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ORIGINAL RESEARCH

A Retrospective Real-World Study of the Effectiveness and Tolerability of Tildrakizumab in UK Adults with Moderate-to-Severe Chronic Plaque Psoriasis

Gabrielle Becher · Sophia Conner · Jennifer A. Ingram · Karen E. Stephen · Alison C. McInnes · Adrian H. Heald · Paul A. Riley · Mark Davies · Arnau Domenech · Ismail Kasujee

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ABSTRACT

Introduction: As with most medicines historically, clinicians prescribing tildrakizumab have relied on information derived from registration studies undertaken in a prospective controlled clinical trial setting. More recently, clinicians, policymakers, and commissioners increasingly rely on real-world data to inform both policy and practice.

Methods: A retrospective real-world data study was undertaken at four specialist dermatology departments in the United Kingdom. All adult patients treated with tildrakizumab for moderate-to-severe plaque psoriasis were included, with data being collected for 122 patients.

Results: Psoriatic patients on tildrakizumab tended to be overweight (median body mass index of 32 (range 19–59) ($n = 61$); 26/68 (38%) < 90 kg, 32/68 (47%) between 90 and 120 kg, and 10/68 (15%) > 120 kg). The study population had high levels of comorbidities (83/116, 72%), multiple special sites (39/117, 33%), and histories of biological treatments (81/100, 81%). Most patients (61/80, 76%) initiated on tildrakizumab were switched from another biological treatment. Tildrakizumab was effective, with 91/122 (75%) patients remaining on treatment for the duration of the study—a median of 12 months per patient (range 1–29 months)—and achieving a change in median Psoriasis Area and Severity Index (PASI) from 12 to 0.35 and in Dermatology Life

G. Becher · S. Conner
West Glasgow Ambulatory Care Hospital, NHS Greater Glasgow and Clyde, Glasgow, Scotland, UK

J. A. Ingram
Department of Dermatology, The Princess Alexandra Hospital NHS Trust, Harlow, England, UK

K. E. Stephen
Department of Dermatology, NHS Tayside, Dundee, Scotland, UK

A. C. McInnes
Dermatology Unit, Royal Cornwall Hospitals NHS Trust, Truro, England, UK

A. H. Heald
School of Medical Sciences, Manchester University, Manchester, England, UK

P. A. Riley · M. Davies
Res Consortium, Fosse House, East Anton Court, Icknield Way, Andover SP10 5RG, England, UK
P. A. Riley
e-mail: priley@resconsortium.com

A. Domenech · I. Kasujee (✉)
Almirall SA, Ronda General Mitre, 151, 08022 Barcelona, Spain
e-mail: ismail.kasujee@almirall.com

Quality Index (DLQI) from 20 to 0. The response rate was 57/66 (86%) when tildrakizumab was used as the first- or second-line biologic compared to 19/31 (61%) when used as the third- to seventh-line. Thirty-three (78.6%) patients over 90 kg of weight received the 200-mg dose of tildrakizumab. All but one ($n = 8$) patient with body weight over 120 kg maintained response over time. There was one treatment discontinuation; a patient who had a local sensitivity reaction.

Conclusions: In UK clinical practice, tildrakizumab was well tolerated and effective at doses of 100 mg or 200 mg in a range of patient phenotypes.

Keywords: Plaque psoriasis; Real world; Tildrakizumab

Key Summary Points

Why carry out this study?

Data obtained from this study build on that available from prospective clinical studies and provides a real-world assessment of the effectiveness and tolerability of tildrakizumab in patients being treated for plaque psoriasis.

The intention is that the data will be considered by policymakers, commissioners, and clinicians when determining (1) which biologic to use, (2) when, and (3) in which patients.

What was learned from the study?

This study offers insights into the use of the 100-mg and 200-mg tildrakizumab doses in a real-world setting.

Tildrakizumab was generally effective and well tolerated achieving a median Psoriasis Area and Severity Index (PASI) and Dermatology Life Quality Index (DLQI) of 0.35 and 0, respectively.

The likelihood of a response to tildrakizumab was greatest when it was used as the first- or second-line biologic.

Use of the 200-mg dose of tildrakizumab achieved a response in 8/9 (89%) of the patients with body weight over 120 kg.

