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CLINICAL EFFICACY OF SECUKINUMAB TREATMENT AFTER 12 WEEKS IN PATIENTS WITH ANKYLOSING SPONDYLITIS

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Annoattion.
This study analyzed the clinical efficacy of the IL-17 inhibitor Secukinumab 150 mg after 12 weeks of treatment in patients with ankylosing spondylitis. By the end of the 12th week, clinical improvement was observed, including disease activity reduction (ASAS 50), pain relief, enhanced spinal functional capacity, and improved quality of life. Additionally, Secukinumab administration led to a decrease in MMP-9 levels.
Keywords: Ankylosing spondylitis, secukinumab.

Objective: The aim of this study is to evaluate the clinical outcomes of secukinumab treatment after 12 weeks in patients with ankylosing spondylitis, based on changes in disease activity and MMP-9 levels.

Introduction. Ankylosing spondylitis (AS) is a chronic autoimmune disease primarily affecting the axial skeleton [1]. The disease progresses with chronic back pain, stiffness, and limited mobility. Inadequately treated AS can lead to disability, including complete axial skeletal fusion (spine fusion), significantly impacting the quality of life. Nonsteroidal anti-inflammatory drugs (NSAIDs) and cs-DMARDs such as sulfasalazine are recommended as first-line treatments for active AS [2]. It is well known that in patients with persistent disease activity, treatment with TNF-α and TNF-αR inhibitors has revolutionized AS management [3]. However, not all patients respond adequately to TNF-α inhibitors, and issues such as drug tolerance and decreased efficacy over time necessitate the development of new treatment strategies [4]. The ACR, SAA, and SPARTAN guidelines were among the first to introduce biologic non-TNF-α inhibitors, particularly IL-17 inhibitors, as a treatment option [5]. IL-17A, a member of the IL-17 cytokine family, plays a key role in immune inflammation and immune response regulation [6]. Blocking the biological activity of interleukin-17A (IL-17A) is considered an effective strategy for controlling immune inflammation in

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spondyloarthritis. Additionally, other IL-17 family members contribute to chronic inflammation and bone remodeling in AS, as reported in several studies [7]. IL-17A acts as a crucial mediator between bone tissue and the immune system throughout disease progression. Inhibiting IL-17A can potentially halt bone erosions and slow bone loss while also reducing osteoproliferation, enthesitis, and syndesmophyte formation in AS [8]. Several studies have confirmed the significant role of IL-17A in AS pathogenesis [9]. Research findings indicate that an increased number of IL-17A-producing cells in the subchondral bone marrow and circulation of AS patients [10]. Secukinumab, the first IL-17A inhibitor approved for AS treatment, has been extensively studied for its pharmacological properties [11]. Updated treatment guidelines recommend IL-17A inhibitors, JAK inhibitors, and biosimilar-TNF inhibitors as essential options for active disease management [12].The ASAS/EULAR recommendations emphasize that b-DMARDs (TNF inhibitors and IL-17 inhibitors) should be prioritized for managing persistent disease activity [13]. According to the UK's NICE guidelines, secukinumab is recommended when NSAIDs or TNF inhibitors fail to provide an adequate response [14]. Multiple clinical trials have demonstrated that secukinumab 150 mg effectively improves disease activity signs and symptoms [15]. The clinical efficacy of secukinumab has been maintained for up to 3, 4, and even 5 years following a 52-week treatment regimen [16]. Notably, secukinumab has shown efficacy both in TNF inhibitor-naïve patients and in those previously treated with TNF inhibitors [16]. ASAS-EULAR guidelines suggest switching to either another TNF inhibitor or an IL-17 inhibitor if the first TNF inhibitor is ineffective, highlighting that switching to an IL-17 inhibitor might be the more rational approach [17,18].The ACR/SAA/SPARTAN guidelines conditionally recommend switching to another TNF inhibitor if the first one fails [19]. Given AS's chronic nature, the development of structural damage, and the associated risk of disability, long-term disease management remains a crucial goal. Studies have associated secukinumab treatment with reductions in inflammatory biomarkers and slower radiographic disease progression in AS patients [20]. Moreover, cohort studies conducted across multiple countries suggest that patients who respond well to secukinumab demonstrate superior cost-effectiveness compared to those treated with TNF inhibitors [21]. A 104-week clinical trial found no cases of tuberculosis development or reactivation among patients receiving either 150 mg of secukinumab subcutaneously or 75 mg intravenously, reinforcing the significance of these dosing strategies [22]. In this study, the relationship between IL-17A levels and disease activity, particularly its direct proportional association with matrix metalloproteinase-9 (MMP-9), was analyzed. The effectiveness of IL-17 inhibitors in the pathogenic treatment of AS was evaluated based on changes in ASDAS, BASDAI, BASFI, VAS, MASES, and CRP indices. It is worth noting that while MMP-9 is recognized as a key factor in the pathogenesis of AS, the results of ongoing trials on its inhibitors are highly anticipated [17]. If

