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ORIGINAL RESEARCH

Clinical Benefits of Baricitinib Therapy According to Scalp Hair Regrowth in Patients with Severe Alopecia Areata

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ABSTRACT

Objectives: The present analyses report integrated results from BRAVE-AA1 (NCT03570749) and BRAVE-AA2 (NCT03899259) on the clinical benefits of baricitinib treatment on the basis of the amount of scalp hair regrowth through 52 weeks of treatment.

Methods: This post hoc analysis was conducted with data from patients who were treated continuously for 52 weeks with baricitinib 4 mg or 2 mg. Clinical outcomes were assessed using the Severity of Alopecia Tool (SALT) and Clinician-Reported Outcome (ClinRO) for Eyebrow (EB) and Eyelash (EL) hair. Secondary measures included the Hospital Anxiety and Depression Scale and Skindex-16 adapted for alopecia areata. At week 52, patients were classified into three subgroups: SALT $\leq$ 20 response, intermediate response (achieved a 30% improvement from baseline ($SALT_{30}$) without a SALT score $\leq$ 20), or nonresponse (never achieved $SALT_{30}$). The criterion of $SALT_{30}$ approximates a minimal clinical meaningful response to therapy.

Results: At week 52, with baricitinib 4 mg treatment, the greatest (70%) improvement in EB and EL was observed in responders, but approximately 50% of patients with intermediate response and 20% of nonresponders experienced complete/nearly complete EB and EL regrowth. Improvement in emotional distress was directionally related to improvements in scalp hair regrowth, while impact on quality of life was proportionately greater for the responder subgroup.

Conclusions: Clinically meaningful regrowth in eyebrow and eyelash hair can occur in the

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absence of complete scalp hair regrowth after treatment with baricitinib. Emotional distress and quality of life improvement is most associated with obtaining a clinical meaningful improvement in scalp hair.
Trial Registration Number: BRAVE-AA1, ClinicalTrials.gov number, NCT03570749, start date, 24 September 2018; BRAVE-AA2, ClinicalTrials.gov number, NCT03899259, start date, 8 July 2019.

Keywords: Alopecia areata; Baricitinib; Immunology; Eyebrow; Eyelash

Key Summary Points

After 52-week treatment with baricitinib, regrowth of eyebrow and/or eyelash hair to full or minimal gaps was observed in patients who did not achieve complete or near complete scalp hair regrowth.

Patients who achieve clinically meaningful scalp regrowth of SALT $\leq$ 20 had significantly greater improvements in emotional distress compared with intermediate of nonresponders.

INTRODUCTION

Alopecia areata (AA) is an autoimmune disorder characterized by nonscarring hair loss that can affect any hair-bearing site [1], often leading to emotional and psychosocial distress [2–4]. Severe AA is unlikely to remit without treatment [5]. Recently, baricitinib, an oral selective JAK inhibitor that has been previously approved for the treatment of rheumatoid arthritis, became the first approved systemic therapy in the USA, Europe, and Japan for the treatment of adults with severe AA [6]. In the BRAVE-AA1 and BRAVE-AA2 phase 3 trials [7, 8], each met their primary endpoint of a greater percentage of participants achieving Severity of Alopecia Tool (SALT) score $\leq$ 20 (at least 80% scalp coverage) by week 36 in the baricitinib treatment groups versus placebo, and scalp hair regrowth continued to improve through week 52 [7, 8]. Safety data for baricitinib are well characterized across several indications [9, 10] and safety data are available up to 2 years in AA [8, 11, 12].

Reflecting the heterogeneity of the disease, the amount of scalp hair regrowth can vary with treatment, and other hair-bearing sites may also respond differentially to therapy. In a large case series of patients treated with tofacitinib, Liu et al. observed that patients could achieve full eyebrow (EB) and eyelash (EL) regrowth despite not achieving complete scalp hair regrowth [13]. We have previously reported that the amount of scalp hair regrowth at week 36 was associated with improvements in emotional symptoms and quality of life [14]. Here, we extend this analysis by examining regrowth at week 52 and whether the patients who do not achieve a SALT score $\leq$ 20 may experience holistically other clinically meaningful benefits, including EB/EL regrowth, improvement in psychological distress, or improvement in quality of life (QoL).

