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Adalimumab Biosimilar Efficacy and Safety in a 5-Year-Old Patient with Severe Plaque Psoriasis During SARS-CoV-2 Pandemic Outbreak

Lucia Gallo, Gianmarco Capasso, Francesca Nastro, Gabriella Fabbrocini*, Matteo Megna

Department of Clinical Medicine and Surgery, University of Naples Federico II, Naples, Italy

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***Correspondence:** Gabriella Fabbrocini, Department of Clinical Medicine and Surgery, University of Naples Federico II, Naples, Italy.
E-mail: dermofabbrocini@gmail.com
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Abstract

BACKGROUND: Psoriasis is a chronic inflammatory disease that affects 2% of population. About 0.5–2% of psoriatic cases develop during pediatric age. In most cases, the condition is responsive to topical treatment. However, a small percentage of children require systemic treatment with conventional systemic drugs or biological agents, such as anti-tumor necrosis factor (TNF)-α. Adalimumab (ADA) is an anti-TNF-α recently approved for pediatric psoriasis in the European Union (from 4 years of age, 2015).

CASE PRESENTATION: We describe our experience treating a 5-year-old female patient affected by severe plaque psoriasis with ADA biosimilar during SARS-CoV-2 pandemic outbreak also using teledermatology.

CONCLUSION: The case reported in this article highlights the safety and the effectiveness of ADA biosimilar MSB11022 (Idacio®) in the treatment of a 5-year-old female affected by plaque psoriasis and paves the way to bigger trials for a more extensive use of TNF-α inhibitor biosimilars for psoriasis in pediatric population.

Introduction

Adalimumab (ADA) is a recombinant human monoclonal antibody against tumor necrosis factor (TNF)-α approved for adult plaque psoriasis (2008) and hidradenitis suppurativa (2015). In 2015, ADA was approved by the European Medicines Agency (EMA) in pediatric patients (from 4 years of age) for use in severe plaque psoriasis, enthesitis-related arthritis, severe Crohn's disease, and active juvenile idiopathic arthritis. However, many case reports justify its use in children, also in other medical conditions such as pustular and erythrodermic psoriasis, acrodermatitis continua of Hallopeau, and non-infectious uveitis [1], [2], [3]. Nowadays, several different ADA biosimilars are available on the market with the first being authorized by European Commission in August 2017, presenting with the same indications of ADA originator. At present, scientific literature on efficacy and safety of ADA biosimilar is limited, especially as regards pediatric patients affected by plaque psoriasis. Plaque psoriasis may develop at any age with the prevalence of psoriasis in childhood and adolescence ranging between 0.5% and 2% [4]. We herein report the case of a 5-year-old female patient affected by severe plaque psoriasis successfully treated with ADA biosimilar MSB11022 (Idacio® 20 mg s.c.) in 12 weeks.

Case Presentation

A 5-year-old female patient referred to our dermatology department, presenting small (2–10 mm) itchy erythematous-desquamative raindrop-like plaques located on the scalp, trunk, abdomen, arms, and legs (Figure 1). Her medical history was unremarkable and family history for psoriasis was negative. The mother of the patient reported that she had been suffering from pharyngitis 2 weeks before skin lesions appearance. A pharyngeal swab was executed and resulted positive for *Streptococcus pyogenes* β-hemolytic, thus antibiotic treatment with amoxicillin + clavulanic acid was prescribed for 6 days with a negative swab being observed 3 weeks after antibiotic treatment completion. Considering lesions' morphology and distribution, a clinical diagnosis of guttate psoriasis

