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BRIEF REPORT

Effectiveness of Tildrakizumab 200 mg in Moderate-to-Severe Plaque Psoriasis: A Multicenter Real-World Study Analyzing Patient Outcomes by Weight, PASI, BMI, and Previous Therapies

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ABSTRACT

Introduction: Psoriasis is a chronic immune-mediated disease with significant systemic implications. Tildrakizumab, an IL-23p19 inhibitor, has demonstrated efficacy in moderate-to-severe plaque psoriasis. Higher doses may be beneficial for patients with elevated body weight or greater disease burden. This study evaluates the effectiveness of tildrakizumab 200 mg in a real-world setting, analyzing outcomes based on weight, Psoriasis Area Severity Index (PASI), body mass index (BMI), and prior biologic exposure.

Methods: A multicenter retrospective study was conducted across 10 Italian hospitals. Adult patients (≥ 18 years) with moderate-to-severe plaque psoriasis treated with tildrakizumab 200 mg for ≥ 36 weeks were included. Patients were stratified by weight (≥ 90 kg vs. < 90 kg), BMI (≥ 30 vs. < 30), PASI (≥ 15 vs. < 15), and biologic history (naïve vs. biologic (bio)-experienced). PASI100 response rates at 36 weeks were assessed. Statistical analyses included Fisher's exact test ($p < 0.05$ significant).

Results: Among 137 patients, PASI100 response rates were 67.1% for patients < 90 kg vs. 49.2% for ≥ 90 kg ($p = 0.04$), 61.5% for PASI < 15 vs. 50%

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for PASI ≥ 15 ($p = 0.03$), and 60.8% for bio-naïve vs. 57.1% for bio-experienced ($p = 0.08$). BMI ≥ 30 was associated with lower PASI100 (44.2%) compared to BMI < 30 (61.4%) ($p = 0.05$). Despite subgroup differences, all patients exhibited clinical improvement.

Conclusion: Tildrakizumab 200 mg effectively treated moderate-to-severe psoriasis across diverse patient subgroups. While higher weight and PASI were associated with slightly lower PASI100 rates, significant improvements were observed, supporting its role in difficult-to-treat patients.

Keywords: Psoriasis; Biologics; Tildrakizumab; Body mass index; Pasi; Weight

Key Summary Points
Efficacy of tildrakizumab 200 mg: demonstrated effectiveness in treating moderate-to-severe plaque psoriasis in a real-world setting.
Patient stratification: outcomes analyzed based on weight, body mass index (BMI), Psoriasis Area Severity Index (PASI), and prior biologic exposure.
Key findings: PASI100 response was higher in patients < 90 kg (67.1%) and those with PASI < 15 (61.5%), while higher BMI (≥ 30) was linked to lower PASI100 (44.2%).
Clinical improvement: despite subgroup differences, all patients experienced significant clinical benefits.
Implications: supports the use of tildrakizumab 200 mg in difficult-to-treat psoriasis cases, especially in patients with higher disease burden.

INTRODUCTION

Psoriasis is a complex, chronic immune-mediated inflammatory disease that primarily affects the skin but can extend beyond cutaneous involvement, with an estimated global prevalence of 2–4% worldwide [1]. The disease is largely driven by cytokine signalling pathways, notably the interleukin (IL)-23/T-helper (Th)-17 axis [2]. This pathway plays a central role in sustaining chronic inflammation, leading not only to skin disease development but also driving associated comorbidities, including psoriatic arthritis, cardiovascular disease, metabolic syndrome, and mental health issues such as depression and anxiety [3]. These comorbidities not only compound the disease burden but also contribute to an increased risk of adverse health outcomes, particularly among patients with higher body mass index (BMI) and other metabolic conditions [3]. Studies suggest that the chronic systemic inflammation associated with psoriasis contributes to these comorbid risks, underscoring the importance of effective, sustained anti-inflammatory treatment. Recent therapeutic advancements have focused on inhibiting key cytokines within IL-23/Th17 pathway, including IL-23, to achieve targeted suppression of psoriatic inflammation [4]. Such biologic therapies have been revolutionary for patients with moderate-to-severe psoriasis, who often struggle to manage their symptoms with traditional systemic therapies. Body weight and BMI are important factors in psoriasis therapeutic management, particularly when selecting and dosing biologic treatments. Studies indicate that patients with higher BMI (> 30) or body weight (≥ 90 kg) often exhibit reduced drug bioavailability due to pharmacokinetic dilution effects, which may diminish the clinical efficacy of standard biologic dosages [5]. These patients may require higher doses of biologics to achieve optimal therapeutic outcomes. Additionally, obesity itself is associated with a heightened inflammatory state, potentially exacerbating psoriasis severity and treatment resistance [6]. Among biologic agents, tildrakizumab has emerged as a therapeutic option, especially in patients with obesity, with the dosage of 200 mg. This study seeks to evaluate the effectiveness of tildrakizumab 200 mg in a cohort of adult patients with moderate-to-severe plaque psoriasis by examining their outcomes in 36 weeks across various stratifications, including body weight (≥ 90 kg vs. < 90 kg), baseline Psoriasis

Area Severity Index (PASI) (≥15 vs. <15), BMI (≥30 vs. <30), and previous biologic treatments (biologic (bio)-naïve vs. bio-experienced). This stratified approach aims to potentially guide more personalized therapeutic strategies.

