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ASSESSMENT OF THE EFFICACY OF ADALIMUMAB TREATMENT IN HIDRADENITIS SUPPURATIVA: A SINGLE-CENTER STUDY
HİDRADENİTİS SÜPÜRATİVADA ADALİMUMAB TEDAVİSİNİN ETKİNLİĞİNİN DEĞERLENDİRİLMESİ: TEK MERKEZLİ BİR ÇALIŞMA

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ABSTRACT

Hidradenitis suppurativa (HS), is a chronic disease characterized by recurrent subcutaneous nodules, abscesses, and draining sinuses. Adalimumab is used for moderate to severe HS cases that do not respond to systemic treatments. The aim of our study was to evaluate the efficacy of adalimumab treatment in patients with HS who received treatment at our clinic. The medical records of patients aged 18 years and older who received adalimumab treatment for HS between 2016 and 2021 were retrospectively reviewed. When patients were evaluated in terms of Hidradenitis Suppurativa Clinical Response (HISCR) at the end of 3 months, 6 (31.6%) patients had achieved HISCR within 3 months. After 6 months of treatment, an additional 9 (47.4%) patients had reached the HISCR endpoint. At the end of 6 months, no response was observed in 4 patients (21.1%). Based on the data obtained from the study, adalimumab is considered to be an effective and safe treatment method for moderate to severe HS patients.

Keywords: Adalimumab, Hidradenitis suppurtiva, therapy, drug, efficiency

ÖZ

Hidradenitis süpürativa (HS), deri altında nodüller, apseler ve drene olan sinüslerin görülebildiği tekrarlayıcı bir hastalıktır. Adalimumab, sistemik tedavilere yanıt vermeyen orta ila şiddetli HS için kullanılmaktadır. Çalışmamızda kliniğimizde adalimumab tedavisi alan HS hastalarında etkinliği değerlendirmeyi amaçladık. Çalışmaya kliniğimize 2016-2021 yılları arasında başvuran, 18 yaşından büyük HS nedeniyle adalimumab tedavisi alan hastaların dosyaları retrospektif olarak taranmıştır. Hastalar 3 ay sonunda Hidradenitis Suppurativa Clinical Response (HiSCR) ile değerlendirildiğinde 6 (%31.6) hasta HiSCR'ye ulaşmıştı. Altı aylık tedavi sonrasında 9 (%47.4) hasta daha HiSCR değerine ulaşmıştı. Altı ayın sonunda 4 hastada (%21.1) tedaviye herhangi bir yanıt elde edilmedi.Çalışmadan elde edilen veriler neticesinde orta-şiddetli HS hastalarında adalimumabın etkili ve güvenli bir tedavi yöntemi olduğu düşünülmüştür.

Anahtar kelimeler: Adalimumab, Hidradenitis süpürativa, tedavi, ilaç, etkinlik

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INTRODUCTION

Hidradenitis suppurativa (HS), commonly referred to as acne inversa, is a chronic inflammatory dermatosis marked by recurring painful subcutaneous nodules, abscesses, and draining sinuses, which can result in scarring. This condition profoundly diminishes the quality of life for those affected (1).Several risk factors have been associated with HS, including a positive family history, obesity, and smoking habits (2). The prevalence of HS varies geographically, with estimates ranging from 0.00033% to 4.10% in different regions, and it is more commonly observed in women (3,4). HS has also been found to be associated with various comorbidities such as hypertension, obesity, dyslipidemia, thyroid disorders, arthropathies, and psychiatric disorders (5,6).

The treatment of HS varies across different countries. Generally, first-line treatments for mild to moderate HS (Hurley stage I and II) consist of tetracyclines or a combination of clindamycin and rifampicin. Additional treatment options include combination therapy with metronidazole, moxifloxacin, or rifampicin, as well as dapsone, colchicine, ertapenem, and retinoids such as acitretin and isotretinoin (7-11). Biological agents are recommended for moderate to severe HS (Hurley stage II-III) that is resistant to conventional therapies. Adalimumab, a tumor necrosis factor-alpha inhibitor, is recommended as a first-line biological agent for moderate to severe HS that does not respond to systemic treatments, according to all guidelines (8,9,11,12). In our country, adalimumab approved for use in HS patients in 2019.

The aim of this study is to evaluate the efficacy of adalimumab treatment in patients with HS who received treatment at our center between 2016 and 2021.

MATERIALS AND METHODS

This retrospective study enrolled patients who visited our clinic between 2016 and 2021 and underwent adalimumab treatment for HS (Patients using 2016-2019 off-label, 2019-2021 in-indication). The study cohort comprised individuals aged 18 years or older. Approval from the local ethics committee was obtained to review the patients' medical records (no: 2021/522). Relevant data, including age, gender, co morbidities, and prior treatments for HS, were extracted from the medical records. The severity of HS was retrospectively assessed using the Hurley score, which classifies the condition into three stages: Stage I, characterized by single or multiple abscesses without sinus tracts and scarring; Stage II, characterized by recurrent distinct abscesses with fistulous tracts and scarring; and Stage III, encompassing patients with diffuse or nearly diffuse involvement, along with numerous interconnected tracts and abscesses across the affected area. The patients' response to adalimumab treatment was evaluated using the HISCR scale.

HISCR was considered achieved if there was a reduction of at least 50% in the total number of abscesses and inflammatory nodules, with no increase in the number of abscesses and draining fistulas compared to baseline. Follow-up examinations were conducted at 3 and 6 months to assess treatment response. Treatment was considered ineffective if patients did not achieve HISCR within 6 months.