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the efficacy of this new class of biologic therapy is confirmed, it could

Materials and methods: The study included 77 patients diagnosed with AS, between 18 and 50 years (mean age: 34.7±8.3 years), comprising 55 (71.4%) males and 22 (28.6%) females. The average disease duration was 5.3±0.6 years. Based on the 12-week treatment period, the patients were divided into two groups. The first group consisted of 40 patients (51.9%), with an average age of 34.9±8.5 years, who received secukinumab 150 mg. The second group included 37 patients (48.1%), with an average age of 33.9±7.1 years, who received baseline therapy with sulfasalazine (2.0 g). The effectiveness of the treatment was assessed using the ASAS 50 (Assessment of SpondyloArthritis International Society), BASFI (Bath Ankylosing Spondylitis Functional Index), Visual Analog Scale (VAS) for pain, MASES (Maastricht Ankylosing Spondylitis Enthesitis Score), and ASQoL (Ankylosing Spondylitis Quality of Life) indices. MMP-9 levels were evaluated using enzyme-linked immunosorbent assay (ELISA). The obtained data were statistically processed.

Results and discussion: In the first group, 70% of the patients were male, while 30% were female, with an average age of 34.9±8.5 years. In the second group, 72.9% were male and 27.1% were female, with an average age of 33.9±7.1 years (Table 1). All patients were in the active phase of the disease. Morning stiffness was observed in all groups of patients with AS.

represent a significant turning point in the management of AS.

Table1

Distribution of patients with ankylosing spondylitis by gender and age

Groups		Sex		Mean age, years
		Male	Female	
Group I (Secukinumab), n=40	abs	28	12	34,9±8,5
	%	70	30	
Group II (Sulfasalazine),n=37	abs	27	10	33,9±7,1
	%	72,9	27,1	

According to the obtained results, notable differences were observed between the two groups during treatment. Specifically, among the patients receiving secukinumab, 31 (77.5%) experienced a significant reduction in morning stiffness, whereas in the sulfasalazine group, 15 (40.5%) still had persistent symptoms. After 12 weeks of treatment, lower back pain persisted in 13 (32.5%) patients from Group I and 18 (46.6%) from Group II. Neck stiffness complaints remained in 11 (27.5%)

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patients from Group I and 16 (43.3%) from Group II. Additionally, VAS (Visual Analog Scale) assessment showed a significant reduction in pain scores. In Group I, the baseline VAS score of 8.5±1.2 cm decreased significantly to 1.1±0.5 cm after 12 weeks ($p<0.01$). In Group II, the baseline VAS score of 8.9±2.3 cm reduced to 4.7±1.1cm ($p<0.05$).This difference was statistically significant. Moreover, by the end of the 12th week, there was a statistically significant difference ($p<0.05$) between the two groups. At the beginning of the study, disease activity levels (ASDAS, $p>0.05$) were high in both groups, with significant pain and morning stiffness. Differences in treatment efficacy between the groups were evident. As shown in Figure 1, by the 4th week, there was no marked difference in ASAS 50 response between the groups, with only Δ9% difference. However, by the 8th week, the primary group (secukinumab) showed nearly twice the improvement compared to the control group ($p<0.05$). This difference persisted, and by the 12th week, treatment efficacy in the primary group reached Δ26.6%.