INTRODUCTION

Psoriasis is an immune-mediated chronic inflammatory disease associated with extensive comorbidities and affecting 2–4% of the population in Europe and North America [1–3]. Psoriasis is associated with both physical and psychological burden and has severe effects on the quality of life, comparable to those seen in cancer, heart disease, and depression [4]. Measurement of disease severity in psoriasis involves objective measures, such as the Psoriasis Area and Severity Index (PASI) rating scale, as well as subjective measurements such as the Dermatology Life Quality Index (DLQI), which assesses the impact of skin disease on the quality of life of the affected person. Moderate-to-severe psoriasis is often defined as PASI > 10, or DLQI > 10 [5]. As many patients switch directly from one treatment to another, new treatment guidelines increasingly focus on residual disease and actual PASI instead of relative improvement.

A key mechanism for pathogenesis in psoriasis includes the dysregulated interactions between the innate and adaptive immune system involving proinflammatory cytokines [2]. In particular, IL-23 is regarded as a 'master regulator' of autoimmune inflammation, and a target for the effective treatment of psoriasis and other autoimmune inflammatory disorders [6]. Tildrakizumab (Ilumetri®, Almirall SA), a monoclonal antibody targeting IL-23, was approved in 2018 by both the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for the treatment of patients with moderate-to-severe chronic plaque psoriasis [7, 8]. The approved dosing regimen for tildrakizumab is 100 mg injection subcutaneously (SC) at weeks 0 and 4, followed by 100-mg injection every 12 weeks thereafter. The EMA marketing authorization also includes dosage at 200 mg in patients with

certain characteristics (examples in the Summary of Product Characteristics (SmPC) include a high disease burden and/or body weight $\geq$ 90 kg). Furthermore, the EMA marketing authorization acknowledges that some patients with initial partial response may subsequently improve with continued treatment beyond 28 weeks.

The aim of the present study was to further document the real-world tolerability and effectiveness of the two tildrakizumab doses, 100 mg and 200 mg, and to assess whether the likelihood of patients having a good response to treatment can be predicted by any routinely collected measures.

METHODS

Subjects

This retrospective real-world data study was undertaken at four specialist dermatology departments within NHS hospitals, two in England and two in Scotland. All adults receiving tildrakizumab or having previously received tildrakizumab for treatment of moderate-to-severe plaque psoriasis were included in the study. Data were collected by specialist dermatology nurses or pharmacists. Prior to data collection, ethics approval was obtained and a data-sharing agreement was put in place at each site. The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Consent from patients for the use of their data in the study and its publication was not required as the study comprised purely a retrospective review of selected data from anonymized medical records.

Measurements

Data collected included demographic data, use of non-biologic and/or biologic treatments prior to tildrakizumab, initiation dose of tildrakizumab and subsequent titrations, and tildrakizumab tolerability, and effectiveness. Because of the real-world retrospective nature of the study, and due to part or all of the timeline being during the recent COVID-19 pandemic, it was not possible to measure with accuracy PASI scores at defined timepoints, e.g., PASI75, PASI90, PASI100. Instead, subjects were defined as responders or non-responders based on whether they were maintained on treatment with tildrakizumab or treatment was withdrawn.

Statistical Analyses

Continuous normally distributed variables were reported using means and standard deviation. Variables were compared between the groups of responders and non-responders using a *t* test if the normality was met. Otherwise, the Mann–Whitney test was applied. Equality of variances was tested using Levene's test. Continuous not normally distributed variables were reported using median, first and third quartile (Q1 and Q3). Normality was assessed using the Shapiro–Wilk test. Categorical variables were compared using the chi-squared test (with the Yates correction when necessary). The binary response to tildrakizumab was assessed using a multivariate logistic regression model built for this outcome. The initial model contained the following variables as predictors: sex, age, body mass index (BMI), number of special sites, time from psoriasis diagnosis, number of previous non-biologic systemic treatments (continuous), number of previous biologic systemic treatments (continuous), psoriatic arthritis, hypertension, current or past smoker, dose increase to 200 mg, initial dose, initial DLQI score, and initial PASI score. The final model was obtained using a stepwise backward procedure with a p value for removal of > 0.1. Only the final model was reported. For the predictors from the final logistic regression, an effect plot was presented. The significance level was set to 0.05 but the results with p value equal to 0.05 were also interpreted. All statistical calculations were conducted using R v. 4.02 and R Studio v. 2021.09.2 software.