METHODS

This retrospective analysis was conducted across 10 second-level dermatological centers in Italy and included adult patients (age ≥18 years) with a confirmed diagnosis of moderate-to-severe plaque psoriasis who had been treated with tildrakizumab 200 mg for a minimum of 36 weeks. To be included in the study, patients were required to have been treated from the start with tildrakizumab 200 mg; patients who had initially started treatment with tildrakizumab 100 mg and were subsequently switched to 200 mg due to partial response were excluded to avoid potential selection biases, ensuring no differences related to tildrakizumab treatment. All treatments were administered following Good Clinical Practice (GCP) guidelines. Patients with other clinical forms of psoriasis or those treated with other conventional disease-modifying antirheumatic drugs (cDMARDs) in combination with tildrakizumab were excluded from the study. The study was conducted in accordance with the Declaration of Helsinki (1964 and subsequent amendments) and it was approved by the local ethics committee (N° 22045). Written informed consent was obtained from all participants prior to inclusion in the study. To evaluate the effectiveness of tildrakizumab 200 mg, patients were stratified and compared based on key characteristics: weight (≥90 kg vs. <90 kg), BMI (≥30 vs. <30), PASI (≥15 vs. <15), and prior biologic treatment (bio-naïve vs. bio-experienced). We also evaluated effectiveness in patients with both high weight and high PASI. Data were collected retrospectively at baseline, at week 4 (W4), week 16 (W16), and week 36 (W36) from databases, and all the authors had permission to use the data.

Statistical Analysis

Comparative statistical analyses were performed to validate differences across these subgroups, providing insights into the effectiveness of tildrakizumab 200 mg in diverse patient profiles. Descriptive statistics were carried out and absolute frequencies and percentages were estimated. Fisher exact test was performed to evaluate the association between weight > 90, BMI > 30, PASI > 15 at baseline, and PASI100 at 36 weeks. A p value < 0.05 was considered statistically significant. All the analyses were carried out with R version 4.3.1

RESULTS

A total of 137 patients were enrolled, 48 female (35.1%) and 89 male (64.9%). Mean age was 53.9 ± 0.7 years and mean duration of disease was 17.5 ± 8.9 years. Mean weight was 88.42 ± 9.19 and mean BMI 29 ± 3.58. Forty-six patients (33.6%) were bio-naïve while 91 patients (66.4%) had been already treated with other biologics. Among the 91 bio-experienced patients, all had previously received anti-tumor necrosis factor (TNF) inhibitor (100%). Forty patients (44.0%) had been treated with anti-IL17 agents, including 25 with secukinumab (27.5%), 10 with ixekizumab (11%), and 5 with brodalumab (5.5%). Additionally, 8 patients (8.8%) had received anti-IL23 agents: 6 guselkumab (6.6%) and 2 risankizumab (2.2%). Regarding the number of prior biologics, 75 patients (82.4%) had received one biologic, 12 (13.2%) had received two, and the remaining 4 (4.4%) had been treated with three biologics. The patients' clinical data, including their psoriasis history and treatment details, are summarized in Table 1. Patients were stratified based on weight, BMI, and PASI at baseline. In detail, 69 patients (50.36%) were in the group with weight ≥90 kg (mean weight 103.6 ± 1.4) and 68 patients (49.64%) in the group < 90 kg (mean weight 72.8 ± 8.1); there were 54 patients (39.4%) in the group with BMI ≥30 (mean BMI 34.7 ± 10.8) and 83 patients (60.6%) in the group with BMI < 30 (mean value 25.5 ± 3.6). Considering

Table 1 Demographic and clinical characteristics of the study population, including age, gender, weight, BMI, baseline PASI score, disease duration, and prior treatments

