

Adalimumab in the management of psoriasis and psoriatic arthritis: Results from a Delphi investigation

Marco Matucci-Cerinic^{1*}, Francesco Ciccia², Rosario Foti³, Alessandro Giunta⁴, Francesco Loconsole⁵, Francesca Prignano⁶, Rossana Scivo⁷, Giampiero Girolomoni⁸

¹Department of Experimental and Clinical Medicine & Department of Geriatric Medicine, Division of Rheumatology AOUC, University of Florence, Italy and Unit of Immunology, Rheumatology Allergy and Rare Disease (UnIRAR), IRCCS San Raffaele, Milan, Italy

²Department of Precision Medicine, University of Campania L. Vanvitelli, Naples, Italy

³Unit of Immunology, Rheumatology Allergy and Rare Disease (UnIRAR), IRCCS San Raffaele, Milan, Italy

⁴Department of Dermatology, University of Rome Tor Vergata, Rome, Italy

⁵Department of Medicine Dermatology Section, University of Bari, Italy

⁶Department of Health Science, Section of Dermatology, University of Florence, Florence, Italy

⁷Department of Clinical Internal, Anesthesiological and Cardiovascular Sciences, Rheumatology Unit, Sapienza University of Rome, Italy

⁸Department of Medicine, Section of Dermatology, University of Verona, Verona, Italy

Received Oct 24, 2023 accepted Feb 15, 2024

Abstract

Background and Objectives: Psoriasis (PsO) and psoriatic arthritis (PsA) are often undertreated and require a multidisciplinary approach. In recent years, patent expiration has allowed the introduction of tumor necrosis factor inhibitor (anti-TNF) biosimilars, which have stimulated a significant increase in the use of biological therapies. This article reports the findings of a multidisciplinary approach to achieve a consensus on the use of adalimumab in patients with PsO or PsA.

Methods: A voting panel of 36 Italian dermatologists and rheumatologists were chosen by eight Italian clinicians (the Board), to provide a consensus on the real-world management of PsO and PsA with adalimumab using the Delphi Method, comprising three survey rounds. Twelve statements were defined by the Board and submitted to the panel (rating scale 1–7).

Results: Clinicians reached a wide consensus on the effectiveness (score 6–7: 67%) and long-term efficacy (6–7: 100%) of adalimumab in all clinical forms of PsO and PsA, including pediatric patients (6–7: 85%). Considering cost-effectiveness and safety, adalimumab is suggested as a first-line treatment in patients with enthesitis, predominant peripheral arthritis, axial involvement or associated inflammatory bowel disease (IBD) or uveitis. Adalimumab can be also considered after failure of etanercept (6–7: 94%).

Conclusion: Results from this Delphi study clearly show an overall consensus on the use of adalimumab in the management of PsO and PsA, particularly as first-choice for specific subpopulations (uveitis, IBD, hidradenitis suppurativa). Considering the cost-effectiveness of biosimilars within Italy, adalimumab may represent an effective and safe first-line treatment for patients with moderate-to-severe PsO or PsA, and a valid choice for switching after failure.

Keywords

adalimumab • consensus • psoriasis • psoriatic arthritis • switch

Introduction


Immune-mediated inflammatory diseases (IMIDs) are chronic disorders sharing common epidemiological and genetic features, and underlying pathogenetic pathways.^[1,2] Indeed, evidence suggests that multiple IMIDs may coexist in the same patient.^[3] In the first year of disease, peripheral arthritis may occur in about 12% of patients with inflammatory bowel

disease (IBD).^[4] These patients are also prone to develop psoriasis (PsO) or rheumatoid arthritis (RA).^[5] In women with PsO and psoriatic arthritis (PsA), the former is associated with a significantly increased risk of Crohn's disease.^[6]

PsA occurs in 0.04%–1% of the general population and between 20%–40% of PsO patients.^[7,8] Metabolic, cardiovascular,^[9] and psychological comorbidities overlap in PsO, with a significant impact on quality of life^[10] and increased mortality.^[11] The heterogeneous clinical presentation of PsA and PsO represents a clinical challenge when choosing a suitable therapy, in particular when treating concurrent comorbidities.^[12] Undertreatment is also significant,^[13,14] where up to 24% of patients with moderate-to-severe PsO are not treated, and 30% are only receiving topical therapy, which

Address for correspondence:

*Marco Matucci-Cerinic, Department of Experimental and Clinical Medicine & Department of Geriatric Medicine, Division of Rheumatology AOUC, University of Florence, Firenze 20121, Italy. Email: marco.matuccicerinic@unifi.it