Table 1 Baseline characteristics

Characteristic	*n*/*N* (%), or mean ± SD (*N*), or median, min–max (*N*)
Male	69/122 (57%)
Age (years)	48.5 ± 14.6 (117)
Body weight (kg)	94, 48–158 (65)
BMI (kg/m^2)	32, 19–59 (58)
Previously received number of biologic therapies	
0 lines (bio-naive)	19/100 (19%)
1 line	50/100 (50%)
2 lines	17/100 (17%)
3 or more lines	14/100 (14%)
Previously received classes of biologic therapy	
Anti-TNF	87/138 (63%)
Anti-IL-12/23	20/138 (14%)
Anti-IL-17	31/138 (22%)
Comorbidities	83/116 (72%)
Psoriatic arthritis	24/117 (21%)
Obesity	37/58 (64%)
Diabetes	18/117 (15%)
Hypercholesterolemia	8/117 (7%)
Hypertension	21/117 (18%)
Depression	28/117 (24%)
Psoriasis duration (years)	18, 4–67 (106)
Current or past smoker	42/114 (37%)
Special sites	
No special sites	45/117 (38%)
1 site	33/117 (28%)
2 sites	18/117 (15%)
3 or more sites	21/117 (18%)
Basal PASI	12, 0–40 (112)
Basal DLQI	20, 0–30 (108)

RESULTS

Data on 122 patients were collected across four study sites, each of which contributed 59, 40, 13, and 10 patients, respectively. Data for some patients were incomplete. The earliest tildrakizumab treatment initiations of study subjects were in April 2019. Data were collated between September 2021 and January 2022.

Study Population

Characteristics of the study population are presented in Table 1. Patients ranged in age from 17 to 82 years, reflecting the breadth of the adult population. Patients tended to be overweight and exhibited relatively high levels of comorbidities; the median number of comorbidities per patient was two, with a range of 0–6. The median time since diagnosis of plaque psoriasis was considerable, and the history of previous non-biologic and biologic therapy varied accordingly.

For systemic non-biologics, patients had previously received a median of two (range 0–5) treatments during their treatment for plaque psoriasis. For biologics, the number and type of treatments represented in the study population ranged from zero to six biologics from each of the three different biologics treatment classes. The most common biologic that patients had been exposed to previously was adalimumab, with 54/100 (54%) patients having received it. The next most common biologics were etanercept (29/100, 29%), ustekinumab (20/100, 20%), secukinumab (19/100, 19%), brodalumab (8/100, 8%), ixekizumab (4/100, 4%), certolizumab (2/100, 2%), and infliximab (2/100, 2%). Tildrakizumab was used as the first-line biologic in 19/100 (19%) patients.

Sex Differences

Males and females receiving tildrakizumab differed in certain characteristics. The median body weight for females was 89 kg versus males 100 kg ($p = 0.03$) although this did not translate into a difference in BMI, which was 33 for females and 32 for males ($p = 0.33$). Depression

was more frequent in females than males (28 vs. 9%, $p = 0.01$). Although males had higher baseline PASI scores (median initial PASI of 12 for females and 15 for males, $p = 0.05$) the baseline DLQI scores were similar (16 for females and 20 for males, $p = 0.17$). For females and males, median final PASI scores were 1.7 and 0.75 ($p = 0.41$) and median final DLQI scores were 3 and 0 ($p = 0.13$), respectively. There was a significant difference in the absolute percentage change from baseline for the DLQI score; the median change for males was equal to 100% and for females 80% ($p = 0.02$).

Previous Treatments

A partial response to the previous biologic was the most common reason for patients being initiated on tildrakizumab (61/80, 76%). The other reasons were a full lack of response to the previous biologic (11/80, 14%) or an adverse reaction (5/80, 6%).

Effectiveness

At the end of the study collection period, most patients (91/122, 75%) were continuing treatment with tildrakizumab (Fig. 1). Of the remaining patients, 24/122 (20%) were regarded as not having responded fully or partially to tildrakizumab after a mean treatment duration of 33 weeks (SD 13 weeks), with duration of treatment ranging from 9 to 55 weeks. Seven of these patients discontinued treatment earlier than 28 weeks. Treatment was discontinued in an additional 7/122 (6%) patients for reasons unrelated to response including non-attendance at follow-up ($n = 2$), lymphoma diagnosis ($n = 1$), lung cancer diagnosis ($n = 1$), local sensitivity reaction ($n = 1$), patient choice ($n = 1$), and an unknown reason ($n = 1$).