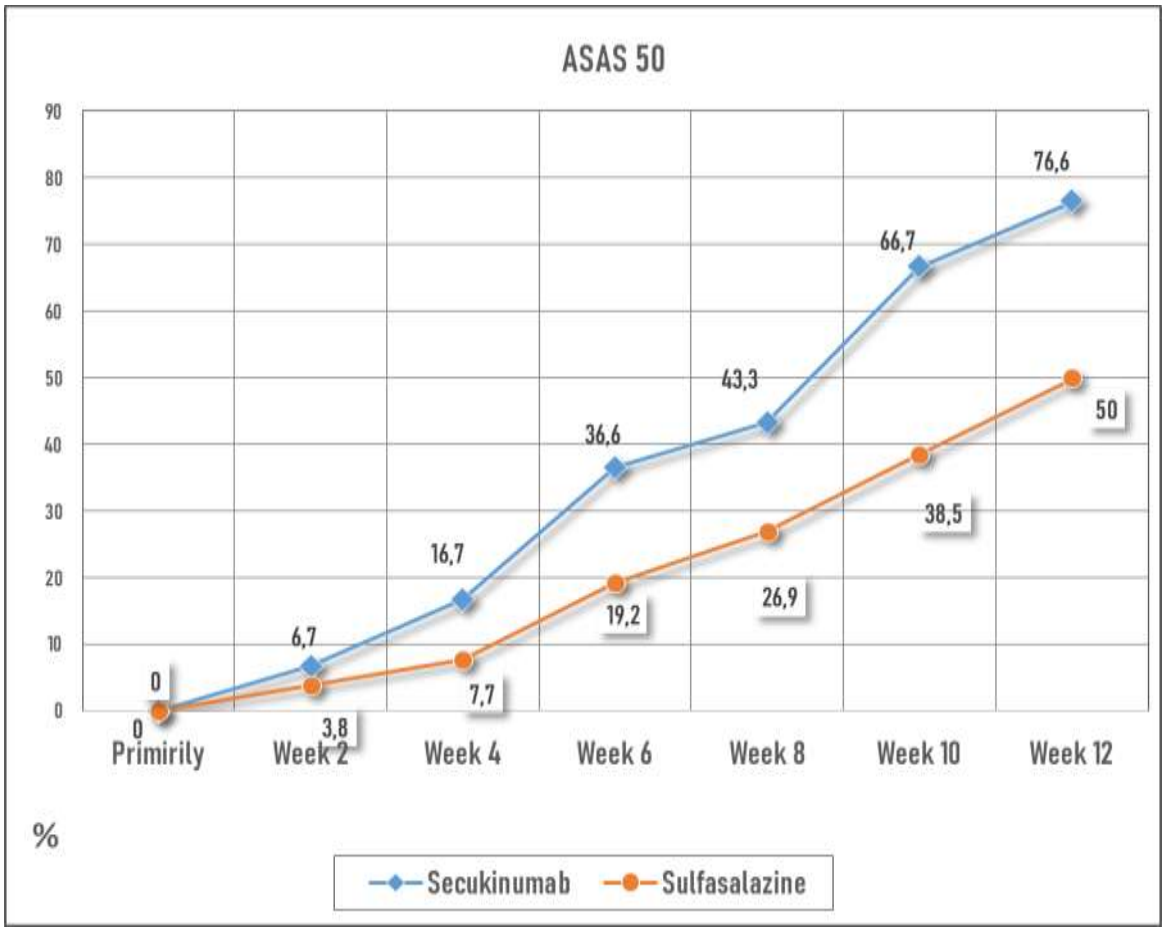

Figure 1. ASAS 50 response dynamics in study groups receiving secukinumab and sulfasalazine.