	Overall ($n = 137$)	≥ 90 kg ($n = 69$)	< 90 kg ($n = 68$)	PASI ≥ 15 ($n = 72$)	PASI < 15 ($n = 65$)	BMI ≥ 30 ($n = 54$)	BMI < 30 ($n = 83$)	Naïve ($n = 46$)	Bio-exp ($n = 91$)	High weight + high PASI ($n = 47$)
Gender										
Male	89 (64.9%)	31 (44.9%)	34 (50%)	46 (63.8%)	39 (60%)	31 (57.4%)	56 (67.4%)	29 (63%)	56 (61.5%)	32 (68%)
Female	48 (35.1%)	48 (55.1%)	34 (50%)	26 (36.2%)	36 (40%)	23 (42.6%)	27 (32.6%)	17 (37%)	35 (38.5%)	15 (32%)
Age	53.9 ± 0.71	53.6 ± 2.8	53.9 ± 0.7	53.5 ± 2.12	54.2 ± 12.1	56.9 ± 2.12	51.8 ± 0.7	56.1 ± 2.8	52.7 ± 0.7	54.6 ± 2.82
Weight	88.4 ± 9.1	103.5 ± 4.1	72.8 ± 9.1	94.1 ± 18.3	82.1 ± 12.7	104 ± 31.1	78.4 ± 9.2	87.3 ± 60.8	88.9 ± 9.2	103.3 ± 1.41
BMI	29 ± 3.58	32.7 ± 0.4	25.3 ± 3.5	30.5 ± 3.7	27.4 ± 3.8	34.7 ± 10.8	25.5 ± 3.6	29.1 ± 20.7	29.1 ± 3.58	32.7 ± 0.4
Duration pso (years)	17.5 ± 8.9	18 ± 4.9	17 ± 14.1	17.2 ± 7.7	17.9 ± 21.2	16.8 ± 5.7	18 ± 14.1	16.8 ± 2.8	17.8 ± 14.1	18.3 ± 4.9
Prior cDMARDs	126 (91.9%)	64 (92.7%)	60 (88.2%)	61 (84.7%)	60 (62.3%)	45 (83.3%)	74 (89.1%)	36 (78.2%)	85 (93.4%)	40 (85.1%)
Prior bDMARDs	91 (66.4%)	48 (69.5%)	42 (61.7%)	50 (69.4%)	38 (58.5%)	36 (66.6%)	55 (66.3%)	0 (0%)	91 (100%)	36 (76.6%)
Mean PASI	14.8 ± 11.3	17.2 ± 7.55	12.6 ± 11.3	20.3 ± 7.1	8.8 ± 1.4	17.7 ± 1.4	13.1 ± 11.2	14.6 ± 11.3	15 ± 11.3	20.7 ± 3.5

PASI Psoriasis Area Severity Index, *BMI* body mass index, *Bio-exp* biologic-experienced, *pso* psoriasis, *cDMARDs* conventional disease-modifying anti-rheumatic drugs, *bDMARDs* biologic disease-modifying anti-rheumatic drugs

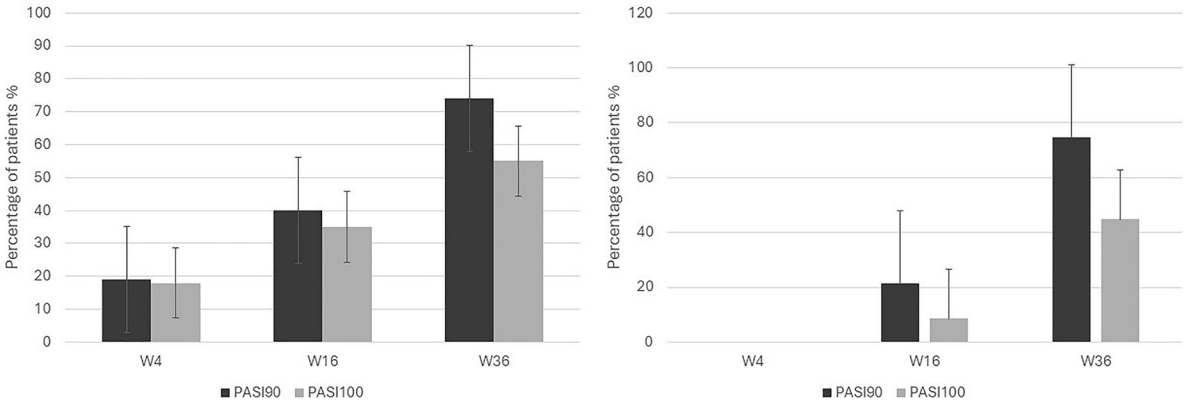

Fig. 1 Percentages of patients achieving Psoriasis Area Severity Index (PASI)-90 and PASI100 responses at different time points (week 4, week 16, and week 36) across the study population (**a**) and in patients with both high PASI and high weight (**b**). The overall percentages of patients achieving PASI90 and PASI100 shows a steady increase is observed over time, with higher percentages for PASI90 compared to PASI100 at all time points. The group with both high weight and high PASI shows improvement over time, though response rates for PASI90 and PASI100 are lower compared to other subgroups, indicating a potential challenge in achieving optimal responses in this population