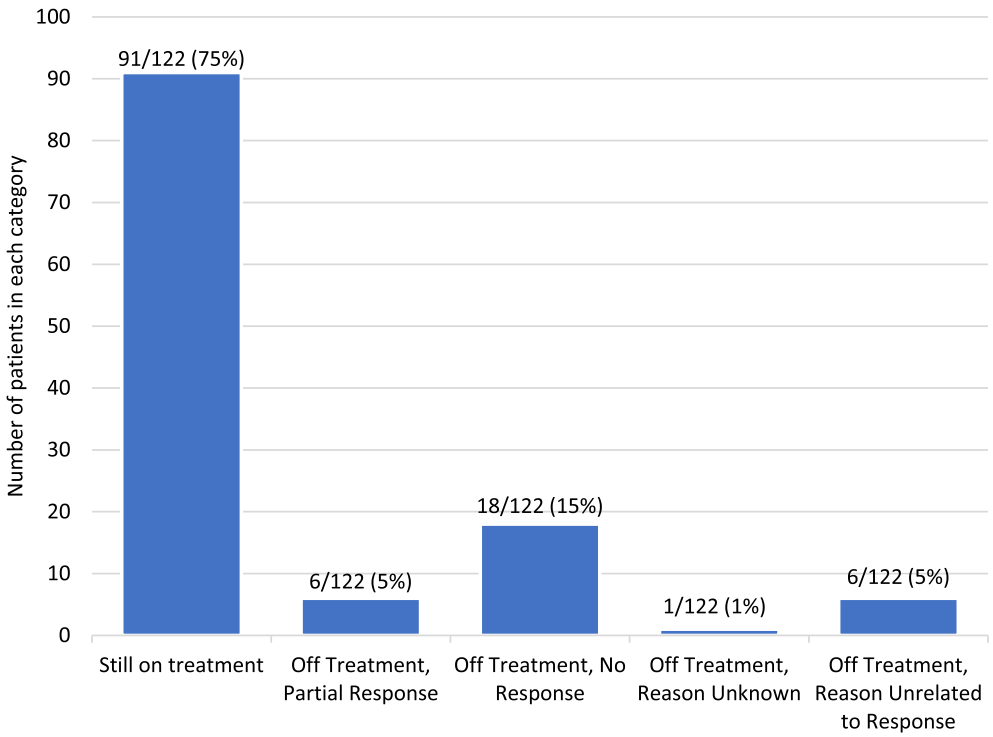

Fig. 1 Response to tildrakizumab**.** Response was described as primary failure ('No Response') if the psoriasis did not respond adequately to tildrakizumab, and as secondary failure ('Partial Response') if the psoriasis initially responded adequately but the response was subsequently lost

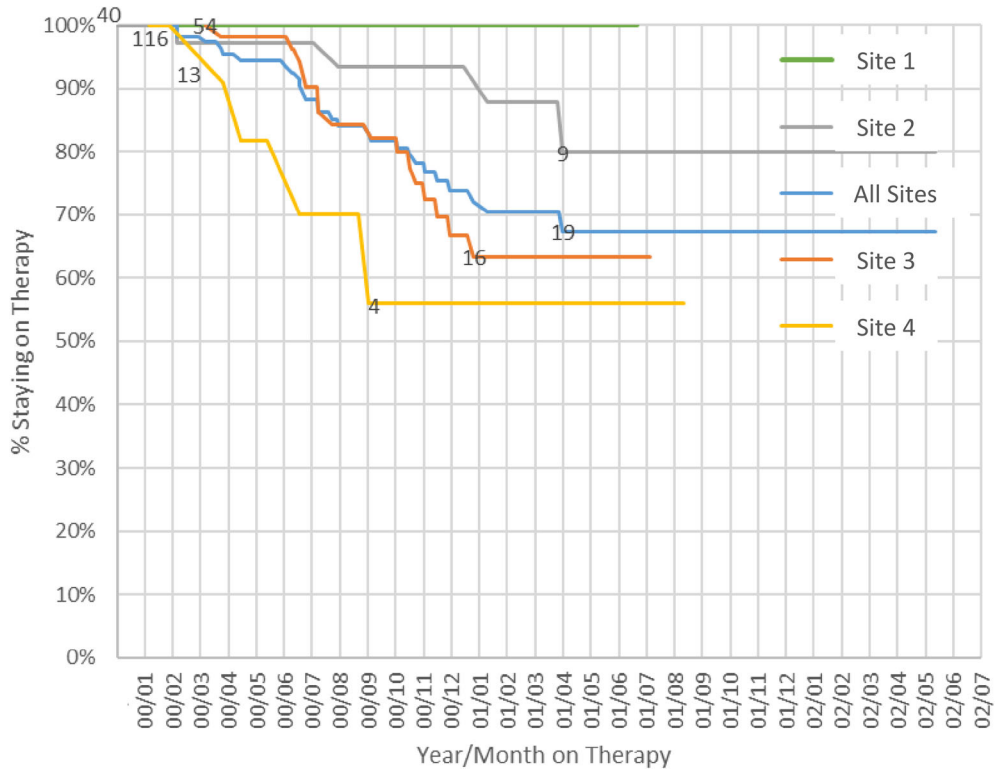

Fig. 2 Variation between study sites in persistence with tildrakizumab. The Kaplan–Meier survival curve is a statistical model used here to predict the length of time patients remain on tildrakizumab. The curve shows the cumulative risk of a patient discontinuing treatment; the risk is recalculated at each timepoint a patient discontinues treatment and uses, as the denominator, the patients remaining at risk of discontinuation

Patients receiving tildrakizumab for more than one year tended to remain on treatment (Fig. 2). The probability of a patient remaining on tildrakizumab after one year was 73%, ranging from 57 to 100% among the four sites.

