Materials and Methods

The study was carried out in 80 patients with severe alopecia areata (AA) attending the outpatient Department of Dermatology, Farwaniya Hospital, Kuwait, between January 2015 and July 2017. The study was approved by the Dermatology Review Board of Farwaniya Hospital.

Inclusion criteria were patients >18 years of age with a clinical diagnosis of severe AA, for at least 6 months duration, and resistant to other treatment modalities. Severe types of AA included severe multifocal alopecia (MFA; with a bald surface exceeding 30% of the scalp), alopecia totalis (AT; with a complete absence of terminal scalp hair), and alopecia universalis (AU; with a total loss of terminal scalp hair and body hair).

Patients with less than 30% scalp involvement, those with co-existent androgenetic alopecia, active scalp inflammation, active malignancy or history of malignancy, history of systemic or infectious disease, and pregnant women were excluded from the study. The nature of the treatment, possible benefits, and side effects were carefully explained to all the patients. Each patient signed a written consent for inclusion into the study, and for clinical photographs.

Patients were randomly divided into 2 equal groups. The first group of patients received oral ruxolitinib 20 mg twice daily, while the second group received tofacitinib citrate 5-mg tablets twice daily. Treatment was continued for 6 months, and participants were followed up monthly for an additional 3 months to assess the durability of treatment response. All the patients were advised to stop taking any treatment known to affect AA for at least 3 months before commencement of the study, as well as during the study.

Before treatment, a complete physical examination and baseline laboratory testing – complete blood count, liver and renal function tests, electrolytes, viral markers for hepatitis B, C, and HIV, a chest X-ray, and a tuberculin skin test, antithyroglobulin antibody, and antinuclear antibody – were performed.

Patients were assessed once a month during the 6-month treatment period, as well as during the 3-month follow-up period to evaluate hair growth and monitor for possible side effects. The hair growth was assessed on a percentage scale, ranging from 0 to 100% using the Severity of Alopecia Tool (SALT) scale, which is a validated tool that quantifies percent scalp hair loss [24]. The whole scalp was divided into 4 parts based on the surface area, top (40%), posterior (24%), right side (18%), and left side of the scalp (18%). The percentage of hair loss in each area was determined independently and multiplied by the percentage of scalp covered in that area of the scalp, so adding the products of each area gave the SALT score.

According to the percentage improvement in SALT scores the patients were divided into 5 categories as follows: low grade responders (0–24% SALT score improvement), medium grade responders (25–49% improvement), good grade responders (50–74% improvement), excellent-grade responders (75– 99%), and complete grade responders (100% improvement). Only growth of terminal hair from the lesions was considered as regrowth. During the follow-up period, hair loss >25% was considered a relapse.

Statistical analysis was performed using SPSS version 14.0 for Windows statistical package (SPSS Inc., Chicago, IL, USA). A minimal significance of $p < 0.05$ two-tailed was considered as statistically significant.