PASI at baseline, 72 patients (52.6%) reported a value ≥ 15 (mean PASI 20.3 ± 7.07) and 65 patients (47.4%) had a PASI < 15 (mean value 8.76 ± 1.41). Forty-seven patients (34.3%) reported both high weight and high PASI. The groups were homogeneous with no statistically significant differences observed ($p = 0.72$). The statistical analyses revealed that despite observed differences across these groups, all patients exhibited a positive response to the therapy. As reported in Fig. 1a, at week 16, 40.4% of patients reached PASI90 and 35.2% PASI100, while 74.2% and 55.1% reported respectively PASI90 and PASI100 at week 36. The subgroup analysis of patients with both high PASI and high weight demonstrated a response rate of 44.7% (Fig. 1b). Patients with a body weight < 90 kg showed a higher PASI100 response rate (67.1%) compared to those with a weight ≥ 90 kg (49.2%) (Fig. 2a). However, across all weight categories, tildrakizumab 200 mg demonstrated substantial efficacy. Similarly, patients with a baseline PASI < 15 achieved PASI100 in 61.5% of cases, while those with a PASI ≥ 15 had a response rate of 50% (Fig. 2b). Patients with obesity (BMI ≥ 30) showed a PASI100 response rate of 44.2% compared to 61.4% in patients without obesity, yet tildrakizumab 200 mg was still effective in all groups (Fig. 2c). As reported in Fig. 2d, bio-naïve patients exhibited a PASI100 response rate of 60.8%, slightly higher than those previously treated with other biologics (57.1%), though this difference was not statistically significant. Despite these differences, tildrakizumab 200 mg provided substantial clinical improvement in all cases. The mean PASI scores (Fig. 3) showed a marked and progressive reduction over time across all patient groups, reflecting a consistent improvement in disease severity. At the overall population level, mean PASI decreased from 20.7 at baseline to 4.9 at week 16, and further to 1.2 by week 36. Subgroup analyses revealed that patients with higher body weight (> 90 kg) and higher baseline PASI (> 15) experienced substantial improvement, with PASI reductions from 17.2 to 1.1 and from 20.3 to 1.1, respectively. Similarly, patients with both high PASI and high weight showed a robust decrease from 20.7 at baseline to 1.2 at week 36. Lower baseline PASI (< 15) and lower weight (< 90 kg) were associated with lower initial scores and faster improvements, with mean PASI reaching 0.7 and 0.8 at week 36, respectively. Patients with BMI > 30 also showed substantial benefit (from 17.7 to 1.2), though those with BMI < 30 had slightly lower PASI at all time points (13.1 to 0.8). Regarding treatment history, both bio-naïve and bio-experienced patients showed meaningful

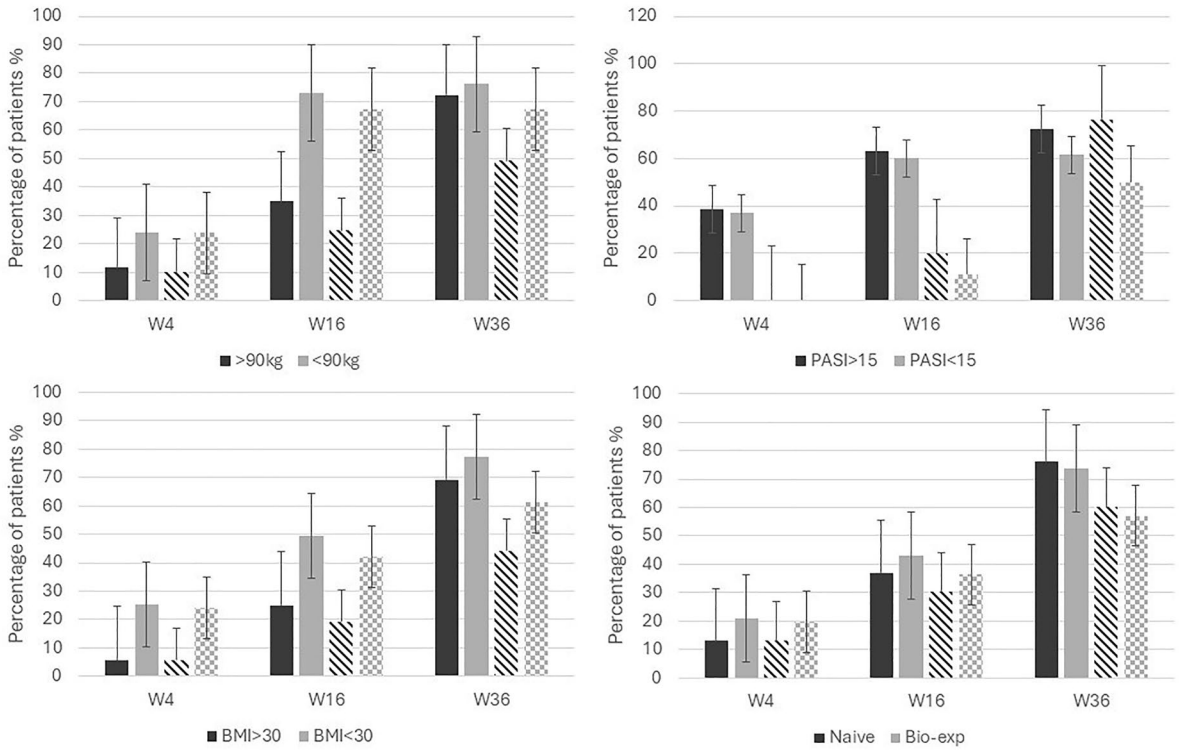

Fig. 2 **a** Weight-based stratification: both groups exhibit increasing Psoriasis Area Severity Index (PASI)-90 and PASI100 responses over time, with the < 90 kg group showing slightly higher response rates, particularly for PASI100. **b** PASI-based stratification: patients with baseline PASI ≥ 15 show higher PASI90 and PASI100 responses, reflecting a greater relative improvement in those with more severe disease at baseline. **c** Body mass index (BMI)-based stratification: the BMI < 30 group demonstrates consistently higher PASI90 and PASI100 responses compared to the BMI ≥ 30 group, suggesting better outcomes in patients with lower BMI. **d** Treatment history stratification: naïve patients achieve notably higher PASI90 and PASI100 responses compared to biologic-experienced patients, particularly at week 16 and week 36

