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SAFETY AND EFFICACY OF TOCILIZUMAB IN PATIENTS WITH RHEUMATOID ARTHRITIS

Introduction

Rheumatoid arthritis is a chronic inflammatory disease of joints which particularly affects the joint space by causing inflammation of synovium leading to edema and pain in the affected joints. The disease can also cause extra articular manifestations including skin, eyes, lungs and cardiovascular system. Moreover rheumatoid arthritis is an autoimmune disease where the body's immune system produce its own antibodies that attack joint capsule destroying the cartilage and bone [1].

Tocilizumab is the first drug with the ability to suppress IL-6-dependent inflammatory reactions, approved for use in RA [1].

DAS criteria is used to measure the activity of rheumatoid arthritis. The criteria is based on physician's overall assessment of patient's body including the total number of painful and swollen joints out of 28, acute phase reactants ESR (widely included) and CRP (less included). Accordingly rheumatoid arthritis activity is subdivided as less than 2.6 in remission, greater than or equal 2.6 to less than 3.1 mild activity. Greater than or equal 3.1 to less than 5.1 moderate activity, greater than or equal 5.1 and above high activity [2].

Visual Analog Scale is used to measure the acute and chronic pain where the scores are recorded by hand on a linear scale either from zero to ten in centimeters or ten to hundred in millimeters which ranges from no to worst pain respectively [3].

Goal

To determine safety and efficacy of Tocilizumab in patients with rheumatoid arthritis, those who were on inpatient treatment in the rheumatology department of the Gomel Regional Clinical Hospital.

Material and Methods of research

64 patients with rheumatoid arthritis who have received Tocilizumab injections were selected from rheumatology department of Gomel regional hospital. The study involves 50 females (78.13 %) and 14 males (21.87 %), 36 to 72 years of age (mean age 54.3 ± 12.7 years). All patients took methotrexate as a disease modifying drug (the average dose of which was 18,75 ± 3,25 mg). All patients took non-steroidal anti-inflammatory drugs (NSAIDs) on regular basis. The patients were then subdivided into groups based on dose and frequency of Tocilizumab injections used as 400/1 – 16 patients (25 %), 400/2 – 8 patients (12.5 %), 400/3 – 7 patients (10.94 %), 400/4 – 4 patients (6.25 %), 400/5 – 1 patient (1.56 %), 400/6 – 2 patients (3.13 %), 600/1 – 11 Patients (17.19 %), 600/2 – 1 patient (1.56 %), 600/3 – 4 patients (6.25 %), 600/4 – 5 patients (7.81 %), 600/6 – 3 patients (4.69 %), and 800/1 – 2 patients (3.13 %). The activity of rheumatoid arthritis based on DAS 28 before and after injection with Tocalizumab was recorded. Similarly, the pain of these patients represented according to visual analog scale at the beginning, after one month and two months with Tocilizumab injection were recorded in millimeters. All the data were then taken into a google spreadsheet for analysis. Then for comparison based on visual analog scale the obtained values were simplified into ten small groups as between 0 to less than 10 group 1, greater than or equal 10 to less than 20 group 2, greater than or equal 20 to less than 30 group 3, greater than or equal 30 to less than 40 group 4, greater than or equal 40 to less than 50 group 5,

greater than or equal 5o to less than 60 group 6, greater than or equal 60 to less than 70 group 7, greater than or equal 70 to less than 80 group 8, greater than or equal 80 to less than 90 group 9, greater than or equal 90 to less than or equal 100 group 10.

The results of the research and their discussion

Out of all 64 patients according to DAS 28 before Tocilizumab injection 30 patients were recorded of moderate activity (46.87 %) and 34 patients were recorded of high activity (1.56 %) while zero patients were in remission and mild activity groups. (0 %). After treatment with injectable tocalizumab in 26 patients went into remission (40.63 %), 10 patients had mild activity (15.63 %), 26 patients had average activity (40.63 %), 1 patient had high disease activity (1.56 %). Therefore, with Tocilizumab injection mild and remission groups which recorded zero patients before increased up to 36 (56.25 %) while moderate and high activity groups that recorded 64 patients before (100 %) went down to 27 (42.19 %).

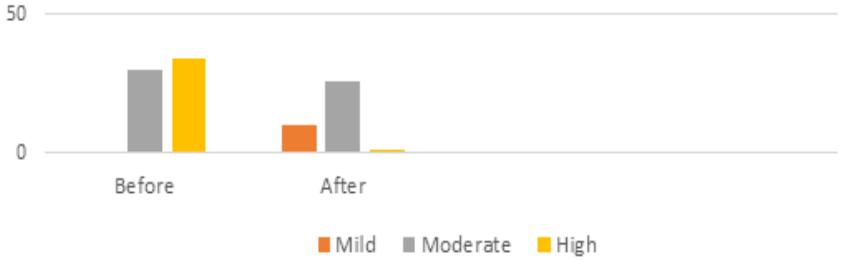

Figure 1 – Results of patients before and after injection with Tocilizumab

According to Visual analog scale at the beginning of infusion 1 patient in group 2 (1.56 %), 1 in group 3 (1.56 %), 4 in group 4 (6.25 %), 8 in group 5 (12.5 %), 13 in group 6 (20.31 %), 14 in group 7 (21.87 %), 13 in group 8 (20.31 %) and 9 in group 9 (14.06 %). After one month with Tocilizumab injection 1 in group 1 (1.56 %), 6 in group 2 (9.38 %), 9 in group 3 (14.63 %), 7 in group 4 (10.94 %), 18 in group 5 (28.13 %), 12 in group 6 (18.75 %), 9 in group 7 (14.06 %), and 1 in group 8 (1.56 %). After two months with subsequent injections in 35 patients 1 in group 1 (1.56 %), 5 in group 2 (7.81 %), 11 in group 3 (17.18 %). 7 in group 4 (10.94 %), 8 in group 5 (12.5 %), 2 in group 6 (3.13 %), and 1 in group 7 (12.56 %).

Also, the mean pain value according to visual analog scale after one month with only one Tocilizumab injection is 40.67 while those who received subsequent injections recorded a mean value of 29.31. Also one patient from all 64 participants (1.56 %) had toxicity to Tocilizumab and was presented with toxic hepatitis.

One patient (1.56 %) continued to take NSAIDs on a regular basis, in 32.81 % (21 patients) of cases the NSAIDs were episodic and in 65.62 % (42 patients) of cases patients did not require pain relief, indicating sufficient inflammatory control.

Conclusion

From the study it is evident that many patients recorded positive results based on Visual analog scale and DAS 28 criteria for rheumatoid arthritis. Also the subsequent introduction of patients with Tocilizumab provided better results in patients rather than single injection and also Tocilizumab proved to rather less toxicity in people with rheumatoid arthritis. Therefore, from the study it is evident that Tocilizumab can be used as a safe and efficient drug in treatment of patients with rheumatoid arthritis.

LITERATURE

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