 Open Access. © 2024 The author(s), published by De Gruyter on behalf of NCRC-DID. This work is licensed under the Creative Commons Attribution 4.0 International License.

may not control the disease.^[13] Similarly, PsA is a heterogeneous and potentially severe disease, which may require a multidisciplinary approach to treatment.^[15]

In the last two decades, the number of disease-modifying antirheumatic drugs (DMARDs) has significantly increased.^[16] The introduction of biologic DMARDs, such as tumor necrosis factor (TNF) inhibitors has greatly improved patients' quality of life,^[1] with anti-TNFs often prescribed as first-line treatment for PsO and/or PsA.^[15,17] Guidelines also recommend anti-TNFs when there is an insufficient response to nonsteroidal anti-inflammatory drugs (NSAIDs) or local glucocorticoid injections.^[1,15,18] In PsA, a biologic DMARD is recommended after an inadequate response to at least one conventional synthetic DMARD, while an interleukin (IL)-17 or IL-12/23 inhibitor may be preferred when there is significant skin involvement.^[15] However, IL-17 inhibitor treatment has been associated with exacerbations of and new onset IBD or colitis. Fortunately, the cessation of IL-17 inhibitors and initiation of an alternative treatment (*e.g.*, corticosteroids and anti-TNF therapy) can generally lead to clinical remission.^[19,20]

The efficacy and tolerability of adalimumab have been demonstrated in PsA, plaque PsO, RA and IBD (including Crohn's disease, ulcerative colitis, pediatric Crohn's disease, and pediatric ulcerative colitis),^[21,22] Assessment of the clinical efficacy and cost-effectiveness of adalimumab has shown it to be a valid treatment choice in a large number of patients.^[1] Two Italian studies have demonstrated that, economically, adalimumab is below the threshold value for health care interventions for all its main indications, as it significantly reduces societal costs for RA, PsO and PsA, ankylosing spondylitis, and Crohn's disease.^[23,24] The long-term safety profile of adalimumab has also been well established in multiple clinical trials,^[25] with infections being the most commonly reported serious adverse event, and in the real-world setting.^[26,27]

It is generally accepted that patients with IMIDs should receive effective treatment as early as possible to prevent and limit organ damage, comorbidities, and the natural progression of the disease.^[28] Recent patent expiration has introduced numerous anti-TNF biosimilars, which have markedly increased the overall uptake of biological therapies for patients with PsO.^[29] Anti-TNF biosimilars provide cost reduction and increased patients' access to biological treatment, positively influencing the course of their disease.^[1]

The aim of the present work was to convene rheumatologists and dermatologists experienced in the use of anti-TNF agents, to achieve a consensus on the use of adalimumab in patients with PsO and/or PsA.

Materials and Methods

A total of eight Italian clinicians (four rheumatologists and four dermatologists, hereafter referred to as the Board), with long-standing expertise in the treatment of PsA and PsO, gathered to reach a consensus on the management of both diseases with anti-TNF agents, by adopting the Delphi methodology.^[28–31] The Delphi method is a highly regarded approach which involves an iterative process, characterised by multiple rounds of voting, to ascertain consensus on clinical matters in healthcare where there is limited guidance and/or a scarcity of evidence.^[30]

In the present study, the methodology was stratified into four phases: [1] the Board identified 12 statements lacking clinical consensus and developed a Delphi questionnaire (Table 1), [2] the questionnaire was then submitted to a panel of 36 Italian clinical experts in the field of PsO and PsA through an online platform for a first Delphi round. The voting panel were chosen by the Board members, who nominated 4–5 collaborators or colleagues, each operating in distinct geographic regions (*e.g.*, North-East, North-West). Geographical criteria were adhered to, ensuring homogeneous coverage of the Italian national territory. The panel were then asked to express their agreement or disagreement on each item using a Likert-type scale from 1 to 7 (1 = strongly disagree to 7 = strongly agree) for a maximum of three rounds. [3] Responses were collected and analysed. [4] Common and conflicting viewpoints were identified. At the end of Round 1, the median value, the 25th (Q1) and 75th (Q3) percentiles and the interquartile range (IQR) of each statement were calculated.

In Round 2, experts were asked to answer the same statements taking into account the IQR of each question, as an index of the responses of their colleagues. In case of a score outside the IQR, experts were required to provide a reason. The results of the first and second rounds and the reasons were discussed by the Board, focusing on the motivations/theses of those who responded outside the IQR. After discussing and commenting on the results of each of the 12 statements, the Board members re-formulated the statements.