METHODS

Trial Design

BRAVE-AA1 and BRAVE-AA2 were randomized, double-blind, parallel-group, placebo-controlled trials conducted at 169 centers in ten countries [7]. The trials had identical eligibility criteria and primary and key secondary objectives for the 36-week placebo-controlled treatment periods. In BRAVE-AA1 and BRAVE-AA2, first patients entered treatment in March 2019 and July 2019, respectively, and last patients entered treatment in June 2020 and May 2020, respectively. A full description of the trial design has been previously published [7].

Patients were initially randomized to receive placebo, baricitinib 2 mg, or baricitinib 4 mg in a 2:2:3 ratio. At week 36, nonresponder patients on placebo were rerandomized to either baricitinib 2 mg or 4 mg; however, since they had not yet had 52 weeks of active therapy, they are not included in this post hoc analysis. Patients who were treated continually with either dose of

baricitinib through week 52 comprised this analysis.

Patient Eligibility

Patients were aged ≥ 18 years and ≤ 60 years for males and ≤ 70 years for females [15]. Inclusion criteria required SALT score ≥ 50 (at least 50% of scalp hair loss) [16] and a current episode lasting > 6 months to < 8 years, without spontaneous improvement (≤ 10-point SALT score reduction) over the past 6 months. There were no inclusion requirements for EB or EL hair loss. A full description of inclusion and exclusion criteria has been previously published [7]. Treatment with finasteride (or other 5α-reductase inhibitors) and with oral or topical minoxidil was permitted if patients had been on a stable dose for 12 months before randomization and were anticipated to continue a stable dose until week 36. Treatment of eyelids with bimatoprost ophthalmic solution was permitted if patients had been on a stable dose for ≥ 8 weeks before randomization. However, less than 5% of patients were receiving these concomitant medications.

Clinical Outcomes

Scalp hair loss was assessed using the SALT measure [17]. SALT scores are derived from a physician examination of the four quadrants of the scalp and are calculated so that scores are equivalent to the percentage of scalp hair loss. A SALT score ≤ 20 means there is less than 20% scalp hair loss. Scores that reflect a change from the patient's baseline are referenced using subscript; for instance, $SALT_{30}$ means a 30% improvement from the patient's baseline SALT score. EB and EL were assessed using the Clinician-Reported Outcome (ClinRO) for Eyebrow and Eyelash hair [18]. A ClinRO score of 0 indicates no EB/EL hair loss, a score of 1 indicates minimal gaps, a score of 2 indicates significant loss or gaps, and a score of 3 indicates total hair loss.

Emotional distress was assessed using the Hospital Anxiety and Depression scale (HADS) [19], and QoL impact was measured using the Skindex-16 adapted for AA (Skindex-AA) [20]. The HADS is scored into two separate scales: HADS Anxiety and HADS Depression. Each scale can range from 0 to 21 and scores of 8–10 are interpreted as borderline abnormal, while scores ≥ 11 are considered clinically relevant [19]. The Skindex-AA consists of 16 items grouped under three domains: symptoms (four items), emotions (seven items), and functioning (five items), and these domain scores assess how hair loss affects symptoms, emotions, and functioning. The Skindex-AA total score can range from 0 to 100, with higher scores indicating greater impairment. The Skindex-AA was administered to the majority of patients in BRAVE AA1 and to all patients in AA2 on the basis of its contract availability at the time of study initiation.

Statistical Analyses

Baricitinib patient subgroups were categorized into one of three response subgroups on the basis of their SALT score at week 52:

1. SALT criterion response, defined as those achieving SALT score ≤ 20 by week 52.
2. Intermediate response, defined as failure to reach SALT score ≤ 20 but achieving a $SALT_{30}$ at one or more post-baseline visits by week 52; or
3. Nonresponders, defined as never achieving $SALT_{30}$ by week 52.

ClinRO Eyebrow and ClinRO Eyelash were assessed in participants who had substantial hair loss in either EB or EL (a ClinRO score ≥ 2 at baseline). Response was defined as a ClinRO score of 0 or 1 with ≥ 2-point improvement from baseline. Response rates were reported using descriptive statistics. Mean change from baseline in HADS Anxiety and Depression scores, and Skindex domain scores, were summarized by subgroups for each treatment arm. Nonresponder imputation and modified last observation carried forward were used to impute data censored after permanent drug discontinuation or data collected remotely due to the coronavirus disease 2019 (COVID-19) pandemic, for binary and continuous

endpoints, respectively. Comparisons between the SALT response subgroups were conducted using analysis of variance (ANOVA) for the endpoints of the HADS and Skindex. Main subgroup effect was further tested by pair-wise t-tests for between group differences and *p*-values were corrected using Bonferroni method.

