretical conventional doses cost.

Results: A total of 260 patients were included in the study. Switching were observed in 32.7%. From all patients, 53% were candidates for BT optimization (according to diagnosis: 60.9% with RA, followed by 52.2% with SA and 43.4% with PsA)

A 40% of patients with BT optimization were treated with adalimumab and etanercept being also the most common BT used in RD treatment. BT optimization allowed a pharmaceutical saving of € 177,539.40 per year against the use of conventional therapy, resulting in a reduction of the total cost of €1,065,236.40 in the last 6 years. The saving per patient / year was € 707.63 for RA; € 850.40 for SA and of € 493.21 for the PsA.