improvements, with PASI scores reducing from 14.6 to 0.8 and from 15.0 to 1.0, respectively. These findings suggest that the downward trend over time is consistent and clinically significant across all groups. Figures 4 and 5 further illustrate the distribution and variability of mean PASI scores across patient subgroups using box plots. Figure 4 highlights the differences in PASI progression over time according to body weight (a), PASI (b), BMI (c), and prior biologic treatment exposure (d). In all panels, a significant and steady decline in PASI scores is observed regardless of subgroup, with consistently lower median values and reduced interquartile ranges over time. Patients with lower weight, lower baseline PASI, BMI < 30, and treatment-naïve status showed slightly faster and more homogeneous responses, as reflected by narrower box plots and lower values at each time point. Conversely, patients with higher baseline disease burden or obesity exhibited greater variability in early phases but achieved comparable outcomes by week 36. Figure 5 focuses on the subgroup with both high baseline PASI and high body weight, showing a similarly favorable trajectory. Despite more severe initial presentation, these patients demonstrated a clear and progressive decrease in PASI scores, supporting the efficacy of the treatment across even the most challenging clinical profiles. No adverse effects were reported in the patients.

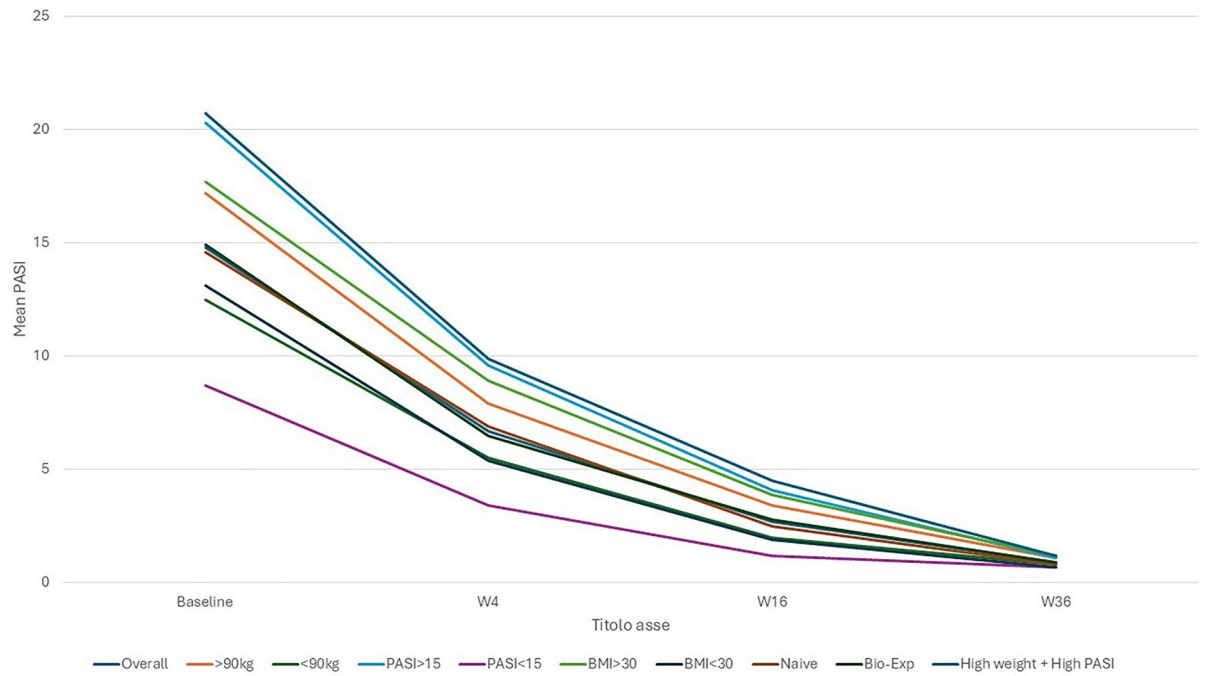

Fig. 3 Progression of mean Psoriasis Area Severity Index (PASI) scores from baseline to week 36 across different patient subgroups, stratified by weight, baseline PASI, body mass index (BMI), and treatment history. All groups show a substantial reduction over time, reflecting overall treatment effectiveness