In Round 3, the panel were invited to express their agreement/disagreement with the same statements considering the antitheses and the new IQRs. At this time, those who answered outside the IQR were asked to provide a new motivation. The statements were ranked based on the Q1 and the IQR (Figure 1). The "level of agreement or disagreement" achieved was measured according to the following criteria: a) agreement and consent ($Q1 \geq 4$, $Q3 > 4$ and $IQR \leq 2$), b) agreement and low consent ($Q1 \geq 4$ and $IQR \geq 3$), c) indecision ($Q1 = Q3 = 4$ or $Q1 = 3$ and $Q3 = 5$), d) disagree and consent ($Q1 < 4$ and $IQR \leq 2$ and $Q1 \neq 3$ and $Q1 \neq 5$) and e) disagree and low consent ($Q1 < 4$ and $IQR \geq 3$).

Table 1: Delphi consensus statements

NO	Statement
S1	A synergistic collaboration between dermatologists and rheumatologists may be very important for a more comprehensive and personalized management of patients with psoriatic disease (PsA and PsO)
S2	Adalimumab is highly effective in all clinical forms of PsO (scalp, nails, palmoplantar, inverse, face)
S3	Pediatric patients (>= 4 years old) with moderate to severe PsO and eligible for a systemic therapy are good candidates for treatment with adalimumab
S4	Adalimumab has a long-term sustained effectiveness in patients with PsA and PsO
S5	Cost-effectiveness considerations are very relevant in the choice of the treatment for patients with PsO and PsA
S6	Based on effectiveness, safety and costs, a patient with PsO eligible for a systemic treatment is a good candidate for adalimumab biosimilar as first-line treatment
S7	Patients with PsA and predominant enthesitis are good candidates for treatment with adalimumab
S8	Patients with PsA and predominant peripheral arthritis are good candidates for treatment with adalimumab
S9	Patients with PsA and predominant axial involvement are good candidates for treatment with adalimumab
S10	Adalimumab is a drug of choice when PsO and/or PsA are associated with uveitis or hidradenitis suppurativa
S11	Adalimumab is a drug of choice when PsA and/or PsO are associated with inflammatory bowel disease
S12	In patients with PsA and moderate skin involvement the switch to adalimumab can be considered after failure of etanercept

PsA, psoriatic arthritis; PsO, psoriasis; S, statement.

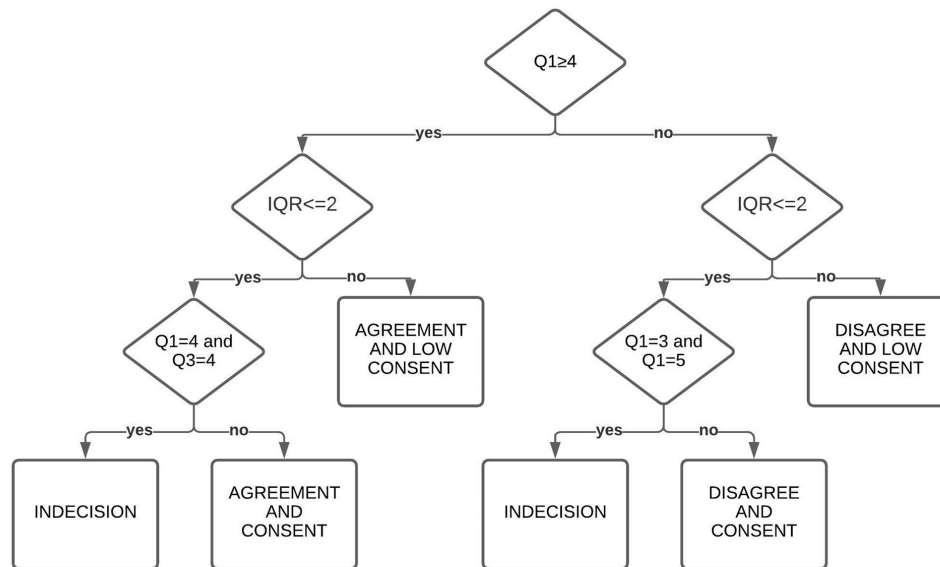


Figure 1. Flow diagram of the statement classification in terms of level of agreement or disagreement. IQR, interquartile range; Q, quartile.

Statistical Analysis

Descriptive statistics (median and IQR) were used for the analysis of surveys in rounds. For each question and round the panel's changes of opinion and related IQRs are reported, where the IQR is defined as the absolute value of the difference between Q3 and Q1, with smaller values indicating higher degrees of consensus. Statistical analyses were performed using Stata Version 16.1.