Median baseline PASI and DLQI scores were 12 (range 0–40) and 20 (range 0–30). Median final PASI and DLQI scores were significantly lower in responders (0.35 and zero) than non-responders (6 and 10) ($p < 0.001$). The absolute percentage changes in PASI and DLQI from baseline to final assessment were significantly greater in responders (96 and 100%) than non-responders (62 and 58%) ($p < 0.001$). The duration for which patients received tildrakizumab varied because of the real-world nature of the study. Accordingly, to give a sense of the change over time in PASI scores, Fig. 3 provides the trend, exponential, and weighted by the number of results, in PASI over time for patients receiving tildrakizumab.

The only significant predictor in the multivariate logistic regression model was the number of previous biological treatments: with every single additional treatment, the probability of the response to tildrakizumab decreased by 40% (Table 2). The effect plot for this continuous predictor is presented in Fig. 4.

Treatment Dosage

The 100-mg dose of tildrakizumab was used most frequently in patients under 90 kg, with the 200-mg dose reserved more for patients over 90 kg, particularly those over 120 kg (Fig. 5). Among the ten patients with body weight over 120 kg, eight patients were initiated on a dose of 200 mg and one was escalated from 100 to

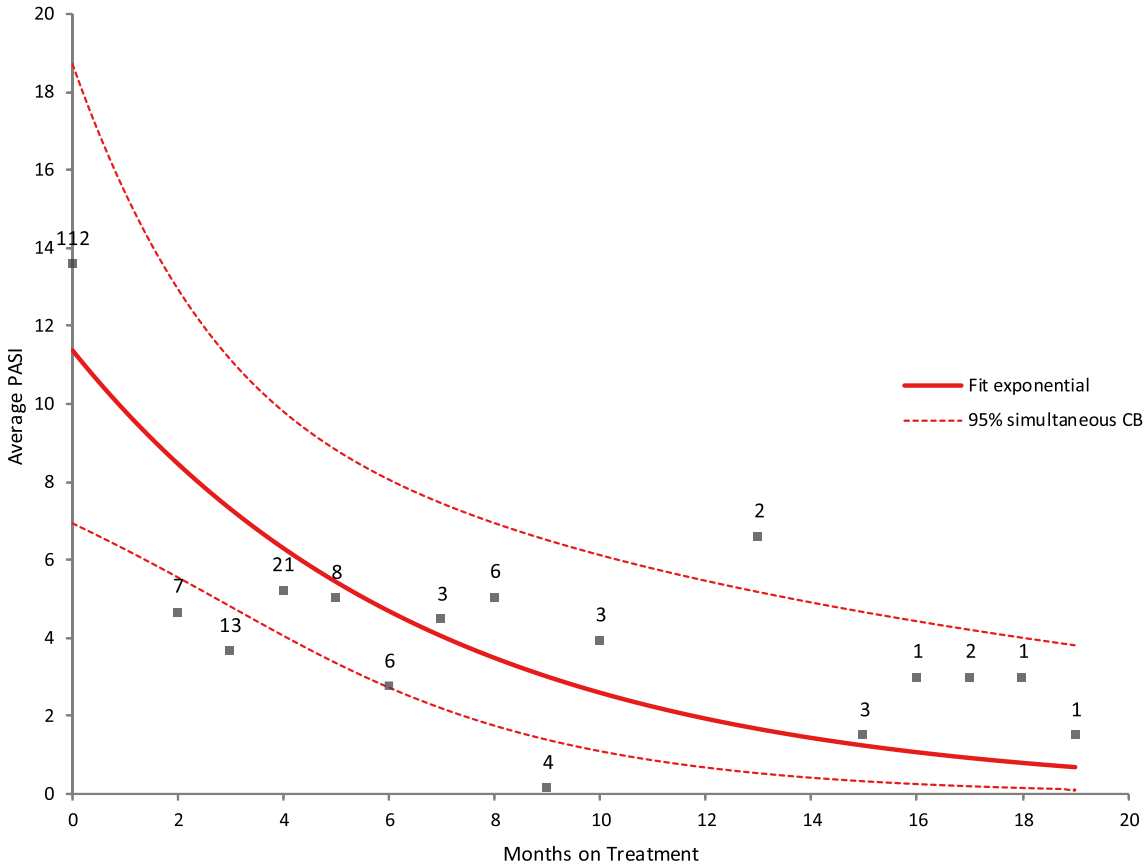

Fig. 3 Change in average PASI score over time for the cohort of patients receiving tildrakizumab**.** The *solid line* is the trend, which is exponential and weighted by the number of results. The *broken line* is the 95% simultaneous confidence band

