Journal of Dermatological Treatment

ISSN: (Print) (Online) Journal homepage: www.tandfonline.com/journals/ijdt20

Effectiveness, speed of action and safety of brodalumab in elderly psoriasis patients: a multicenter real-world study – IL PSO (Italian Landscape Psoriasis)

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To cite this article: D. Orsini, D. Graceffa, M. Burlando, A. Campanati, E. Campione, C. Guarneri, A. Narcisi, P. Pella, P. Romita, M. Travaglini, L. Zichichi, L. M. H. Arancio, G. Baggini, R. Balestri, L. Bianchi, A. M. G. Brunasso, A. E. Cagni, Giacomo Caldarola, G. Calianno, A. Carpentieri, M. Carriero, A. Carugno, F. Cona, A. Costanzo, E. Cozzani, Giacomo Dal Bello, Giovanni Carlo Lazzaro Danzuso, A. Dattola, A. Di Tano, F. Diotallevi, M. Donnarumma, E. De Col, M. Esposito, C. S. Fiorella, M. Galluzzo, F. Graziola, M. Licciardello, A. Legori, P. Malagoli, Federica Mola, G. Moretta, A. Muracchioli, A. Musumeci, M. L. Musumeci, G. Pagnanelli, V. Panasiti, E. Provenzano, D. Rizzo, M. Rubatto, Oriele Sarno, D. Strippoli, F. Vaira & M. C. Fargnoli (2025) Effectiveness, speed of action and safety of brodalumab in elderly psoriasis patients: a multicenter real-world study – IL PSO (Italian Landscape Psoriasis), Journal of Dermatological Treatment, 36:1, 2452948, DOI: 10.1080/09546634.2025.2452948

To link to this article: https://doi.org/10.1080/09546634.2025.2452948

Published online: 06 Feb 2025.

JOURNAL OF DERMATOLOGICAL TREATMENT
2025, VOL. 36, NO. 1, 2452948
https://doi.org/10.1080/09546634.2025.2452948

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LETTER TO THE EDITOR

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Effectiveness, speed of action and safety of brodalumab in elderly psoriasis patients: a multicenter real-world study – IL PSO (Italian Landscape Psoriasis)

Dear Editor,

Brodalumab is a recombinant, fully human immunoglobulin IgG2 monoclonal antibody specifically targeted against interleukin-17RA that has been approved for the treatment of moderate-to-severe psoriasis (1). Differently from other IL-17A agents, brodalumab selectively binds the A subunit of the IL-17 receptor by blocking the biological activity of pro-inflammatory cytokines IL-17 (IL-17A, IL-17F, IL-17A/F heterodimer, IL −17C and IL-17E [IL-25]). The result is a stronger anti-inflammatory effect and faster improvement in the clinical signs and symptoms of psoriasis (2,3).

Currently, there is a lack of real-world data on the efficacy and safety of brodalumab in elderly psoriasis patients (aged 65 years and older). The review of RCTs found no significant differences in the overall safety profile of brodalumab compared with other biologics, with the exception of slightly higher rates of mild fungal infections (4).

However, in this particular subgroup of patients frequently affected by multiple coexisting chronic diseases and polymedication, the use of brodalumab was limited by its immunosuppressive potential.

We conducted a retrospective multicenter real-world study to evaluate the efficacy and safety of brodalumab in elderly patients with moderate-to-severe psoriasis. Our cohort consisted of 69 elderly patients (mean age 70.7 ± 4.3 years) with long-standing plaque psoriasis (mean disease duration 24.9 ± 13.9 years). The choice of brodalumab over other biologic drugs was made by the clinician only on the basis of the patient's clinical and anamnestic characteristics according to current clinical practice. Most patients were male (48, 69.6%) and had multiple comorbidities, including overweight (mean BMI 26.9), hypertension (47, 68.1%), hyperlipidemia (30, 43.5%) and heart disease (20, 29%). Mean baseline Psoriasis Area and Severity Index (PASI) was 15.4 (±6.4). Baseline demographic characteristics of the study population are summarized in Table 1. 16/41 (39.0%) patients have taken more than one previous biologic drug; Last previous biological therapies are summarized in Table 2.

All patients were treated continuously with standard-dose brodalumab according to current Italian guidelines (5) and were monitored for 52 weeks. The PASI score significantly decreased from baseline in all patients examined. Significant clinical improvement was observed in most patients as early as week 4, and the same trend was maintained at each time point of the study (15.4 ± 6.4 at baseline, 5.2 ± 3.9 at week 4, 1.5 ± 2.5 at week 16, 0.5 ± 1 at week 36, and 0.5 ± 1.2 at week 52; $p < 0.001$) (Figure 1). At week 16, 82.4% (56/68) of patients achieved PASI 75, 69.1% (47/68) PASI 90, and 55.9% (38/68) PASI 100. The improvement achieved was then maintained at the surveys performed at 36 and 52 weeks. At the end of the study, 95.5% (63/66) of patients achieved PASI 75, 86.4% (57/66) PASI 90 and 75.8% (50/66) PASI 100. As expected, Dermatology Life Quality Index (DLQI) scores also improved significantly, (14.4 at baseline vs 1.2 at 1 year; $p < 0.001$). Adverse events were reported in 5.8% (4/69) of patients: edema (1, 16.7%), hypotension (1, 16.7%), maculopapular rash (1, 16.7%), conjunctivitis (1, 16.7%), latent tuberculosis (1, 16.7%) and fatigue (1, 16.7%). Therapy was discontinued in 8.7% (6/69) of patients, mainly due to adverse events. One patient discontinued treatment on worsening of previously diagnosed psoriatic arthritis. In conclusion, our real-world experience shows that brodalumab has comparable efficacy to that observed in RCTs and an acceptable safety profile even in elderly patients. The treatment resulted in a fast and sustained improvement in terms of psoriasis severity, and quality of life of patients.