Ethics Approval and Patient Consent

The trials were conducted in accordance with ethical principles of the Declaration of Helsinki and Good Clinical Practice guidelines, and the research protocols were approved by each center's institutional review board or ethics committee. All patients provided written informed consent.

Patient and Public Involvement Statement

Patients were not involved in the development of the protocol.

RESULTS

Baseline Characteristics and Disease Activity

In the pooled population from BRAVE AA1 and AA2, at baseline, 502/855 (59%) patients had a SALT score range of 91–100 (Fig. 1). As patients treated with baricitinib 4 mg had a greater response rate compared with baricitinib 2 mg, the patient's response at week 52 was classified according to treatment dose. Among the patients treated with baricitinib 2 mg, 22.6% were criterion responders, 28.5% were intermediate responders, and 48.8% were nonresponders for scalp involvement. Among the patients treated with baricitinib 4 mg, 39.0% of patients were criterion responders, 29.9% were intermediate responders, and 31.1% were nonresponders. Patients who met criterion and intermediate response tended to have a lower baseline SALT score and a shorter duration of episode of current disease compared with nonresponders (Table 1).

ClinRO Measure for Eyebrow and Eyelash by Response-Based Subgroup at Week 52

At week 52, among patients treated with baricitinib 4 mg, 68.9% of criterion responders achieved a ClinRO Eyebrow (0, 1) and 69.2% achieved a ClinRO Eyelash (0, 1). For intermediate responders, the proportion of patients who achieved a ClinRO Eyebrow (0, 1) was 50.5%, and for ClinRO Eyelash (0, 1) it was 47.7%. For nonresponders, 15.7% and 21.7% reached ClinRO Eyebrow (0, 1) and ClinRO Eyelash (0, 1), respectively. There was a similar pattern across the response subgroups for the baricitinib 2 mg group, with greater achievement in ClinRO Eyebrow (0, 1) and Eyelash (0, 1) for the responder and intermediate responder subgroups than for the nonresponder subgroup (Fig. 2).

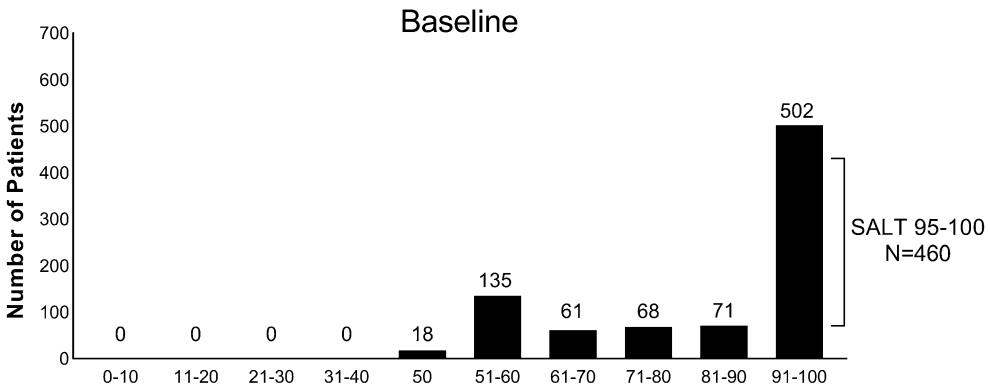

Fig. 1 Baseline SALT scores. *N* number of patients in the analysis, *SALT* severity of alopecia tool