Table 2 Final logistic model for the drug binary response

	OR	95% CI (OR)	*p*-value
Number of previous biologic treatments	0.7	(0.49; 1)	0.050

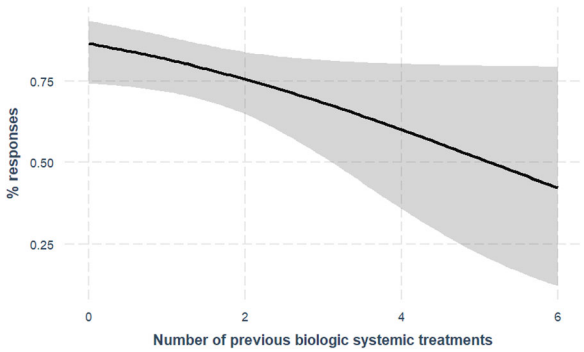

Fig. 4 Effect plot for the number of previous biologic treatments from the final logistic model. The number of previous biological treatments in the multivariate logistic regression model predicts that with every single additional treatment, the probability of the response to tildrakizumab (% responders) decreases by 40%

200 mg. The dose of the remaining patient was not recorded. Interestingly, eight of these nine patients achieved a good response, with three of them reaching a PASI $\leq$ 1 and DLQI = 0. In 13 patients, tildrakizumab was escalated from the 100-mg to 200-mg dose, with eight (62%) of them responding to treatment. PASI scores decreased in 83% patients and DLQI decreased in half of them. Confidently attributing the reduction in PASI and DLQI to the dose change

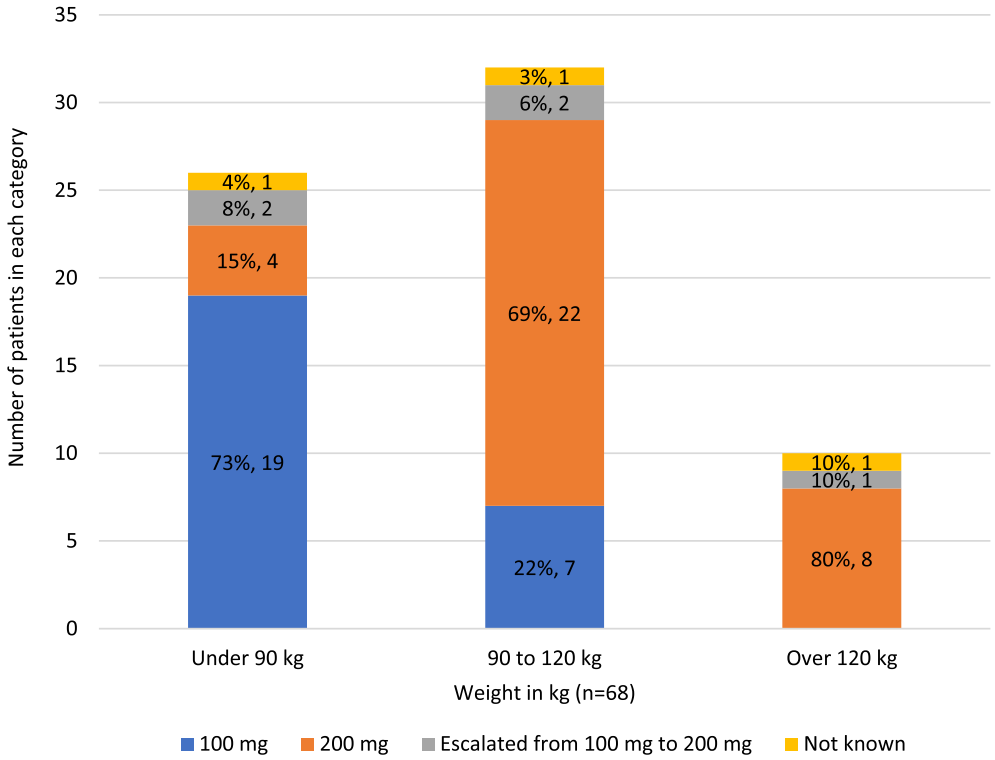

Fig. 5 Doses of tildrakizumab by patient body weight category

was not possible in all cases because of insufficient data being recorded.

