US16.1. BEZBEDNOST ADALIMUMABA KOD INFLAMATORNIH BOLESTI CREVA: ISKUSTVA IZ KLINIČKE KOHORTE

B. Milašinović[1], S. Marković[2,3], S. Vezmar Kovačević[1], P. Svorcan[2,3], B. Miljković[1], K. Vučićević[1]
[1]Univerzitet u Beogradu – Farmaceutski fakultet, Beograd, Srbija, [2]Kliničko odeljenje za gastroenterologiju i hepatologiju, Kliničko-bolnički centar Zvezdara, Beograd, Srbija, [3]Univerzitet u Beogradu – Medicinski fakultet, Beograd, Srbija

Podaci o bezbednosti adalimumaba iz kliničke prakse su od ključnog značaja za kontinuirano praćenje bezbednosti leka, dok su dugoročni podaci i dalje ograničeni. Cilj ove studije bio je da se procene neželjeni događaji (ND) i njihovi vremenski obrasci u kohorti pacijenata sa zapaljenjskim bolestima creva. Retrospektivna opservaciona studija obuhvatila je 217 odraslih pacijenata sa zapaljenjskim bolestima creva lečenih adalimumabom u Univerzitetskom kliničkom centru „Zvezdara" u Beogradu, Republika Srbija. ND su identifikovani iz medicinske dokumentacije i kodirani korišćenjem MedDRA terminologije. Stope incidencije ND su izračunate na 100 pacijent-godina (PG) izloženosti. Analiza vreme do događaja korišćena je za procenu pojave prvog ND. Ukupna izloženost adalimumabu iznosila je 591,29 PG, uz 630 prijavljenih ND (106,55/100 PG). Najčešće prijavljeni ND pripadali su MedDRA sistemskim organskim klasama infekcija i infestacija, ispitivanja, opštih poremećaja i reakcija na mestu primene, kao i bolesti kože i potkožnog tkiva. Najčešći pojedinačni ND bili su COVID-19, nazofaringitis, infekcija respiratornog trakta, povišena telesna temperatura i povišeni jetreni enzimi. Adalimumab je obustavljen zbog ND kod 17 pacijenata, najčešće zbog infekcija, reakcija na mestu injekcije i dermatoloških reakcija, lupus-sličnog sindroma i neuroloških događaja. Nisu zabeleženi smrtni ishodi. Weibullova distribucija najbolje je opisala pojavu prvog ND, sa medijanom vremena do prvog ND od 12,7 meseci (95% interval pouzdanosti, CI: 10,6–15,2). Bezbednosni profil adalimumaba u kliničkoj kohorti pacijenata bio je u skladu sa dostupnim podacima. Prvi ND su se javljali tokom celokupnog perioda lečenja, što ukazuje na potrebu za kontinuiranim praćenjem bezbednosti tokom dugotrajne terapije.

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US16.1. SAFETY OF ADALIMUMAB IN INFLAMMATORY BOWEL DISEASE: INSIGHTS FROM A CLINICAL COHORT

B. Milašinović[1], S. Marković[2,3], S. Vezmar Kovačević[1], P. Svorcan[2,3], B. Miljković[1], K. Vučićević[1]
[1]University of Belgrade – Faculty of Pharmacy, Belgrade, Serbia, [2]Department of Gastroenterology and Hepatology, University Hospital Medical Center "Zvezdara", Belgrade, Serbia, [3]University of Belgrade – Faculty of Medicine, Belgrade, Serbia

Real-world data on the safety of adalimumab are essential for ongoing pharmacovigilance, while long-term evidence remains limited. This study aimed to evaluate adverse events (AEs) and their temporal patterns in a cohort of patients with inflammatory bowel disease (IBD). A retrospective observational study included 217 adult patients with IBD treated with adalimumab at University Medical Center "Zvezdara" in Belgrade, Republic of Serbia. AEs were identified from medical records and coded using MedDRA terminology. Incidence rates were calculated per 100 patient-years (PY) of exposure. Time-to-event (TTE) analysis was performed to evaluate the occurrence of the first AE. The total adalimumab exposure was 591.29 PY, with 630 AEs (106.55/100 PY) recorded. The most frequently reported AEs belonged to the MedDRA system organ classes of infections and infestations, investigations, general disorders and administration-site conditions, and skin and subcutaneous tissue disorders. The most commonly reported individual AEs were COVID-19, nasopharyngitis, respiratory tract infection, pyrexia, and elevated liver enzymes. Adalimumab was discontinued due to AEs in 17 patients, most commonly infections, injection-site and dermatological reactions, lupus-like syndrome, and neurological events, consistent with its known safety profile. No deaths were recorded. TTE analysis showed that the Weibull distribution provided the best fit for the occurrence of the first AE, with an estimated median time of 12.7 months (95% confidence interval, CI: 10.6–15.2). Adalimumab safety profile in this real-world IBD cohort was consistent with the available data. First AEs occurred throughout treatment exposure, highlighting the need for ongoing safety monitoring during long-term treatment.

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