Table 1 Baseline SALT score and category by response subgroup

	Criteria response subgroup[a]		Intermediate response subgroup[b]		Nonresponse subgroup[c]	
	Baricitinib 2 mg (*N* = 77)	**Baricitinib 4 mg (*N* = 201)**	**Baricitinib 2 mg (*N* = 97)**	**Baricitinib 4 mg (*N* = 154)**	**Baricitinib 2 mg (*N* = 166)**	**Baricitinib 4 mg (*N* = 160)**
Age, years	37.6 (11.44)	36.7 (12.94)	38.2 (13.83)	37.6 (12.96)	38.9 (12.97)	37.1 (13.18)
Female *n* (%)	54 (70.1)	132 (65.7)	52 (53.6)	88 (57.1)	106 (63.9)	89 (55.6)
Race *n* (%)						
White	41 (53.2)	111 (55.2)	57 (59.4)	79 (51.6)	87 (52.4)	77 (48.1)
Asian	34 (44.2)	71 (35.3)	31 (32.3)	60 (39.2)	60 (36.1)	50 (31.3)
Black	1 (1.3)	12 (6.0)	4 (4.2)	11 (7.2)	14 (8.4)	23 (14.4)
Other[d]	1 (1.3)	7 (3.5)	4 (4.2)	3 (2.0)	5 (3.0)	10 (6.3)
BMI, kg/m^2	25.4 (4.84)	26.0 (5.07)	26.2 (4.79)	26.8 (5.63)	26.4 (5.77)	26.5 (4.94)
Time since onset of AA, years	10.6 (9.38)	10.2 (10.47)	11.4 (10.99)	11.0 (10.53)	14.1 (11.03)	14.8 (11.84)
Duration of current AA episode, *n* (%)	2.9 (4.09)	3.0 (2.87)	3.8 (4.43)	3.5 (3.15)	4.9 (6.24)	4.6 (3.91)
$<$ 4 years	65 (84.4)	151 (75.1)	67 (69.1)	102 (66.2)	98 (59.0)	76 (47.5)
$\geq$ 4 years	12 (15.6)	50 (24.9)	30 (30.9)	52 (33.8)	68 (41.0)	84 (52.5)
Patients with AU, *n* (%)	31 (40.3)	81 (40.3)	45 (46.4)	71 (46.1)	77 (46.4)	86 (53.8)
SALT score, mean (SD)	76.9 (19.1)	80.6 (18.8)	84.4 (19.0)	84.4 (17.9)	91.7 (14.7)	91.4 (15.7)
SALT category						
Severe[e], (non-AT) *n* (%)	53 (68.8)	127 (63.2)	45 (46.4)	77 (50.0)	49 (29.5)	44 (27.5)
Very severe[f], (consistent with AT) *n* (%)	24 (31.2)	74 (36.8)	52 (53.6)	77 (50.0)	117 (70.5)	116 (72.5)
ClinRO measures, *n* (%)						
Eyebrow hair loss score of 2 or 3	45 (58.4)	119 (59.5)	64 (66.0)	103 (67.3)	131 (78.9)	127 (80.4)
Eyelash hair loss score of 2 or 3	35 (45.5)	104 (52.0)	56 (57.7)	88 (57.5)	109 (65.7)	115 (72.8)
HADS Depression	3.4 (3.16)	4.2 (3.58)	4.5 (3.85)	4.2 (3.61)	4.0 (3.39)	3.3 (2.97)

Table 1 continued

	Criteria response subgroup[a]		Intermediate response subgroup[b]		Nonresponse subgroup[c]	
	Baricitinib 2 mg (*N* = 77)	**Baricitinib 4 mg (*N* = 201)**	**Baricitinib 2 mg (*N* = 97)**	**Baricitinib 4 mg (*N* = 154)**	**Baricitinib 2 mg (*N* = 166)**	**Baricitinib 4 mg (*N* = 160)**
HADS anxiety	5.7 (3.51)	6.8 (3.96)	6.6 (3.92)	6.3 (4.00)	6.2 (3.85)	5.6 (3.53)
Skindex-16 adapted AA score for emotions	71.5 (21.98)	68.8 (27.71)	71.9 (24.60)	69.6 (31.04)	65.3 (28.73)	62.5 (31.84)
Skindex-16 adapted AA score for functioning	46.1 (29.18)	54.0 (32.39)	51.0 (34.70)	53.8 (33.23)	48.5 (31.69)	43.5 (31.81)
Skindex-16 adapted AA score for symptoms	20.8 (20.29)	17.7 (20.07)	21.8 (24.12)	18.3 (19.51)	15.4 (18.37)	15.5 (18.16)

AA alopecia areata, *AT* alopecia totalis, *AU* alopecia universalis, *BMI* body mass index, *ClinRO* Clinician-Reported Outcome, *HADS* Hospital Anxiety and Depression Scale, *N* number of patients in the analysis, *n* number of patients in the specified category, *SALT* severity of alopecia tool

[a]Criterion responders, defined as those achieving SALT score $\leq$ 20 by week 52

[b]Intermediate responders, defined as failure to reach SALT score $\leq$ 20 but achieving a $SALT_{30}$ at one or more post-baseline visits by week 52