Tolerability

Tildrakizumab was generally well tolerated, with suspected adverse drug reactions recorded in 6/113 (5%) of patients. There was only one tolerability-related treatment discontinuation, in a patient with a local sensitivity reaction. Four of 59 (7%) patients receiving 100-mg tildrakizumab each experienced one suspected adverse reaction comprising (1) headache and nausea/fatigue the day after injection, (2) fatigue and widespread joint pain, (3) left-sided chest discomfort (although the chest X-ray and electrocardiogram were normal and the event was thought unlikely to be associated with tildrakizumab), and (4) diarrhea and vomiting after the first dose. Two of 51 (4%) patients receiving 200-mg tildrakizumab each experienced one suspected adverse reaction comprising (1) a local sensitivity reaction, and (2) facial swelling and breathlessness after the first dose. Thus, a good safety profile was observed for both 100-mg and 200-mg doses of tildrakizumab in a real-world setting.

DISCUSSION

Biological therapy can be complicated by poor response profiles in some patients, with potential primary and secondary treatment failure across the spectrum of biologics. In this relatively challenging population, tildrakizumab was effective with 75% of patients remaining on treatment at the end of the study with a median PASI and DLQI of 0.35 and 0, respectively. The duration of the study was a median of 12 months (range 1–29 months). The response rate was 57/66 (86%) when tildrakizumab was used as the first- or second-line biologic compared to 19/31 (61%) when used in more bio-experienced patients.

Our findings are in line with other real-world studies. For example, Drerup and colleagues compared 150 patients receiving tildrakizumab

in a real-world setting to the respective phase 3 clinical trials. As with our study, the population differed substantially from the patients in the phase 3 clinical trials; in the real-world setting, there was a higher rate of previous systemic and biologic therapy and comorbidity. Even so, after 1 year of treatment with tildrakizumab, 71% of patients showed a PASI $\leq$ 3 and 52% of patients a DLQI of 1 or 0 [9]. The authors concluded that although their cohort of patients treated in routine practice with tildrakizumab differed substantially from the phase 3 studies, tildrakizumab showed comparable efficacy and safety in the real-world and clinical trial settings. Another study involving a retrospective chart review of 30 patients treated with tildrakizumab for moderate-to-severe plaque psoriasis from initial presentation to 12-month follow-up found that, similar to our study, the mean PASI reduced from 16 to 1.5 and that no serious adverse events were reported [10].

Another real-world data study featuring 59 patients treated with tildrakizumab also reported a favorable response to tildrakizumab, with a PASI $\leq$ 3 being achieved at 28 weeks in 80% of patients. However, unlike our study, the authors reported no statistically significant association between prior exposure to biological therapies and effectiveness – PASI90 at 28 weeks was achieved by 23/34 (68%) bio-naïve patients and by 15/25 (60%) bio-experienced patients [11]. In contrast, in our study, multivariate analysis of 117 patients found that with every single additional treatment, the probability of the response to tildrakizumab decreased—although it should be acknowledged that the statistical significance of this finding was borderline, with a p value of 0.05. A much larger retrospective sub-group analysis of a phase 2 study and two phase 3 studies of tildrakizumab featuring 2217 patients found no association between prior exposure to biological therapies and effectiveness; there was a numerically greater response to tildrakizumab in bio-naïve patients than bio-experienced patients, but it was not statistically significant [12]. It is possible that the finding in our study was spurious, or it may have been affected by the degree of prior exposure; almost one-third of patients in our cohort had received multiple prior biological therapies, with 14/100 (14%) having received three or more prior biological therapies.

Other considerations when treating psoriasis are the difficult to treat areas of the body. In our study, 39/117 (33%) patients had two or more of these areas, referred to as special sites, but this did not appear to reduce the effectiveness of tildrakizumab. Similar findings have been reported from other real-world studies, which have found tildrakizumab to be well tolerated and effective in difficult to treat areas including the scalp, nail, palmoplantar, and genitals [13–16].

Other than prior biological treatment exposure, there were no effects of patient demographics or disease characteristics on tildrakizumab efficacy. However, a sub-analysis across the four specialist dermatology departments did indicate variation in response to tildrakizumab. While the characteristics of patients across sites were broadly similar, patients from the two sites with the higher tildrakizumab treatment discontinuation rates had lived with psoriasis for longer (24 vs. 16 years) and had on average more comorbidities (2.8 vs. 1.6) compared with the other two sites. Treatment was discontinued in some instances because of a perceived insufficient response, even when PASI and DLQI scores had declined at a rate and extent seen in other patients who were regarded as exhibiting a sufficient response. This might reflect differences between sites in the clinical approach to reviewing the effectiveness of treatment. In fact, we observed that in 7/24 (29%) patients regarded as not having responded fully or partially to tildrakizumab, treatment was discontinued within the first 28 weeks of treatment. However, as noted in the SmPC for tildrakizumab, it is advised to consider discontinuation if there is no response *after* 28 weeks.