DISCUSSION

The results of our study further consolidate the efficacy of tildrakizumab 200 mg in the treatment of moderate-to-severe plaque psoriasis, demonstrating its effectiveness across different patient subgroups, including those with obesity, high baseline disease severity, and prior exposure to biologic therapies. These findings are consistent with previous clinical trials and real-world evidence [7–9]. The ability of tildrakizumab to provide a stable therapeutic response irrespective of patients' weight and BMI is particularly noteworthy, given the well-documented challenges that obesity presents in psoriasis treatment. Obesity is a well-known risk factor for psoriasis, with an established bidirectional relationship that exacerbates disease severity and complicates treatment outcomes. Increased adipose tissue contributes to a pro-inflammatory state characterized by elevated levels of cytokines such as IL-6, TNFα, and IL-17, all of which play crucial roles in psoriasis pathogenesis [3]. Many biologic therapies, including TNF inhibitors and some IL-17 inhibitors, have been shown to exhibit reduced efficacy in patients with obesity due to pharmacokinetic alterations and increased systemic inflammation [10]. However, our study aligns with findings from Thaçi et al. and Torres et al., which demonstrated that tildrakizumab maintains robust efficacy in patients with and without obesity alike [11, 12]. This can be attributed to its targeted inhibition of the IL-23 pathway, which is less susceptible to the pharmacokinetic challenges posed by increased body mass. Additionally, pharmacokinetic modelling suggests that the long half-life and selective action of tildrakizumab allow for consistent drug exposure across different weight categories, ensuring sustained therapeutic benefit [11]. Our study also provides valuable insights into the response of patients with a high baseline PASI score (≥15) to tildrakizumab 200 mg. While patients with lower baseline PASI scores achieved PASI100 at a rate of 60.7%, those with a higher PASI baseline exhibited a slightly lower response rate of 46.3%. Despite this difference,

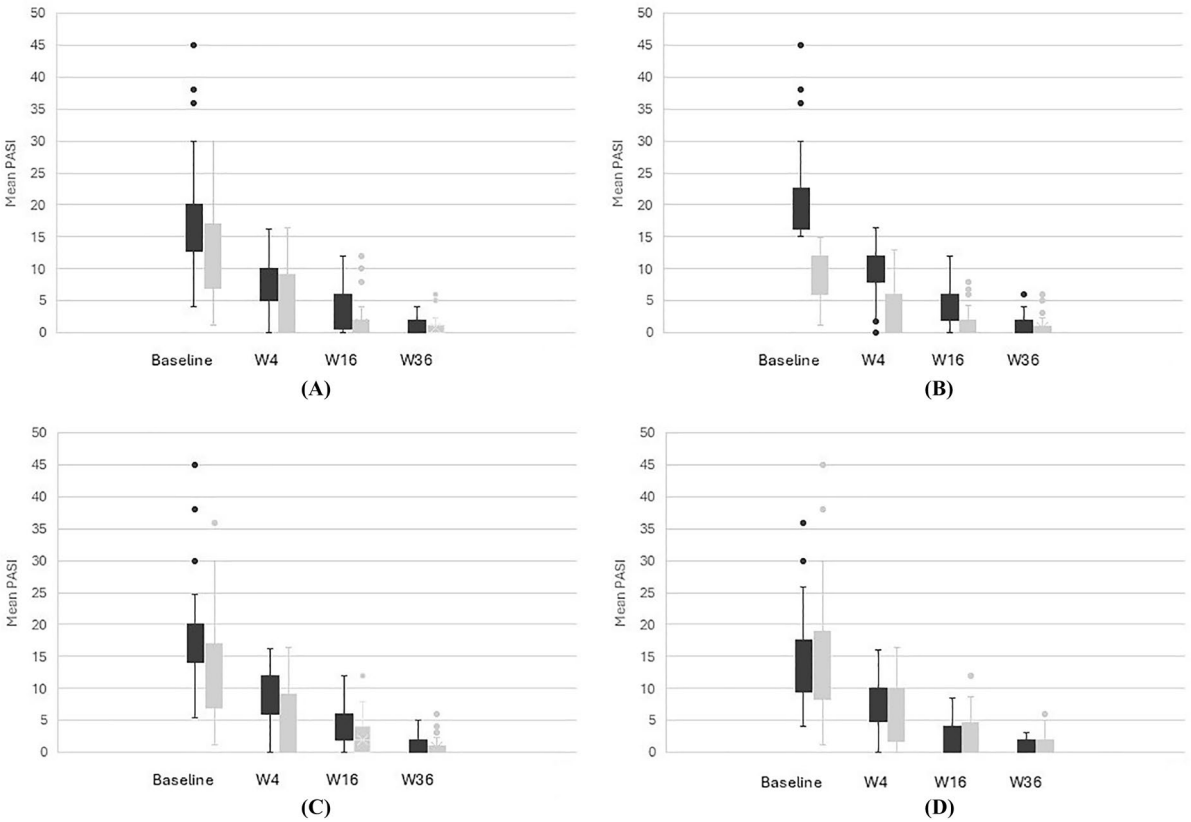

Fig. 4 Box plots showing the distribution of mean Psoriasis Area Severity Index (PASI) scores at baseline, week 4, week 16, and week 36 across patient subgroups stratified by weight (**a**), baseline PASI (**b**), body mass index (BMI) (**c**), and prior biologic treatment (**d**). All subgroups exhibit a consistent reduction in PASI scores over time

