exploratory analysis did not show an association between cognition impairment and demographic characteristics or disease activity.

References:

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SAT0116

COMPARISON OF THE EFFICACY OF ABATACEPT ON ELDERLY AND YOUNG PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: The widespread use of biologic agents has greatly improved the prognosis of rheumatoid arthritis (RA). On the other hand, elderly patients with RA are relatively increasing. Although achieving low disease activity is a goal for those elderly patients as well as young patients, the efficacy of tumor necrosis factor inhibitors were reported to be equally or slightly less effective in elderly patients than in young patients. There is a lack of evidence for the efficacy of abatacept (ABT) in elderly patients.

Objectives: In this study, we aimed to clarify the efficacy of ABT in elderly and young patients with RA compared to csDMARDs.

Methods: This is a multicenter, open-label, prospective, observational study. All patients with RA enrolled this study are refractory to csDMARDs and have not received any biologics. Either ABT or csDMARDs was administered at the discretion of physicians to elderly (65 years and older) and young (20-64 years) patients (ABT-elderly, ABT-young, control (CTL)-elderly, and CTL-young groups). Comparison was made between 4 groups of patients. The primary study endpoint was a good response by EULAR response criteria at week 24 after administration. The research procedure has been approved by the ethics committee of Toho University School of Medicine (Approval number: A17112).

Results: A total of 219 patients, 127 in the ABT group and 92 in the CTL group, were enrolled in this study. The majority of patients were women (82.7%) with a mean age (±SD) of 64.9±13.6 years (74.5±5.9 years in the elderly group and 52.4±10.1 years in the young group). The ABT group had higher disease activity, higher HAQ, and higher steroid use rates and dosage than the CTL group. These were also observed in the elderly group. In the young group, although the ABT group had higher disease activity and higher HAQ than the CTL group, no difference was observed in steroid use rates and dosage. The ABT group more frequently achieved a good response by EULAR response criteria compared to the CTL group at week 24 (58.8% and 27.2%, respectively, $p<0.0001$). The ABT group also showed higher efficacy than the CTL group in the elderly and young groups with a good response. Regarding the improvement in DAS28-ESR and DAS28-CRP, the ABT group was also superior to the CTL group. There was no difference on efficacy between elderly and young patients from the ABT groups.

Based on propensity score matching for disease activity at baseline, 61 matched pairs of patients treated with ABT or csDMARDs were statistically extracted. Although there was no significant difference in the rate of patients with a good response by EULAR response criteria between the ABT and the CTL groups, the ABT group showed significantly better response than the CTL group in the elderly. Furthermore, the ABT group was superior to the CTL group in improvement in both DAS28-ESR and DAS28-CRP, and similar results were obtained in the elderly. However, there was no significant difference between the ABT group and the CTL group in the young. In addition, elderly patients had significant improvement in DAS28-ESR compared with young patients in the ABT group.

Conclusion: Treatment with ABT showed higher efficacy compared with CTL, particularly in elderly patients with RA.

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SAT0117

TRIMESTER EXPOSURE AND PREGNANCY OUTCOMES IN WOMEN EXPOSED TO GOLIMUMAB – RESULTS FROM THE COMPANY PHARMACOVIGILANCE DATABASE

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Background: Rheumatologic disorders and inflammatory bowel disease can affect women of childbearing potential. Golimumab (GLM) is approved for several rheumatologic indications and ulcerative colitis (UC).

Objectives: To characterize pregnancy outcomes in patients treated with GLM, data obtained from maternal exposure to GLM are presented.

Methods: This dataset includes individual patient cases reported to the manufacturer through 06 April 2019. Cases included in the analysis were medically confirmed cases of maternal exposures to GLM during pregnancy or within 3 months prior to conception, and a reported pregnancy outcome. Both prospectively reported (ie, pregnancy outcome not known when first reported) and retrospectively reported cases (ie, pregnancy outcome known when first reported) were included. Cases originated from various sources, including spontaneous reporting, clinical studies, and registries.

Results: Two hundred eight pregnancy cases (131 rheumatologic indications; 43 UC; and 34 other) with 211 reported birth outcomes were identified. Of these 208 pregnancy cases, 119 were prospective and 89 were retrospective. Average maternal age was 31.9 years. Of the 119 prospectively reported pregnancy cases, 89 (74.8%) resulted in live births, 19 (16.0%) resulted in spontaneous abortion (of these, 42.1% (8/19) received GLM in combination with methotrexate [MTX]), 10 (8.4%) resulted in induced/elective abortion, and 1 (0.8%) resulted in ectopic pregnancy. Overall, 9 congenital anomalies were reported (2 prospective and 7 retrospective cases).

For 183 of the 208 pregnancy cases with reported outcomes, the trimester of exposure to GLM was known. Among the 110 prospectively reported cases, 82 (74.5%) were exposed during trimester 0 or 1. Of these, 19 had concomitant exposure to MTX, with the following birth outcomes: 8 live births, 8 spontaneous abortions, 3 elective/induced abortions. Eighteen of the prospectively reported cases (16.4%) were exposed to GLM through trimesters 1-3 and all resulted in live births (none with congenital anomalies; 1 infant with exposure to GLM and MTX was born preterm).

Conclusion: The rates of congenital malformations and spontaneous abortions were consistent with published background rates for the general population. Persistent exposure throughout pregnancy was rare. Limitations of this analysis include the lack of a direct comparison group, the variable amount of data available in the reports, and the possible bias towards reporting more negative outcomes in retrospective cases.

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