Results

All 36 participants responded to Round 1, and 33 responded to the remaining two rounds. All statements reached a positive consensus, with variations in 29% of responses between the first and the second round, and in 17% of responses between the second and the third round. For the 4 statements with values outside the IQR (S6, S7, S9, and S12), the Board was asked to reclarify their statement to avoid confusion in

Table 2 Thesis and antithesis motivation (in bracket the assigned score)

No	Round	Thesis	Antithesis
S6	2	Analysis of costs, safety and effectiveness is not always in favor of a biosimilar (scored 4)	The statement of the board specifically refers to ADA biosimilars, while the objection pertains to biosimilars in general when compared with first-line agents
S7	2	I would consider, at least at the same level, an anti-IL-17 therapy in patients with enthesitis (scored 4)	We agree that both treatments are good candidates for the treatment of enthesitis. The question however was specifically related to ADA
S9	2	Only the MAXIMISE study with secukinumab has demonstrated clinical efficacy of a biologic drug in axial PsA (scored 3)	We agree that MAXIMISE is the only RCT on biotechnological drugs on axial PsA. However, TNF-blocking agents are currently recommended by GRAPPA and EULAR guidelines for the treatments of axial PsA.
S12	2	I personally don't like cycling with anti-TNF (scored 1)	Switching among anti-TNF agents is a therapeutic option supported by scientific evidence
S12	3	We have now different biologic classes. Most of them are approved for both PsO and PsA. In my opinion, after the failure of an anti-TNF, switching to another class of biologics and changing the mechanism of action would be more desirable because anti-ILs have demonstrated superiority (scored 5)	
S12	3	I prefer to switch to another biologic (scored 3)	

ADA, adalimumab; IL, interleukin; RCT, randomized controlled trial; TNF, tumor necrosis factor; PsA, psoriatic arthritis; PsO, psoriasis.

the observations provided by the expert panel (Table 2).

Consensus Statements

The final consensus for each item is summarized in Table 3.

Statement S1. A synergistic collaboration between dermatologists and rheumatologists may be very important for a more comprehensive and personalized management of PsA and PsO patients. This statement showed a high level of agreement in Round 1, with a median equal to 7. In Round 3, 97% of the experts gave 7, the maximum agreement score, with the remaining 3% (1 expert) assigning a score of 6. A 15% variation in answers was observed between the first and the second round, while only 1 expert (3%) changed his answer between the other rounds.

Statement S2. Adalimumab is highly effective in all clinical forms of PsO (scalp, nails, palmoplantar, inverse, face). A median response equal to 5 was obtained in Round 1. In Round 2, all responses were between 5 and 6, while in Round 3, 33% of the experts gave a score equal to 5, 64% assigned a score of 6, and only one expert (3%) assigned the highest score. A 45% variation in answers was observed between the first and the second round, while 7 experts (21%) changed their answers between the other rounds.

Statement S3. Pediatric patients (≥ 4 years old) with moderate-to-severe PsO and eligible for a systemic therapy are good candidates for treatment with adalimumab. The statement showed a high agreement from Round 1 (Table 3). In Round 3, 33% of experts assigned the maximum agreement score of 7. A variation in responses of 24% was observed between Round 1 and Round 2, and 27% between Round 2 and Round 3.

Statement S4. Adalimumab has a long-term sustained effectiveness in patients with PsA and PsO. A median score of 6 was achieved in Round 1. In Round 2, all responses were between 6 and 7. In Round 3, 30% of experts gave the maximum agreement score of 7, with the remaining 70% assigning a score of 6. A variation in responses of 24% was noted between Round 1 and Round 2, while three experts (9%) changed their answers in the other rounds.

Statement S5. Cost-effectiveness considerations are very relevant in the choice of the treatment for patients with PsO and PsA. A high agreement with a median of 6 was achieved in Round 1 and confirmed in Round 2. In Round 3, 33% of experts gave the maximum agreement score of 7, and 42% assigned a score of 6. Between Round 1 and Round 2, there was a variation in responses of 36%, while 33% of responses were modified by the experts between Round 2 and Round 3.

Statement S6. Based on effectiveness, safety and costs, a patient with PsO eligible for a systemic treatment is a good candidate for adalimumab biosimilar as first-line treatment. A high consensus with a median of 6 was reached in Round 1 and confirmed in Round 2. In Round 3, 39% of the experts gave the maximum agreement score of 7, and 61% gave a score of 6. Variations in responses of 36% and 39% were observed between Round 1 and Round 2, and between Round 2 and Round 3, respectively.