it is crucial to highlight that even in patients with more severe disease, tildrakizumab induced substantial clinical improvement. This finding is consistent with data from the reSURFACE 1 and 2 trials, which indicated that patients with high disease burden responded well to tildrakizumab, although the response rate was somewhat lower compared to those with milder disease [13]. This suggests that while disease severity influences treatment response, tildrakizumab remains a viable and effective option even for patients with extensive skin involvement. Another critical aspect explored in our study is the impact of prior biologic exposure on treatment response. In our series biologic-naïve patients exhibited a PASI100 response rate of 56.8%, which was slightly higher than the 44.4% response rate seen in patients previously treated with anti-TNF agents. This not statistically significant difference is consistent with trends reported in previous studies [15] and it confirms tildrakizumab as an effective option for individuals with prior biologic failure. Studies such as those by Papp et al. and Di Brizzi et al. support this observation, demonstrating that tildrakizumab remains effective even in patients who have switched from other biologics because of inadequate response [13–17]. Implications of these findings for clinical practice are significant. First, our study reinforces the notion that weight and BMI should not be primary determinants in the selecting tildrakizumab as treatment for patients with psoriasis. This is particularly important given the global rise in obesity and its associated impact on systemic inflammation. The ability to offer a biologic treatment that is not significantly compromised by body weight provides clinicians with greater flexibility

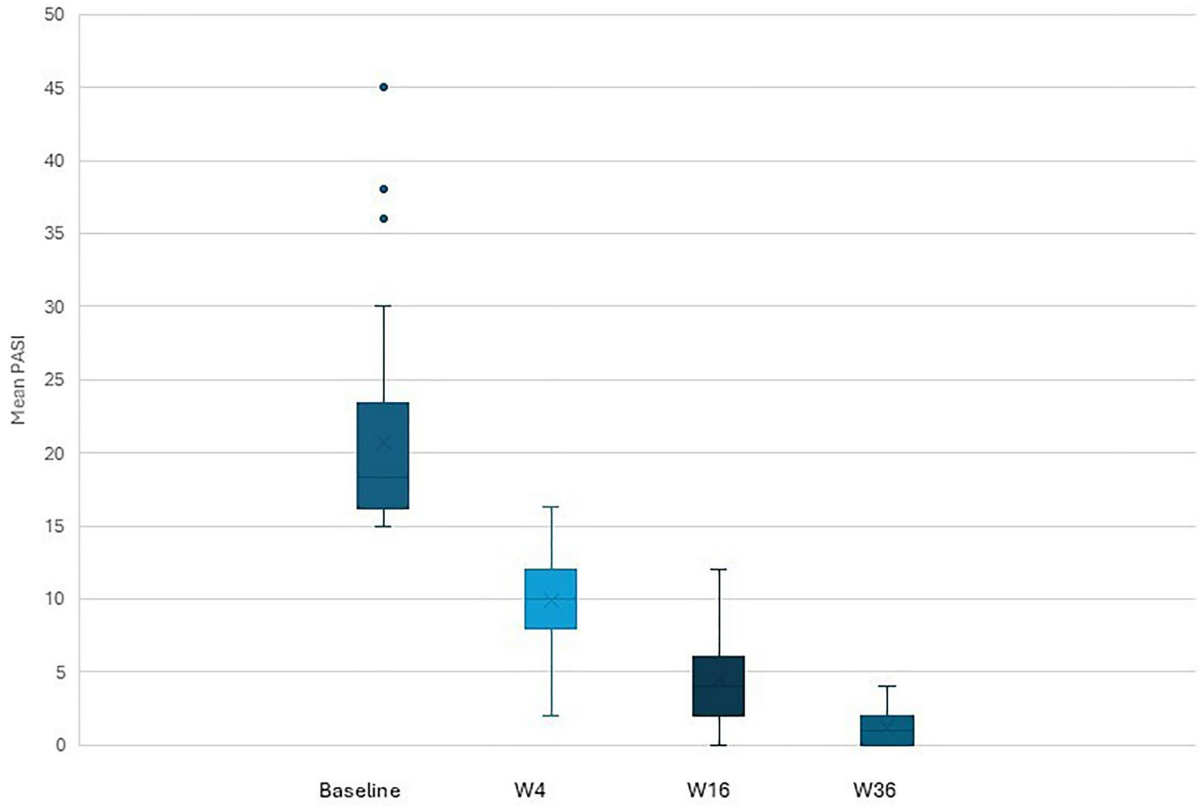

Fig. 5 Box plots of mean Psoriasis Area Severity Index (PASI) scores at each time point for patients with both high baseline PASI and high body weight, illustrating substantial and sustained improvement despite higher disease severity at baseline