The SmPC for tildrakizumab also provides guidance on dose, advising that the 200-mg dose may provide greater efficacy than the 100-mg dose, "in patients with certain characteristics (e.g., high disease burden, body weight $\geq$ 90 kg)". This guidance is based on early pharmacokinetic and pharmacodynamic models from 2017, which indicate that

exposure to tildrakizumab decreases with increasing body weight. In this regard, the mean exposure in adult patients weighing > 90 kg after a dose of tildrakizumab 100 mg or 200 mg was predicted to be approximately 30% lower than in an adult patient weighing ≤ 90 kg [8]. In our study, the 200-mg dose was reserved more for patients over 90 kg, particularly those over 120 kg. Reductions in PASI and DLQI were similar regardless of dose, which we interpret as supporting the use of a 200-mg dose in patients with greater body weights.

The population was unbalanced with respect to sex. In the UK population, there are 98 males for every 100 females [17]; our study population featured a higher proportion of males than the UK average, with 130 males for every 100 females. Males and females were broadly similar in terms of baseline characteristics, but there was one notable difference that has been much reported previously: the likelihood of depression was greater in females than males. As an example, a recent study of over 4500 patients with psoriasis in Sweden found that the prevalence of pharmacologically treated depression was significantly higher among females than males (21.1 vs. 12.6%, $p < 0.001$) [18]. These figures are in line with those in our study; depression featured in 28% of females versus 9% of males ($p < 0.01$). The median baseline PASI score was higher in males than females, and perhaps reflecting that difference, the median absolute reduction in DLQI was greater in males than females.

Tolerability of tildrakizumab in this study was comparable to previous reports from randomized controlled trials and real-world data studies [9–16]. There was no apparent difference in tolerability of the 100-mg and 200-mg doses of tildrakizumab, and only one patient discontinued treatment for reasons related to tolerability (a local sensitivity reaction, regarded as related to treatment). Of particular note, there were no reports of pneumonia, inflammatory bowel disease, or *Candida* infections which have been reported with some other, earlier generation, biological therapies—this is regarded as being related to differences in mechanism of action between therapies. Earlier generation therapies target the IL-17 receptor, and although this has been shown to be effective at treating psoriasis, it has also been associated with increased risk of *Candida* infections, worsening of pre-existing inflammatory bowel disease and, rarely, new-onset ulcerative colitis and Crohn's disease [19]. Tildrakizumab, in contrast, targets the IL-23 receptor, specifically the p19 subunit, which avoids some of the adverse events associated with biologic agents with other mechanisms of action used to treat patients with plaque psoriasis [20].

The usual caveats apply to real-world studies of this type; the risks which the study has mitigated as best as practicable include confounding variables, the risk of bias, a lack of quality control regarding data recorded, and incomplete data.

CONCLUSIONS

Real-world studies can contribute important results to inform clinical practice and supplement randomized controlled trial data by providing a more representative view of prescribing in practice. This real-world evidence study has evaluated data on 122 patients with plaque psoriasis from four centres in England and Scotland. Tildrakizumab was effective in 75% of patients, and was generally well tolerated. Using a dose of 200 mg in patients over 120 kg was shown to be effective, indicating the value of this dose option in higher body weight patients. Overall, the results provide evidence for the effectiveness and tolerability of tildrakizumab in clinical practice in a variety of patients, particularly when used as first- or second-line treatment.

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Medical Writing and/or Editorial Assistance. Arnau Domenech and Ismail Kasujee developed the study concept with Mark Davies, Adrian Heald and Paul Riley. Data were collected by Gabrielle Becher, Sophia Conner, Jennifer Ingram, Karen Stephen, and Alison McInnes. Data were analyzed and the initial study report and manuscript developed by Mark Davies, Adrian Heald, and Paul Riley. All authors reviewed the manuscript.

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Compliance with Ethics Guidelines. Ethics approval and data sharing agreements were obtained from each study site prior to the start of the study. The study was performed in accordance with the Helsinki Declaration of 1964 and its later amendments. Consent from patients for the use of their data in the study and its publication was not required as the study comprised purely a retrospective review of selected data from anonymized medical records.

Data Availability. The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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