The statistical analysis was conducted utilizing SPSS software (Statistical Package for the Social Sciences, version 15.0; SSPS Inc, Chicago, Illinois, USA). The distribution of continuous variables was assessed through the one-sample Kolmogorov-Smirnov test, and the results were presented as mean ± standard deviation or median with minimum-maximum ranges. Categorical variables were reported as frequencies and percentages.

RESULTS

The study included patients with a mean age of 31.95 (± 11.5) years. Among the participants, 16 (84.2%) were male and three (15.2%) were female. The average age of female patients was 31.67 (± 8.5) years, while male patients had an average age of 32 (± 12.2) years. Among the enrolled patients, 10 (52.6%) were non-smokers, while nine (47.4%) were smokers. In terms of prior treatments, four patients had received infliximab, one patient had been treated with etanercept, four patients had undergone acitretin therapy, 15 patients had received systemic antibiotics, and 11 patients had been prescribed isotretinoin. One patient had no history of medication use for HS. During the patients' examinations, Hurley scores were determined as Hurley stage 3 in 16 patients (84.2%) and Hurley stage 2 in three patients (15.8%). Among the patients, four had additional comorbidities, including familial Mediterranean fever in one patient, hypertension in one patient, psoriasis in one patient, and ankylosing spondylitis in one patient (Table I).

At the 3-month evaluation, six patients (31.6%) achieved HISCR. After 6 months of treatment, nine patients (47.4%) reached HISCR. However, in four patients (21.1%), no response was observed after 6 months, and the treatment was considered unsuccessful (Table II). None of the patients reported any adverse effects during the treatment period.

DISCUSSION AND CONCLUSION

HS has gained significant attention in recent research studies. It is commonly observed in individuals in their third and fourth decades of life (13). In our study, the mean age of the patients was 31.95 (± 11.5) years, which aligns with previous findings. Gender distribution varies across different regions, with female predominance observed in Western countries (14,15), while studies from Asian sources indicate a male predominance (16). In the study conducted by Ozkur and colleagues, a significant male dominance has been reported (17).Similarly, some studies have reported that diseases tend to have a more severe course in males (18). Lee and colleagues have suggested that male dominance may be due to higher rates of smoking among men in Asia. In our study, 84.2% of the patients were male, and 15.8% were female. However, it is important to note that our patient population was predominantly classified as Hurley stage 3, which may contribute to the observed male predominance due to the inclusion of more severe cases.

Adalimumab has been utilized as a treatment for HS for a considerable period of time. It approved for the treatment of HS in our country in 2019. Two phase III studies, involving a total of 633 patients, evaluated the effi-

Table I. Demographic data of the patients

Patient no	Age	Gender	Previous Treatments*	Hurley Score	Additional Comorbidities	Smoking
1	57	Male	1.2	3	Ankylosing spondylitis	No
2	19	Male	3.4	3	-	Yes
3	36	Male	4.5	3	-	No
4	22	Male	4.5	3	-	No
5	20	Male	4	3	-	No
6	28	Male	4.5	3	Hypertension	Yes
7	54	Male	4.5	3	-	Yes
8	19	Male	3	3	-	Yes
9	23	Male	4.5	2	Familial mediterranean fever	No
10	30	Male	4.5	2	-	Yes
11	22	Male	1.5	3	-	No
12	23	Female	-	3	Psoriasis	No
13	39	Male	3.4	3	-	Yes
14	38	Male	3.4	3	-	Yes
15	40	Female	4	3	-	Yes
16	46	Male	1.4.5	3	-	No
17	25	Male	1.4.5	3	-	No
18	34	Male	4.5	3	-	Yes
19	32	Female	4.5	2	-	No

*1: Infliximab 2: Etanercept 3: Acitretin 4: Systemic antibiotics 5: Isotretinoin

Table II. HISCR responses after treatment

HiSCR*	n	%
3rd month	6	31.6
6th month	9	47.4
Unresponsive to treatment	4	21.1

*HISCR: Hidradenitis Suppurativa Clinical Response

cacy of adalimumab, with the primary endpoint being the HISCR. In both studies, patients treated with adalimumab demonstrated a higher rate of HISCR compared to the placebo controls (PIONEER I: 41.8% vs. 26%, PIONEER II: 58.9% vs. 27.6%).

In a study by Kimball et al. weekly subcutaneous administration of 40 mg adalimumab not only achieved HISCR but also positively impacted pain and quality of life (19). Another study by Miller et al., involving 21 patients, observed a significant reduction in the Sartorius score after 6 weeks of adalimumab treatment (20). Chiricozzi et al. evaluated clinical response using ultrasound and observed an increasing rate of achieving HISCR 50 over time in patients receiving adalimumab treatment (36.4% at week 52) (21). The post-marketing observational study HARMONY 21 reported rapid (within 12 weeks) and sustained (52 weeks) response in patients with moderate to severe HS (22). In a study conducted in Japan, 83 patients were enrolled, and 57.4% of them achieved HISCR at week 12 (23). Similarly, in our study, HISCR response was observed in 6 patients (31.6%) at 3 months and in a total of 15 patients (79.9%) at 6 months. Only 4 patients (21.1%) were considered non-responsive to treatment.

Smoking is recognized as a risk factor for HS (24), and some studies have associated smoking with disease severity and delayed treatment response (25,26). In our study, 10 patients (52.6%) were non-smokers, while 9 patients (47.4%) were smokers. Among the non-responsive patients, half of them (n=2) were smokers, and the other half (n=2) were non-smokers. This suggests that smoking may not have had a significant impact on the patients in our study.

The study's limitations encompassed a limited sample size, the retrospective nature of the study and the absence of an assessment regarding the long-term efficacy of adalimumab treatment. However, the findings align with the current literature and suggest that adalimumab is a viable and secure treatment choice for patients with moderate-to-severe HS.

Conflict of interest: No conflict of interest

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