Statement S7. Patients with PsA and predominant enthesitis are good candidates for treatment with adalimumab. A high agreement with a median of 6 was achieved in Round 1 and confirmed in Round 2. All the answers ranged between 6 and 7 in Round 3, where 39% of the experts gave the maximum agreement score of 7, and 61% gave a score

Table 3: Statements and results of the Delphi consensus process

No	Round 1 (n = 36) median score (Q1-Q3: IQR)	Round 2 (n = 33) median score (Q1-Q3: IQR)	Round 3 (n = 33) median score (Q1-Q3: IQR)	Consensus degree
S1	7 (7-7: 0)	7 (7-7: 0)	7 (7-7: 0)	Agreement and consent
S2	5 (5-6: 1)	6 (5-6: 1)	6 (5-6: 1)	Agreement and consent
S3	6 (5-7: 2)	6 (5-7: 2)	6 (6-7: 1)	Agreement and consent
S4	6 (6-7: 1)	6 (6-7: 1)	6 (6-7: 1)	Agreement and consent
S5	6 (5-6.5: 1.5)	6 (5-7: 2)	6 (6-7: 1)	Agreement and consent
S6	6 (5-7: 2)	6 (6-7: 1)	6 (6-7: 1)	Agreement and consent
S7	6 (5-7: 2)	6 (5-7: 2)	6 (6-7: 1)	Agreement and consent
S8	6 (6-7: 1)	6 (6-7: 1)	6 (6-7: 1)	Agreement and consent
S9	6 (6-7: 1)	7 (6-7: 1)	7 (6-7: 1)	Agreement and consent
S10	7 (7-7: 0)	7 (7-7: 0)	7 (7-7: 0)	Agreement and consent
S11	7 (7-7: 0)	7 (7-7: 0)	7 (7-7: 0)	Agreement and consent
S12	6 (5-7: 2)	6 (6-7: 1)	6 (6-7: 1)	Agreement and consent

IQR, interquartile range; Q, quartile; S, statement.

of 6. A variation of 27% in responses was observed between Round 1 and Round 2, while 6 experts (18%) changed their answers in the other rounds.

Statement S8. Patients with PsA and predominant peripheral arthritis are good candidates for treatment with adalimumab. A high agreement in Round 1 was achieved and confirmed in Round 2. The highest consensus was detected in Round 3, where 42% of the experts gave the maximum agreement score of 7, and 58% assigned a score of 6. A variation in responses was observed in 30% of responses between Round 1 and Round 2, while the response was modified by 3 experts (9%) in Round 3.

Statement S9. Patients with PsA and predominant axial involvement are good candidates for treatment with adalimumab. A high consensus of 6 was achieved in Round 1, which increased to a median of 7 in Round 2. In Round 3, 55% of experts gave the maximum score of 7, and 45% assigned a score of 6. There was a variation of 36% in responses between Round 2 and 3, while the answer was modified by 3 experts (9%) in Round 3.

Statement S10. Adalimumab is a drug of choice when PsO and/or PsA are associated with uveitis or hidradenitis suppurativa. All three rounds achieved the highest agreement with a median score of 7. While five experts (15%) changed their answers between Round 1 and Round 2.

Statement S11. Adalimumab is a drug of choice when PsA and/or PsO are associated with IBD. The highest median score of 7 was obtained in all rounds. A variation of 24% was seen in responses between Round 1 and 2.

Statement S12. In patients with PsA and moderate skin

involvement, the switch to adalimumab can be considered after failure of etanercept. This statement received a high consensus among experts with a median score of 6 in Round 1. In Round 2, scores ranged between 6 and 7. In Round 3, 33% of the experts gave the maximum score of 7, and 61% gave a median score of 6. A variation of 36% in responses was detected between Round 1 and Round 2, while in Round 3, the answer was modified by 36% of the experts.

Discussion

The results of this Delphi exercise clearly show that an overall, multidisciplinary consensus may be reached for the use of adalimumab in the management of PsO and PsA. The Delphi method is typically used in healthcare research to determine consensus in response to defined clinical questions.^[31] In this study the Delphi questionnaire received controlled feedback from a panel of experts in the field of PsO and PsA management. Moreover, the importance of collaboration between rheumatologists and dermatologists is unanimously accepted in Statement S1. In all statements, the Delphi procedure identified a high degree of consensus. Moreover, the statements are also widely supported in the literature, which further corroborates a satisfactory level of expertise, as well as a good level of communication between the centers. From a general point of view, the statements submitted to the panel have been shaped according to the following principles. Firstly, that the paradigm for the use of biologics in case of failure, intolerance, or contraindications to conventional synthetic DMARDs is getting stronger. Furthermore, in parts of the European Union where the use of biosimilars is characterised by an affordably low cost, their use as first-line treatment is moving progressively forward in light of their good long-term safety profile.^[32] Secondly, the association of a significant reduction in

quality of life and ability to work with moderate-to-severe PsO and PsA^[33] may profit from a reduction in disease burden and the indirect costs of PsO.^[15,34] Moreover, adherence and patient satisfaction are higher with biologic agents when compared to conventional agents.^[35,36]