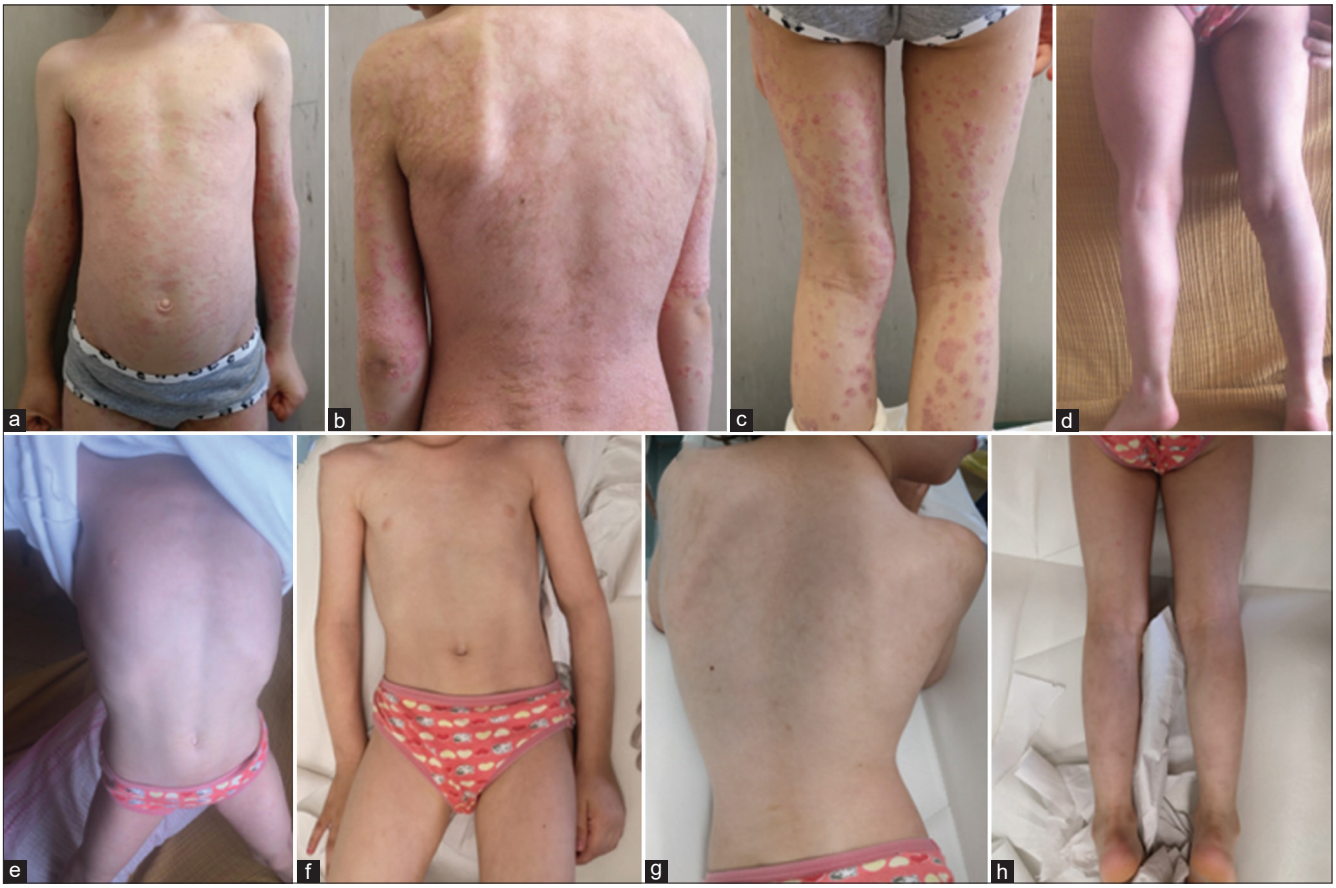

Figure 1: (a-c) Patient at baseline; (d and e) at 5-week follow-up (photos sent by parents); (f-h) at face-to-face 12-week follow-up during treatment with ADA biosimilar MSB11022

was made. Initial treatment with topical Vitamin D derivatives and corticosteroids ointment was started. At 1-month clinical evaluation, despite topical treatment, the patient's lesions worsened and appeared as diffuse infiltrative erythematous desquamative plaques, assuming the clinical form of plaque psoriasis. Psoriasis severity scores were evaluated and resulted in psoriasis area and severity index (PASI) 22.6 and body surface area (BSA) 40%. Routine blood tests were within normal values including hepatitis markers and QuantiFERON-TB gold test. Considering psoriasis severity, the lack of clinical benefits to topical treatment, and the high impact on patient and her parents' quality of life, biological treatment was proposed. Informed written consent was obtained by patient's parents and therapy with ADA biosimilar MSB11022 (Idacio® 20 mg s.c. every 2 weeks) was initiated the 5 of March 2020. Due to SARS-CoV-2 pandemic outbreak, and consequent restrictions measures applied since March 9 in Italy, clinical controls, except for oncologic patients, were not allowed, so we kept in touch with patient's parents through telemedicine. Clinical photos were obtained, before starting treatment at our department while 5 weeks later, clinical images were taken and sent to us by patient's parents (Figure 1) showing significant improvement, with gradual erythema, scaling, and skin lesions size reduction. Face-to-face dermatologic control was made at week 12, thanks to COVID-19-related restriction measures reduction, and a complete disappearance of itch and skin lesions was observed (PASI 0 BSA 0) (Figure 1). After 24 weeks, the patient is still on treatment with ADA biosimilar without any relapse. No adverse drug reactions were reported, and routine blood chemistry always resulted within normal range up to now.