In assessing the functional capabilities of the spine, differences in treatment outcomes were observed. As shown in Figure 2, in Group I, the BASFI (Bath

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Ankylosing Spondylitis Functional Index) score was 10.5±1.7 points before treatment. Over time, there was a positive trend, and by week 12, the score had significantly decreased to 3.2±0.8 points, representing an almost threefold reduction ($p<0.01$). In Group II, there was also a positive change, where the initial BASFI score of 9.7±1.3 decreased to 6.1±1.2 by week 12 ($p<0.05$). However, the final results at week 12 showed a statistically significant difference ($p<0.05$) between the two groups, indicating a greater improvement in Group I.

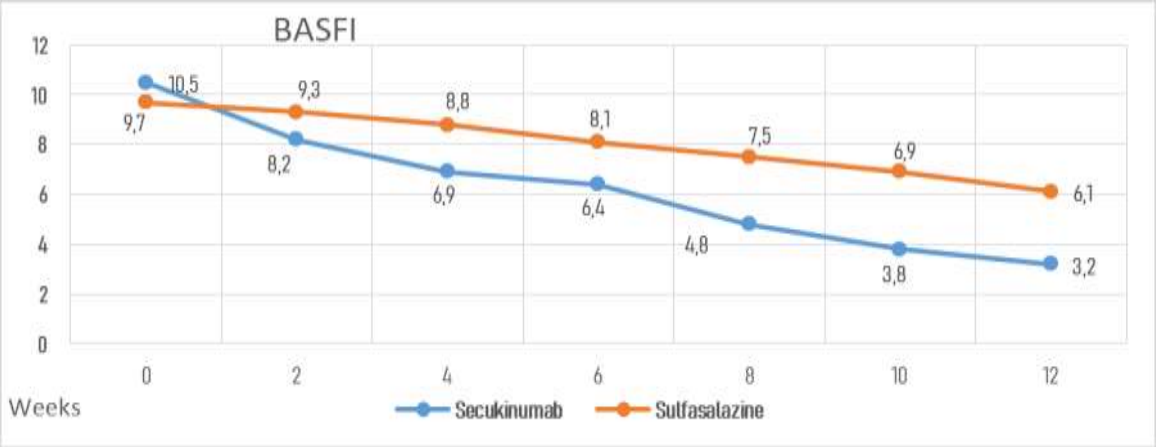

Figure 2. Dynamics of BASFI index in patients with AS over 12 weeks of treatment.

Differences between the groups were also observed in the MASES (Maastricht Ankylosing Spondylitis Enthesitis Score) scale. As shown in Figure 3, in Group I, a notable improvement was seen by the end of week 6 ($p<0.05$), and by week 8, the MASES score had significantly decreased to 4.8±1.1. It should be noted that in Group II, the MASES score showed a decreasing trend throughout the treatment period. However, this reduction was not statistically significant ($p>0.05$).