The reassuring results produced by our study allow brodalumab to be included as a possible choice among those treatments considered safe and effective on elderly patients, a subgroup of patients known to face the challenges of senile comorbidities and drug interactions.

Acknowledgments

Editorial assistance was provided by Valentina Mirisola, and Laura Brogelli (Polistudium, Milan, Italy).

Ethics approval

Institutional review board approval was exempted for this study as its procedure did not deviate from good routine clinical practice. The study was conducted in accordance with the Helsinki Declaration of 1964 and its later amendments.

Consent form

All patients gave written informed consent for the retrospective retrieval of anonymized data. All patients gave written informed consent for the publication of anonymized data.

Authors' contributions

Study conception and design: Orsini D, Fargnoli MC; *collection and interpretation of data:* Orsini D, Fargnoli MC, Graceffa D, Burlando M, Campanati A, Campione E, Guarneri C, Narcisi A, Pella P, Romita P, Travaglini M, Zichichi L, Arancio LMH, Baggini G, Balestri R, Bianchi L, Brunasso AMG, Caldarola G, Cagni AE, Calianno G, Carpentieri A, Carriero M, Carugno A, Cona F, Costanzo A, Cozzani E, Dal Bello Giacomo, Lazzaro Danzuso GC, Dattola A, Di Tano A, Diotallevi F, Donnarumma M, De Col E, Esposito M, Fiorella CS,

Galluzzo M, Graziola F, Licciardello M, Legori A, Malagoli P, Mola F, Moretta G, Muracchioli A, Musumeci A, Musumeci ML, Pagnanelli G, Panasiti V, Provenzano E, Rizzo D, Rubatto M, Sarno O, Strippoli D, Vaira F; *statistical analysis:* Orsini D, Fargnoli MC; *manuscript drafting:* Orsini D, Graceffa D, Fargnoli MC; *manuscript editing:* Orsini D, Fargnoli MC; *approval to submit:* Orsini D, Fargnoli MC.

Table 1. Clinical and demographic characteristics of our population at baseline visit.

Demography	*N* = 69
Male, *N* (%)	48 (69.6%)
Age (years), mean ± *SD*	70.7 (± 4.3)
Disease duration (years), mean ± *SD*	24.9 (± 13.9)
BMI, mean ± *SD*	26.9 (± 4.4)
Obese, *N* (%)	11 (15.9%)
Overweight, *N* (%)	46 (66.7%)
Normal weight, *N* (%)	22 (31.9%)
Diabetes, *N* (%)	15 (21.7%)
Hypertension, *N* (%)	47 (68.1%)
Hyperlipidemia, *N* (%)	30 (43.5%)
Thyroid disease, *N* (%)	4 (5.8%)
Oncologic disease, *N* (%)	6 (8.7%)
Cardiopathy, *N* (%)	20 (29.0%)
Other, *N* (%)	22 (31.9%)
PsA, *N* (%)	10 (14.5%)
≥ 1 Difficult-to-treat areas, *N* (%)	59 (85.5%)
PASI baseline, mean ± *SD*	15.4 (± 6.4)
Bio-naïve, *N* (%)	28 (40.6%)
Naïve for systemic therapies, *N* (%)	9 (13.0%)

Table 2. Last previous biological therapies.

Last previous biological therapies	*N* = 41
Adalimumab	14 (34.1%)
Apremilast	5 (12.2%)
Etanercept	5 (12.2%)
Guselkumab	1 (2.4%)
Ixekizumab	3 (7.3%)
Risankizumab	2 (4.9%)
Secukinumab	6 (14.6%)
Tildrakizumab	2 (4.9%)
Ustekinumab	3 (7.3%)