Discussion

Psoriasis is a chronic inflammatory skin disease that affects 3% of world population [5] being associated with increased mortality and multimorbidity [6]. In the last few years, the increased knowledge of the molecular pathogenesis of psoriasis has led to the introduction of targeted biologic therapies, which have radically improved patient outcomes [7]. Biologics have proven to be safe drugs in all ages including adolescent and children from the age of 4, also during SARS-CoV-2 pandemic [8]. The prevalence of psoriasis in childhood and adolescence ranges between 0.5 and 2%. Approximately one-third of patients with psoriasis have symptoms before age 20, with mean onset between 7 and 11 years of age [9], [10]. Due to psoriasis chronic nature and frequently occurring relapses, also pediatric

psoriatic patients may tend to have an impaired quality of life, often requiring long-term treatment. However, systemic treatment of children is challenging as the absence of standardized guidelines and the fact that evidence-based data form randomized controlled trials are very limited [11], [12]. In this context, biologics such as anti-TNF-α (ADA and etanercept) and anti-IL-12/23 (ustekinumab) are the only approved systemic treatment for pediatric plaque psoriasis with conventional systemic treatments such as cyclosporine, methotrexate, and acitretin being used off-label. Particularly, ADA is indicated for moderate to severe psoriasis in childhood from the age of 4, being recommended as first-line therapy because of greater safety, reduced incidence of adverse effects, a less frequent dosing and laboratory monitoring than traditional agents [13], and the possibility of dose tapering to reduce drug exposure risk and costs and to increase patient compliance [14]. The use of ADA for pediatric psoriasis has been studied in a Phase III clinical trial involving an initial 16-week treatment period followed by a 16-week withdrawal period and a 1-year open-label treatment [15]. A total of 114 subjects were enrolled, ranging from 4 to 17 years of age. ADA was well tolerated, with only one serious infection reported and achieved better clinical response (PASI 75 response) than methotrexate. Biosimilars are compounds that are structurally and functionally similar to biologics that have been developed in the last few years with the aim to lower the cost and increase the accessibility of biologic agents, thereby reducing the burden of disease due to chronic inflammatory conditions worldwide [16], [17], [18]. At present, several anti-TNF-α biosimilars are available for the treatment of psoriasis [17], [18]. The US Food and Drug Administration (FDA) and/or the EMA have approved numerous biosimilars of ADA (Amjevita/Amgevita/Solymbic, Cyltezo, Imraldi/Hadlima, Hyrimoz/Hefiya/Halimatoz, Idacio, Hulio, Abrilada), for the treatment of plaque psoriasis [19], [20]. The ADA biosimilar ABP 501 (Amjevita in the USA; Amgevita/Solymbic in the European Union [EU]) was the first of its type to be approved by the FDA in 2016 and the EMA in 2017 [19], [20]. In a randomized double-blind clinical trial comparing the efficacy of ABP 501 to ADA for psoriasis, PASI percent improvement at week 16 was 83.1 for ADA and 80.9 for ABP 501. There were no differences in the incidence of adverse events or anti-drug antibodies between groups [21]. The ADA biosimilar MSB11022 (Idacio®) was approved by the EMA in April 2019 [22] with a multicenter, double-blind Phase III trial (AURIEL-PsO) demonstrating therapeutic equivalence between MSB11022 and reference ADA with regard to efficacy, safety, and immunogenicity up to 52 weeks of treatment in 443 patients with moderate-to-severe psoriasis [23]. At present, literature lacks controlled clinical trials and case reports on the use of ADA biosimilar in the pediatric population affected by psoriasis. The only case report of ADA biosimilar use in a pediatric patient is about its use in acrodermatitis continua of Hallopeau in a 15-year-old female patient with good clinical results and no adverse drug events reported [24].

Conclusion

Biosimilars are emerging drugs in psoriasis treatment. Literature lacks large studies on the safety and effectiveness of ADA biosimilars for psoriasis in children, even if they have been approved with the same indications of ADA originator in 2017. The case reported in this article highlights the safety and the effectiveness of ADA biosimilar MSB11022 (Idacio®) in the treatment of a 5-year-old female affected by plaque psoriasis and paves the way to bigger trials for a more extensive use of TNF-α inhibitor biosimilars for psoriasis in pediatric population.

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