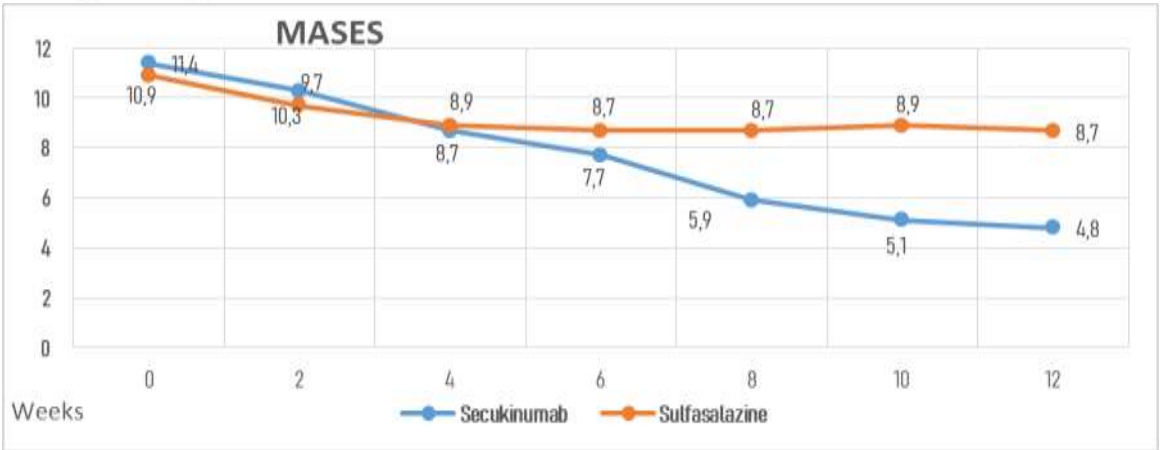

Figure 3. Dynamics of MASES index in study groups during treatment.

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It is well known that assessing patients' quality of life is widely used and holds significant importance. Specifically, in ankylosing spondylitis (AS), evaluating the severity of the pathological process, its dynamics, and the effectiveness of interventions in relation to quality of life has practical significance. In health status (HS) analysis, the use of questionnaires in clinical research has expanded in recent years. This approach allows for a more accurate interpretation of how a chronic disease negatively impacts patients' ability to live a normal life. In this study, quality of life (QoL) scores were statistically analyzed using the ASQoL

(Ankylosing Spondylitis Quality of Life) index. In Group I, the ASQoL index was 12.5±3.2 before treatment and significantly decreased to 6.8±2.5 after 12 weeks of therapy ($p<0.001$). In Group II, the ASQoL index decreased from 11.9±2.9 before treatment to 8.2±2.7 after therapy, but this change was not statistically significant ($p>0.05$). It is known that in autoimmune and hyperinflammatory processes, not only cytokines but also inflammatory proteins and enzymes play a role. Among them, matrix- metalloproteinases (MMPs), a family of zinc-dependent proteolytic enzymes that degrade extracellular matrix components, are particularly important. MMPs play a crucial role in tissue remodeling, angiogenesis (blood vessel formation), and inflammatory processes. Specifically, MMP-9 is involved in tissue remodeling (by degrading extracellular matrix components, including type IV collagen and elastin) and inflammation (by facilitating leukocyte migration across the basement membrane). Given this, the changes in MMP-9 levels in response to treatment were of particular interest in this study.

Table 2

Changes in MMP-9 levels during the treatment across groups

Groups	**Before treatment**	**After treatment**	**p**
Group I (Secukinumab), n=40	6,6±1,2	2,5±0,7	<0,02
Group II (Sulfasalazine), n=37	7,1±1,6	4,4±2,2	>0,05

According to Table 2, significant changes in serum MMP-9 concentrations were observed during the treatment process**.** In Group I (patients treated with secukinumab), the baseline MMP-9 level was 6.6±1.2 ng/ml before treatment. After 12 weeks of therapy, it significantly decreased to 2.5±0.7 ng/ml ($p<0.02$).In Group II (patients treated with sulfasalazine), the baseline MMP-9 level was 7.1±1.6 ng/ml, decreasing to 4.4±2.2 ng/ml after treatment, but this change was not statistically significant ($p>0.05$).

Conclusions: Thus, in patients with ankylosing spondylitis (AS), treatment with secukinumab (150 mg) demonstrated clinical efficacy by the end of the 12-

week therapy. This was reflected in clinical improvement of the disease, reduction of pain syndrome,enhanced functional capacity of the spine, and improved quality of life. Additionally, the use of secukinumab led to a decrease in MMP-9 levels.

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