Disclosure statement

D. Orsini has been a speaker and/or consultant for Abbvie, LeoPharma, UCB, Bristol-Meyer-Squibb and Boehringer- Ingelheim. *R. Balestri* has received support for attending meetings and/or travel for AbbVie, Amgen, Leo Pharma, Lilly, Novartis and Sanofi. *M. Burlando* acted as a speaker or consultant for Abbvie, Eli Lilly, Janssen, Leo-Pharma, UCB, Novartis, Bristol-Meyer-Squibb and Boehringer- Ingelheim. *G. Caldarola* has received honoraria as speaker and consultant for Abbvie, Almirall, Biogen, Eli Lilly, LEO Pharma, Novartis, Janssen, Sanofi, Pfizer, and UCB Pharma outside the submitted work. *A. Campanati* has served as a speaker, consultant or advisory board member for Abbvie, Almirall, Amgen, Eli-Lilly, Leo Pharma, Janssen-Cilag, Novartis, Pfizer, Sanofi-Aventis, Boehringer Ingelheim and UCB Pharma. *E. Campione* has served as advisory board member, received fees for lectures and/or research grants by Almirall, Amgen, Abbvie, Bristol Myers Squibb, Incyte, Leo Pharma, UCB. *A. Carugno* has been a speaker and/or consultant for Almirall, Amgen, Abbvie, Boehringer-Ingelheim, Eli Lilly, Leo Pharma, Janssen-Cilag, Novartis, UCB Pharma. *A. Costanzo* has been a consultant and/or speaker for AbbVie, Almirall, Amgen, Janssen, Leo Pharma, Eli Lilly, Galderma, Boehringer, Novartis, Pfizer, Sandoz, and UCB. *E. Cozzani* acted as a speaker or consultant for Abbvie, Almirall, Eli Lilly, Leo-Pharma, Novartis. *G. Dal Bello* has been consultant for Abbvie, Eli Lilly, Janssen, Sanofi, UCB and Novartis. *A. Dattola* has served as a speaker, consultant or advisory board member for Abbvie, Almirall, Amgen, Eli Lilly, Leo Pharma, Janssen, Novartis, Boehringer Ingelheim and UCB Pharma outside the submitted work. *M. Esposito* has served as speaker/consultant for Abbvie, Amgen, Almirall, Eli Lilly, Janssen, Leopharma, Novartis, Pfizer, Sanofi, UCB. *M.C. Fargnoli* has served on advisory boards, received honoraria for lectures and/or research grants from AMGEN, Almirall, Abbvie, Boehringer-Ingelheim, BMS, Galderma, Kyowa Kyrin, Incyte, LEO Pharma, Pierre Fabre, UCB, Lilly, Pfizer, Janssen, MSD, Novartis, Sanofi, Regeneron, Sun Pharma. *C. Guarneri*

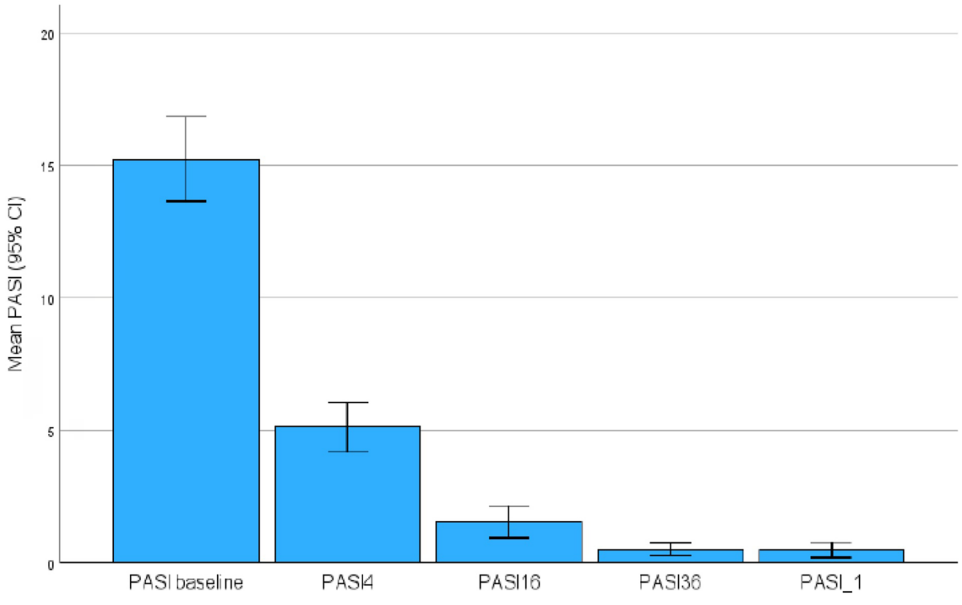

Figure 1. mPASI by visit.

has received consultation fees and/or grants for research projects, advisory panels and giving educational lectures from Wyeth-Pfizer, Abbott Immunology-Abbvie, Janssen-Cilag, Novartis, LEO-Pharma, LEO-Pharma Denmark, Ely-Lilly, Celgene, Merck-Serono, UCB Pharma, Sanofi-Aventis, Amgen and Almirall. *P. Malagoli* has been a speaker for AbbVie, Lilly, Novartis, Janssen-Cilag, Celgene, Leopharma, and Almirall. *A. Narcisi* has served on advisory boards, received honoraria for lectures and research grants from Almirall, AbbVie, BMS, Leo Pharma, Celgene, Eli Lilly, Janssen, Novartis, Sanofi-Genzyme, Amgen and Boehringer Ingelheim.

Funding

None.

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Data availability statement

Additional data supporting the findings of this study are available from the Corresponding Author on reasonable request.

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Received 13 November 2024; accepted 26 December 2024