In the present study, five statements in the Delphi questionnaire were based on the pathogenesis of IMIDs and the dysregulation of inflammatory cytokines. The inhibition of TNF results in a down-regulation of the abnormal inflammatory pathways implicated in the pathogenesis and progression of IMIDs, and anti-TNF inhibitors including adalimumab may improve long-term patient outcomes by preventing the development of future damage and comorbidities.^[28]

Among Delphi expert panel responses, adalimumab emerged as a drug with long-term sustained effectiveness in PsA and PsO. Moreover, the cost-effectiveness of adalimumab is a significant factor when considering treatment options for PsO and PsA. Therefore, the cumulative results of this study suggest

that adalimumab offers a suitable first-line treatment for patients with PsO/PsA, offering an effective therapeutic option with an established long-term, risk/benefit profile. The panel also strongly agreed that adalimumab may be first choice for specific PsO and PsA subpopulations such as those with comorbid uveitis, IBD or hidradenitis suppurativa. The use of adalimumab in PsA patients with predominant enthesitis, and/or peripheral arthritis, and/or axial involvement achieved a high agreement among the Board and expert panel.

In conclusion, the results of this Delphi exercise indicate the need to bridge the gap between patients' expectations and physicians' objectives, with a focus on improving the quality of life and personalized treatment of patients with PsO and PsA. Given the cost-effectiveness of biosimilars in Italy, adalimumab may represent an effective and safe first-line treatment for patients with moderate-to-severe PsO or PsA, as well as patients suffering from non-musculoskeletal symptoms affecting the gut (IBD) or the eyes (uveitis).

Acknowledgement

No applicable.

Source of Funding

This work was supported by Biogen Italia S.r.l and Biogen International GmbH, Baar, Switzerland.

Author Contributions

All named authors meet the International Committee of Medical Journal Editors (ICMJE) criteria for authorship for this manuscript, take responsibility for the integrity of the work as a whole, and have given final approval to the version to be published.

The Delphi exercise was performed by Fullcro S.r.l. Biogen Italia S.r.l. and Biogen International GmbH, Baar, Switzerland provided funding for medical writing support in the development of this article; Giulio D'Alfonso, from Fullcro S.r.l., and Olive Denny, from Springer Healthcare Ltd provided medical writing support based on input from authors. Biogen reviewed and provided feedback on the paper to the authors. The authors had full editorial control of the paper and provided their final approval of all content.

Informed consent

Not applicable

Ethical statement

Not applicable

Conflict of Interest

MMC is an Associate Editor-in-Chief of the journal. The article was subject to the journal's standard procedures, with peer review handled independently of the editor and his research groups. MM-C has received consulting fees or honorarium from Actelion, Janssen, Inventiva, Bayer, Biogen, Boehringer, CSL Behring, Corbus, Galapagos, Mitsubishi, Samsung, Regeneron, Acceleron, MSD, Pfizer, Roche FC consulting fees or honorarium from Actelion, Janssen, Biogen, Boehringer, Lilly, GSK, AbbVie, Galapagos, MSD, Abbvie, Lilly, Pfizer, Roche. RF has received consulting fees or honorarium from AbbVie, Amgen, Biogen, Bristol-Myers Squibb, Eli Lilly, Fresenius Kabi, Galapagos, Novartis, Pfizer and Sanofi.

AG served as a consultant, board member and/or speaker for AbbVie, Amgen, Biogen, Eli Lilly, Pfizer and UCB.

LB has served as a consultant and/or speaker for AbbVie, Janssen, Pfizer and Novartis.

FL served on advisory boards and/or received honoraria for lectures from AbbVie, Janssen-Cilag, Novartis, Eli Lilly, Sanofi.

FP is a member of the editorial board for *Frontiers in Cell and Developmental Biology*, *Biologics targets and therapy*. She is an advisory committee member for *SIDeMAST* (Italian National Society of Dermatology) and is a member of the speakers' bureau for the Department of Health Science Section of Dermatology, Piero Palagi Hospital, Florence. She has received consulting fees from AbbVie, Amgen, Biogen, Eli-Lilly, Janssen-Cilag, Leo-Pharma, and Novartis and has received research grants from Janssen-Cilag, Novartis, and *SIDeMAST*.