[c]Nonresponders, defined as never achieving $SALT_{30}$ by week 52

[d]Other, American Indian or Alaska native, native Hawaiian or other Pacific Islander, or multiple race

[e]SALT score 50–94%

[f]SALT score 95–100%

Emotional Distress and Quality of Life Outcomes at Week 52 by Response Subgroups

In the overall patient population mean scores were higher for the HADS Anxiety score compared with the HADS Depression score. Among patients treated with baricitinib 4 mg, criterion responders had significantly greater mean change from baseline for both the HADS Anxiety for HADS Depression scores compared with nonresponders whose mean change did not significantly differ from the intermediate responders (Fig. 3). Among patients treated with baricitinib 2 mg, there were no main effects of SALT subgroup across the mean changes for the HADS Anxiety, while criterion responders significantly improved compared with the nonresponders.

With respect to impact on QoL, significant differences in mean improvement across SALT subgroups were observed for both the Skindex-AA emotions and functioning scores. For each of these scores, the criterion responder subgroup within both doses had significantly more improvement than the nonresponders; mean improvement in the intermediate responders was also significantly greater than nonresponders for patients treated with baricitinib 2 mg (Fig. 4). The SALT subgroups did not differ across for mean improvement in the Skindex AA symptoms score (Fig. 4).

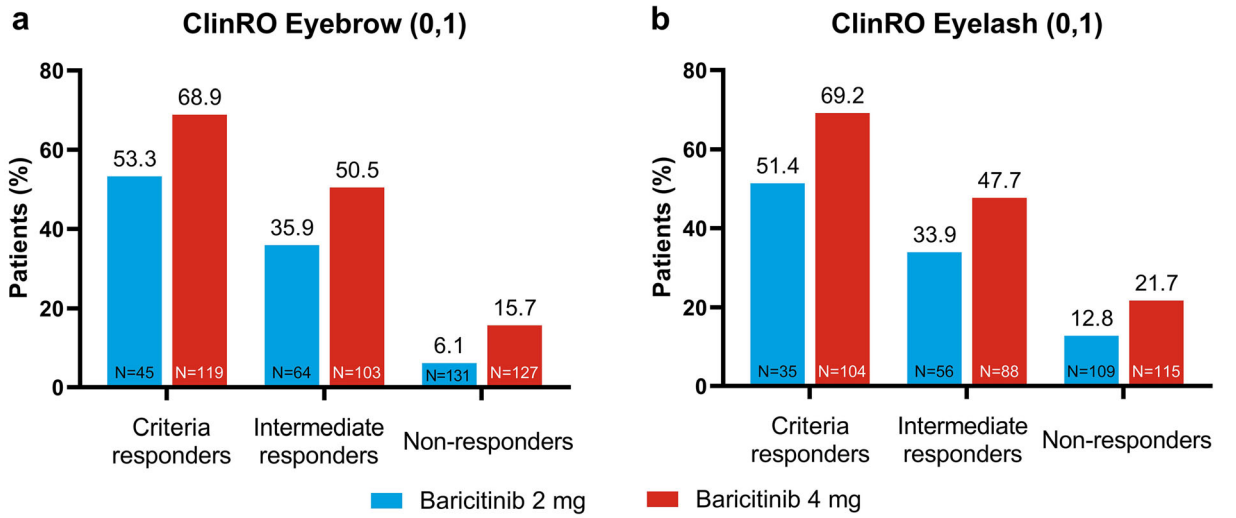

Fig. 2 Proportion of patients in criterion responder, intermediate responder, and nonresponder subgroups, who achieved **a** ClinRO Eyebrow (0 or 1) or **b** ClinRO Eyelash (0 or 1) at week 52 with ≥ 2-point improvement from baseline and whose scores were ≥ 2 at baseline. Responder subgroups defined in methods. *ClinRO* clinician-reported outcome, *N* number of patients in the analysis population