in managing patients with obesity and psoriasis. Second, the data suggest that patients with psoriasis with a high disease burden should not automatically be categorized as poor responders to IL-23 inhibitors. While response rates may vary according to baseline PASI, tildrakizumab 200 mg consistently provides substantial clinical improvement, supporting its use in patients with severe disease, with no additional cost. Personalized treatment approaches that incorporate factors beyond PASI scores, such as patient preference, comorbid conditions, and treatment history, should be prioritized to optimize therapeutic outcomes. Third, the results confirm that patients with prior biologic exposure, particularly to TNF inhibitors, can still achieve meaningful clinical responses with tildrakizumab 200 mg. This reinforces the role of tildrakizumab 200 mg as a viable treatment option for individuals who have experienced biologic failure. Given the growing number of available biologics for psoriasis treatment, these findings highlight the importance of selecting therapies on the basis of individual patient characteristics rather than relying solely on previous treatment history. Furthermore, our study aligns with recent research examining the impact of tildrakizumab 200 mg on quality of life [14]. This underscores the broader benefits of tildrakizumab 200 mg beyond skin clearance, as improved quality of life metrics indicate reductions in the psychosocial burden of psoriasis. We should even consider the molecular side in psoriasis. A relevant aspect that has recently emerged is the involvement of the G protein-coupled receptor GPR15, which appears to be highly specific for psoriasis. It is preferentially expressed in effector T cells infiltrating psoriatic skin, suggesting a direct role in the disease pathogenesis. Furthermore, GPR15 expression can be modulated by pharmacological treatments, indicating its potential as a biomarker for therapeutic response. Its regulation

may be crucial for explaining the effectiveness of certain immunomodulators in reducing inflammatory infiltrates and the characteristic epidermal hyperproliferation of psoriasis [15]. In addition, even genetic background should be highlighted. Transcriptomic profiling in psoriasis can provide valuable insights into the intracellular pathways. Gene expression analysis following drug treatment allows the identification of molecular targets and affected signalling cascades, such as NF-κB, JAK/STAT, and MAPK pathways, which are well known to play central roles in skin inflammation and keratinocyte biology [16]. Monitoring transcriptomic responses not only helps clarify the mechanism of action of the drug but may also uncover biomarkers predictive of therapeutic efficacy or adverse effects. Given that psoriasis is associated with increased rates of depression, anxiety, and social stigma, therapies that provide both dermatologic and psychological relief are highly valuable in clinical practice. Future research should focus on further optimizing treatment strategies for specific subpopulations. One potential area of investigation is the evaluation of dose adjustments in patients with partial responses to tildrakizumab 100 mg. Given the evidence suggesting superior outcomes with the 200 mg dose in certain patient groups, a step-up approach for partial responders may enhance treatment efficacy [17]. Additionally, combination strategies with adjunctive therapies, such as weight management programs or metabolic interventions, could be explored to maximize therapeutic benefit, particularly in patients with obesity. Overall, the findings from our study contribute to the growing body of evidence supporting tildrakizumab 200 mg as a reliable and highly effective treatment option for psoriasis, regardless of BMI, baseline disease severity, or prior biologic exposure.

This study has some limitations. The follow-up period was relatively short, and longer-term data are needed to confirm the durability of the observed responses. The observational design, absence of a control group, and limited sample size in some subgroups may also affect the generalizability and interpretation of the findings.

CONCLUSION

Tildrakizumab represents a promising advancement in the management of moderate-to-severe psoriasis. By exploring the impact of key patient factors on treatment outcomes, this study contributes to the evolving understanding of how biologic therapy can be optimized in different patient populations. The findings are expected to support a more personalized approach to psoriasis management, emphasizing the role of tailored treatment regimens in achieving sustained disease control and improved quality of life for patients with moderate-to-severe plaque psoriasis.

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Author Contributions. Emanuele Trovato: writing and original draft preparation; Federico Bardazzi e Anna Campanati: supervision. Alessandra Cartocci: statistical analysis. Tommaso Bianchelli: data collection and final approval. Giulia Odorici: data collection and final approval. Aldo Cuccia: data collection and final approval. Vito Giuseppe Di Lernia: data collection and final approval. Claudia Lasagni: data collection and final approval. Marco Manfredini: data collection and final approval. Massimiliano Nicolini: data collection and final approval. Giulia Rech: data collection and final approval. Francesca Satolli: data collection and final approval.

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Data Availability. The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Conflict of Interest. Anna Campanati is an Editorial Board member of *Dermatology and Therapy*. Anna Campanati was not involved in the selection of peer reviewers for the manuscript nor any of the subsequent editorial decisions. Emanuele Trovato has nothing to disclose. Tommaso Bianchelli has nothing to disclose. Giulia Odorici has nothing to disclose. Aldo Cuccia has nothing to disclose. Vito Giuseppe Di Lernia has nothing to disclose. Claudia Lasagni has nothing to disclose. Marco Manfredini has nothing to disclose. Massimiliano Nicolini has nothing to disclose. Giulia Rech has nothing to disclose. Francesca Satolli has nothing to disclose. Alessandra Cartocci has nothing to disclose. Federico Bardazzi has nothing to disclose.

Ethical Approval. The study was conducted in accordance with the Declaration of Helsinki (1964 and subsequent amendments) and it was approved by the local ethics committee (N° 22045).

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