RS has received consulting fees or honorarium from Janssen, Biogen, MSD, Eli Lilly, AbbVie, Novartis, Angelini, Sandoz, Pfizer, UCB, Grunenthal, and Celgene.

GG has received personal fees from AbbVie, Almirall, Boehringer-Ingelheim, Bristol-Myers Squibb, Eli-Lilly, Galderma, Genzyme, Leo Pharma, Novartis, Pfizer, Regeneron, Samsung and Sanofi.

The authors have no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Data Availability Statement

No additional data is available.

REFERENCES

- [1] Girolomoni G, Savage L, Gisondi P, *et al.* Increasing Access to Effective Systemic Treatments in Patients with Moderate-to-Severe Psoriasis: Narrative Review. *Dermatol Ther (Heidelb)*. 2023;13:2171–2185.
- [2] Rahman P, Inman RD, El-Gabalawy H, *et al.* Pathophysiology and pathogenesis of immune-mediated inflammatory diseases: commonalities and differences. *J Rheumatol Suppl*. 2010;85:11–26.
- [3] Coto P, Riestra S, Rozas P, *et al.* Improving the standard of care for patients with spondyloarthritis-related immune inflammatory conditions: results of a Delphi study and proposal for early detection. *Ther Adv Chronic Dis*. 2020;11:2040622320904295.
- [4] Palm O, Moum B, Jahnsen J, *et al.* The prevalence and incidence of peripheral arthritis in patients with inflammatory bowel disease, a prospective population-based study (the IBSEN study). *Rheumatology (Oxford)*. 2001;40:1256–1261.
- [5] Weng X, Liu L, Barcellos LF, *et al.* Clustering of inflammatory bowel disease with immune mediated diseases among members of a northern california-managed care organization. *Am J Gastroenterol*. 2007;102:1429–1435.
- [6] Li WQ, Han JL, Chan AT, *et al.* Psoriasis, psoriatic arthritis and increased risk of incident Crohn's disease in US women. *Ann Rheum Dis*. 2013;72:1200–1205.
- [7] Gladman DD, Antoni C, Mease P, Clegg DO, Nash O. Psoriatic arthritis: Epidemiology, clinical features, course, and outcome. *Ann Rheum Dis*. 2005;64:ii14–ii7.
- [8] Truong B, Rich-Garg N, Ehst BD, *et al.* Demographics, clinical disease characteristics, and quality of life in a large cohort of psoriasis patients with and without psoriatic arthritis. *Clin Cosmet Investig Dermatol*. 2015;8:563–569.
- [9] Ferguson LD, Siebert S, McInnes IB, *et al.* Cardiometabolic comorbidities in RA and PsA: lessons learned and future directions. *Nat Rev Rheumatol*. 2019;15:461–474.
- [10] Gudu T, Gossec L. Quality of life in psoriatic arthritis. *Expert Rev Clin Immunol*. 2018;14:405–417.
- [11] Orbai AM, de Wit M, Mease P, *et al.* International patient and physician consensus on a psoriatic arthritis core outcome set for clinical trials. *Ann Rheum Dis*. 2017;76:673–680.
- [12] Gisondi P, Talamonti M, Chiricozzi A, *et al.* Treat-to-Target Approach for the Management of Patients with Moderate-to-Severe Plaque Psoriasis: Consensus Recommendations. *Dermatol Ther (Heidelb)*. 2021;11:235–252.
- [13] Armstrong AW, Robertson AD, Wu J, *et al.* Undertreatment, treatment trends, and treatment dissatisfaction among patients with psoriasis and psoriatic arthritis in the United States: findings from the National Psoriasis Foundation surveys, 2003–2011. *JAMA Dermatol*. 2013;149:1180–1185.
- [14] Selvi P, Pérez OM, Madroñal IMC, Yañez D, Martín C. 4CPS-134 Evolution and analysis of spending on biological medication in psoriasis. *Eur J Hosp Pharm*. 2018;25:A104.1-A.
- [15] Gossec L, Baraliakos X, Kerschbaumer A, *et al.* EULAR recommendations for the management of psoriatic arthritis with pharmacological therapies: 2019 update. *Ann Rheum Dis*. 2020;79:700–712.
- [16] Zhang L, Du D, Wang L, *et al.* Efficacy and safety of topical Janus kinase and phosphodiesterase inhibitor-4 inhibitors for the treatment of atopic dermatitis: A network meta-analysis. *J Dermatol*. 2021;48:1877–1883.
- [17] Amin M, No DJ, Egeberg A, *et al.* Choosing First-Line Biologic Treatment for Moderate-to-Severe Psoriasis: What Does the Evidence Say? *Am J Clin Dermatol*. 2018;19:1–13.
- [18] Nast A, Altenburg A, Augustin M, *et al.* German S3-Guideline on the treatment of Psoriasis vulgaris, adapted from EuroGuiDerm - Part 2: Treatment monitoring and specific clinical or comorbid situations. *J Dtsch Dermatol Ges*. 2021;19:1092–1115.
- [19] Deng Z, Wang S, Wu C, *et al.* IL-17 inhibitor-associated inflammatory bowel disease: A study based on literature and database analysis. *Front Pharmacol*. 2023;14:1124628.
- [20] Grümme L, Dombret S, Knösel T, Skapenko A, Schulze-Koops H. Colitis induced by IL-17A-inhibitors. *Clinical Journal of Gas-*