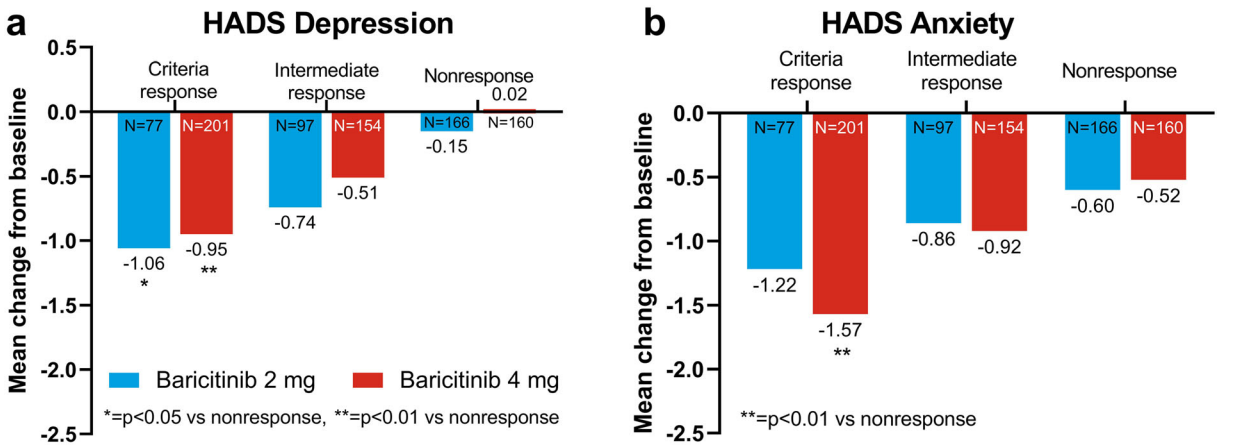

Fig. 3 HADS Depression (**a**) and Anxiety (**b**) scores by response groups at week 52. *HADS* Hospital Anxiety and Depression Scale, *N* number of patients in the analysis population

DISCUSSION

The results of the present analyses suggest that the response to baricitinib therapy resulted in a continuum of scalp hair regrowth in a clinical trial population with a majority who at baseline had a scalp hair loss greater than 90%. At week 52, for patients treated with baricitinib 4 mg, approximately 40% had achieved a SALT score ≤ 20, while approximately 30% had intermediate response, and approximately 30% had a minimal response to treatment. The 40% of patients who met this response at week 52 experienced the highest rate of regrowth in EB and EL, but the findings of these analyses also suggest that patients can achieve meaningful regrowth in other hair-bearing sites even in the absence of complete or nearly complete scalp hair regrowth. Almost half of patients who had

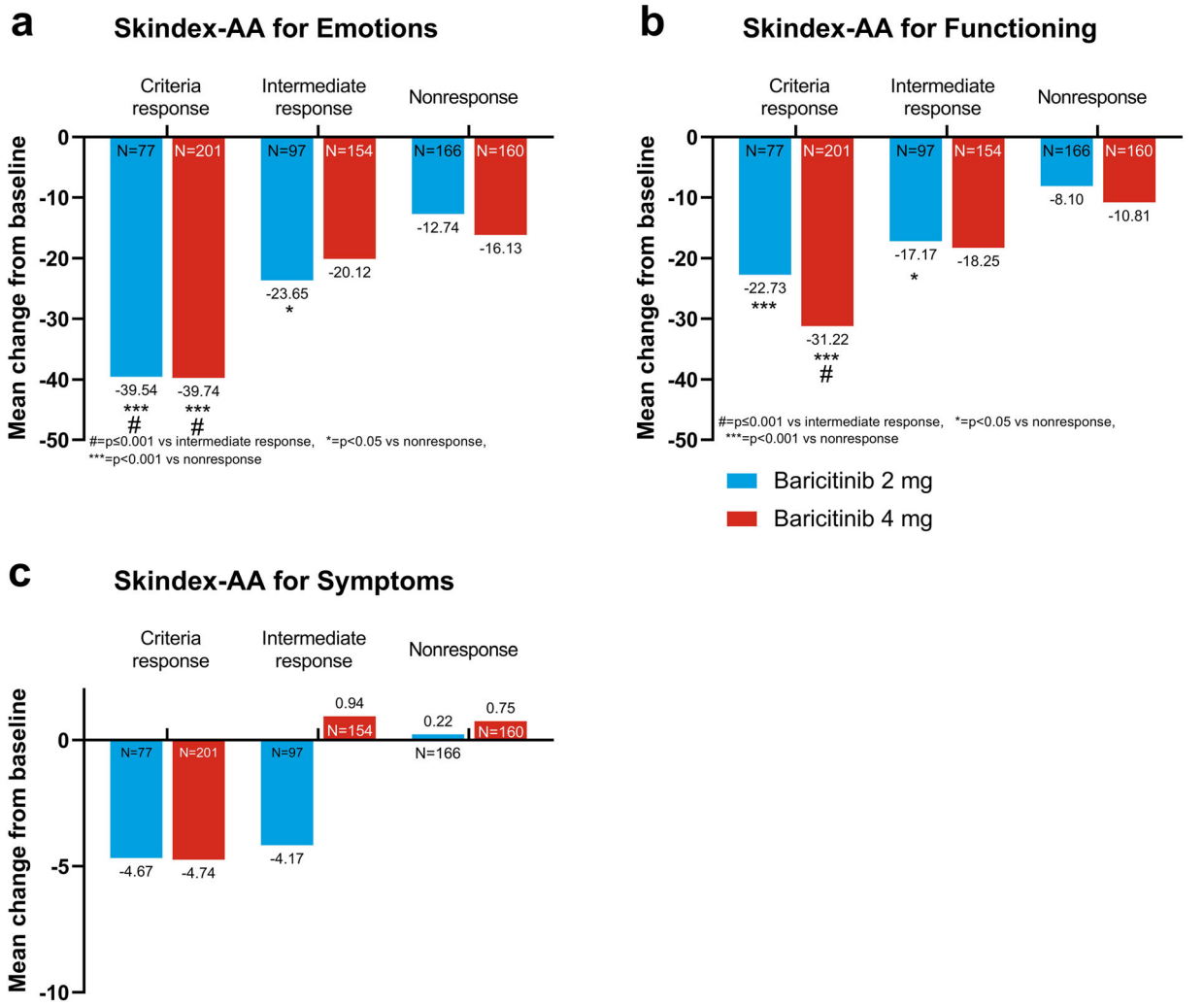

Fig. 4 Skindex adapted for AA score for emotions (**a**), Skindex adapted for AA score for functioning (**b**), and Skindex adapted for AA score for symptoms (**c**) by response groups at week 52. *AA* alopecia areata, *N* number of patients in the analysis population

intermediate regrowth achieved complete regrowth of EB and EL, and approximately 20% of nonresponders also achieved these outcomes when treated with baricitinib 4 mg. The importance of achieving these clinical endpoints should not be understated. Wyrwich et al. found that while scalp hair loss was most identified as the most bothersome symptom of AA, EB and EL hair loss were consistently identified as being in the top three most bothersome symptoms of AA [18]. In an online survey of 1741 adults with AA, approximately one-third would be satisfied with a treatment outcome of complete scalp regrowth but no EB regrowth; conversely, potential satisfaction with treatment increased to more than 90% if complete regrowth was achieved for both scalp and EB [21]. The finding that EB and EL regrowth can respond in the absence of complete scalp hair regrowth further suggests biological differences among the hair-bearing sites in response to therapy.

Baseline HADS Anxiety scores of the pooled population were consistent with mild elevation in severity relative to the general population norm. In a meta-analysis of studies examining the psychological symptoms and psychiatric comorbidities of AA, patients with AA were

found to be approximately 2.5 times more likely to have elevated anxiety and/or depression relative to general population [22]. The findings presented here demonstrate that although patients who achieved the criterion response experienced the largest mean improvement in anxiety, patients with intermediate response also had higher improvements, although they did not differ significantly from the nonresponse group. In a recent mediator analysis using data from the baricitinib clinical trials, improvement in scalp hair regrowth was a direct mediator for the improvements in emotional distress; however, the mediator analyses were unable to include the potential influence of EB and EL regrowth [23]. Given the importance of EB and EL, it may be that regrowth in these areas in the absence of complete scalp hair regrowth could also be emotionally impactful, but this conclusion cannot be determined from the present analyses.

With respect to impact on QoL, at baseline, in the pooled population, patients reported greater impact on the emotional and functioning aspects of QoL rather than on the physical symptoms. The low scores on the physical symptoms domain likely reflect the lack of disease-related symptoms such as itching, burning, or stinging. As observed in the Piracinni et al. study, the association between scalp hair regrowth and improvement in emotional distress and functioning was strongest for patients who achieved a SALT score $\leq$ 20 [14]. For both the emotional and functional domains of the Skindex-AA, the magnitude of improvement was proportionally greater in those patients who were responders. These findings suggest that the functional impact of treatment necessitates that patients achieve the criterion response of at least 80% scalp coverage and reinforces the clinical relevance of a SALT score $\leq$ 20 as a therapeutic goal. Consistent with this interpretation, a SALT score $\leq$ 20 was determined by both clinical experts and patients as the threshold for therapeutic success as an amount of scalp coverage that does not require extraordinary hairstyling or camouflage efforts [16].