- troenterology. 2023.
- [21] Gisondi P, Geat D, Conti A, *et al.* TNF- α inhibitors biosimilars as first line systemic treatment for moderate-to-severe chronic plaque psoriasis. *Expert Rev Clin Immunol.* 2020;16:591–598.
- [22] Croft NM, Faubion WA Jr, Kugathasan S, *et al.* Efficacy and safety of adalimumab in paediatric patients with moderate-to-severe ulcerative colitis (ENVISION I): a randomised, controlled, phase 3 study. *Lancet Gastroenterol Hepatol.* 2021;6:616–627.
- [23] Mennini FS, Marcellusi A, Gitto L, Giannantoni P, Favato G. Comprehensive value estimation of adalimumab-based treatments: covet study [PHP36]. *Value Health.* 2012;15(A19).
- [24] Marcellusi A, Gitto L, Giannantoni P, Russo S, Mennini FS. Social impact of adalimumab in the Italian perspective [PIH26]. *Value Health.* 2012;15(A540).
- [25] Burmester GR, Gordon KB, Rosenbaum JT, *et al.* Long-Term Safety of Adalimumab in 29,967 Adult Patients From Global Clinical Trials Across Multiple Indications: An Updated Analysis. *Adv Ther.* 2020;37:364–380.
- [26] Reich K, Mrowietz U, Radtke MA, *et al.* Drug safety of systemic treatments for psoriasis: results from The German Psoriasis Registry PsoBest. *Arch Dermatol Res.* 2015;307:875–883.
- [27] Curtis JR, Jain A, Askling J, *et al.* A comparison of patient characteristics and outcomes in selected European and U.S. rheumatoid arthritis registries. *Semin Arthritis Rheum.* 2010;40:2–14.
- [28] Girolomoni G, Griffiths CE, Krueger J, *et al.* Early intervention in psoriasis and immune-mediated inflammatory diseases: A hypothesis paper. *J Dermatolog Treat.* 2015;26:103–112.
- [29] Di Giuseppe D, Frisell T, Ernestam S, *et al.* Uptake of rheumatology biosimilars in the absence of forced switching. *Expert Opin Biol Ther.* 2018;18:499–504.
- [30] Owen R, Ashton REM, Ferraro FV, *et al.* Forming a consensus opinion to inform long COVID support mechanisms and interventions: a modified Delphi approach. *EClinicalMedicine.* 2023;62:102145.
- [31] Taylor E. We Agree, Don't We? The Delphi Method for Health Environments Research. *HERD.* 2020;13:11–23.
- [32] Hellgren K, Dreyer L, Arkema EV, *et al.* Cancer risk in patients with spondyloarthritis treated with TNF inhibitors: a collaborative study from the ARTIS and DANBIO registers. *Ann Rheum Dis.* 2017;76:105–111.
- [33] Horn EJ, Fox KM, Patel V, *et al.* Association of patient-reported psoriasis severity with income and employment. *J Am Acad Dermatol.* 2007;57:963–971.
- [34] Feldman SR, Zhao Y, Gilloteau I, *et al.* Higher Psoriasis Skin Clearance Is Associated with Lower Annual Indirect Costs in the United States: A Post Hoc Analysis from the CLEAR Study. *J Manag Care Spec Pharm.* 2018;24:617–622.
- [35] Esposito M, Giunta A, Gisondi P, *et al.* Satisfaction and attitudes toward systemic treatments for psoriasis: A cross-sectional study. *Dermatol Ther.* 2021;34:e14949.
- [36] Dommasch ED, Lee MP, Joyce CJ, *et al.* Drug utilization patterns and adherence in patients on systemic medications for the treatment of psoriasis: A retrospective, comparative cohort study. *J Am Acad Dermatol.* 2018;79:1061–1068.