In summary, the findings from the current post hoc analysis suggest that baricitinib therapy can affect hair regrowth in other hair-bearing sites in the presence of intermediate or nonresponse with scalp hair. Patients who experience scalp hair regrowth that is at least 80% scalp coverage demonstrated larger improvements in emotional status and QoL relative to other groups. Improvement in emotional symptoms and functioning was greatest among patients who achieved the criterion response for the scalp, suggesting that achieving the threshold of complete or nearly complete scalp coverage is necessary for these benefits.

Limitations of this post hoc analysis are that these comparisons resulted in subgroups that were not randomized, so differences in groups may be related to other factors than hair regrowth, such as severity or duration of current disease episode. A patient satisfaction questionnaire was not included, thus it is not possible to assess the importance of EB/EL regrowth in overall treatment satisfaction. Further, it is not possible to separate out the effects of EB/EL severity from overall scalp hair loss severity, as patients with greater scalp hair loss were also more likely to have greater EB/EL hair loss. In addition, these analyses represent the status of the patients at week 52; patients with intermediate response may experience further improvements in hair regrowth with longer treatment duration to achieve a SALT $\leq$ 20.

CONCLUSIONS

After 1 year of treatment with baricitinib, regrowth of EB and/or EL hair was observed in patients who did not achieve complete or near complete scalp hair regrowth. These findings suggest that clinical response to treatment may vary among hair bearing sites affected by AA, and some patients may achieve clinically meaningful regrowth of EB and EL independent of scalp hair regrowth. Emotional and functional improvement is associated with achievement of nearly complete hair regrowth. Altogether, the present findings may further help to set appropriate expectations of treatment benefits for both physicians and patients.

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Data Availability Lilly provides access to all individual participant data collected during the trial, after anonymization, with the exception of pharmacokinetic or genetic data. Data are available to request 6 months after the indication studied has been approved in the US and EU and after primary publication acceptance, whichever is later. No expiration date of data requests is currently set once data are made available. Access is provided after a proposal has been approved by an independent review committee identified for this purpose and after receipt of a signed data sharing agreement. Data and documents, including the study protocol, statistical analysis plan, clinical study report, blank or annotated case report forms, will be provided in a secure data sharing environment. For details on submitting a request, see the instructions provided at http://www.vivli.org.

Ethics Approval The trials were conducted in accordance with ethical principles of the Declaration of Helsinki and Good Clinical Practice guidelines, and the research protocols were approved by each center's institutional review board or ethics committee. All patients provided written informed consent.

Declarations

Conflict of Interests. Susan Ball, Yuxin Ding, Yun-Fei Chen, and Yves Dutronc are all employees and shareholders of Eli Lilly and Company. Brett King has received fees from Abbvie, AltruBio Inc, Almirall, AnaptysBio, Arena Pharmaceuticals, Bioniz Therapeutics, Bristol-Meyers Squibb, Concert Pharmaceuticals Inc, Equillium, Horizon Therapeutics, Eli Lilly and Company, Incyte Corp, Janssen Pharmaceuticals, LEO Pharma, Otsuka/Visterra Inc, Pfizer Inc, Regeneron, Sanofi Genzyme, Sun Pharmaceutical, TWI Biotechnology Inc, and Viela Bio; he has served on speaker bureaus for Abbvie, Incyte, Eli Lilly, Pfizer, Regeneron and Sanofi Genzyme; he has presented data at a scientific venue on behalf of Eli Lilly and Company. Ohsang Kwon has received grants for research from Eli Lilly and Company, Pfizer, AddPharma, and CKD Pharm. Rodney Sinclair has received consultancy fees from Eli Lilly and Company, Pfizer, Reistone Pharmaceuticals, Abbvie and Samson Clinical and has presented data at a scientific venue on behalf of Eli Lilly and Company, Pfizer and Abbvie. Bianca Maria Piraccini has received consultancy fees from Eli Lilly and Company, Pfizer, ISDIN, Almirall, and Vichy, has received payment for presentations or speaker bureaus from Eli Lilly and Company and Pfizer, and has participated on advisory boards for Eli Lilly and Company and Pfizer. Maryanne Senna has received consultancy fees from Arena Pharmaceuticals, Eli Lilly and Company, and Pfizer, has been a speaker for Pfizer and Eli Lilly.

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