Rom J Rheumatol 2024, 33(1):14-25 ISSN (print) 1843-0791, ISSN (online) 2069-6086

Revista Română de Reumatologie
Romanian Journal of Rheumatology

ORIGINAL PAPER

Data from the Romanian Registry of Rheumatic Diseases for patients with psoriatic arthritis treated with biologic and targeted-synthetic disease-modifying anti-rheumatic drugs – 2023 update

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ABSTRACT

Background. The Romanian Registry of Rheumatic Diseases (RRBR) is an electronic database that includes information on all patients with immune-mediated rheumatic diseases undergoing innovative therapies. These real-world data include demographics, clinical manifestations, comorbidities, biologic disease-modifying anti-rheumatic drug (bDMARD) treatment regimens, as well as efficacy and safety data, which are analysed annually.

Methods. The aim of this report was to analyse the data recorded from patients diagnosed with psoriatic arthritis (PsA) enrolled in RRBR in 2022, especially considering the updated therapeutic protocol approved by the National Health Insurance Company of Romania, which now includes newly approved therapeutic agents.

Results. The findings revealed a relatively constant number of patients included in RRBR compared to previous years. Patients with PsA exhibited numerous comorbidities, with cardiovascular conditions being the most frequently observed. Most patients continued to receive combination therapy with a conventional synthetic disease-modifying anti-rheumatic drug (csDMARD), methotrexate being the most commonly used, although at a slightly lower percentage than in previous years. The concurrent use of systemic glucocorticoids was recorded at a very low percentage. There was a trend towards initiating biologic treatment earlier, with 40% of patients having initiated biologic therapy within the first two years after diagnosis. The most commonly prescribed bDMARDs remained TNF blockers, with etanercept (original + biosimilar) being the most prevalent, followed by adalimumab (original + biosimilar), data consistent with previous years, though the prescription percentage of biosimilars increased. Recently, other therapeutic agents with different mechanisms of action, (such as ixekizumab, guselkumab and tofacitinib), have been reimbursed in Romania. These medications were used in 41% of initiated cases and represented the first choice in case of treatment changes. Over 90% of patients included in RRBR exhibited low disease activity or were in remission state. Although the percentage of patients undergoing a tapering regimen remained low, this strategy proved to be a valid option for the majority to whom it was applied.

Conclusion. RRBR represents an invaluable tool for assessing real-world data concerning PsA patients and the therapeutic approaches used in Romania. It allows for the integration and interpretation of these findings in the context of similar registries, identifying aspects that could contribute to enhancing the quality of PsA management in our country.

Keywords: psoriatic arthritis, Romanian Registry of Rheumatic Diseases, biologics

Introduction

Psoriatic arthritis (PsA) is a persistent immune-mediated inflammatory disease classified under spondyloarthritis (SpA) group, affecting several domains, such as peripheral and axial joints, skin, nails, entheses, and dactylitis and being accompanied by multiple extra-articular manifestations and comorbidities [1]. Recent years have witnessed transformative shifts in

the therapeutic landscape for PsA, with the integration of novel drugs, both biologic and targeted synthetic disease-modifying anti-rheumatic drugs (bDMARDs, tsDMARDs). This constant evolution requires an ongoing reassessment of treatment recommendations [1,2].

Given the intricate nature of PsA, influenced by genetic factors, variations in medical systems, national protocols, and therapy accessibility, real-life data have become exceptionally valuable. National registries play a crucial role in this regard, acting as reservoirs of authentic information on demographic specifics, clinical forms, comorbidities, therapeutic approaches, safety and efficacy data, revealing trends in patient populations, and shedding light on evolving treatment strategies [3-7].

In Romania, the Romanian Registry of Rheumatic Diseases (RRBR) was established in 2013, including a spectrum of rheumatic conditions such as rheumatoid arthritis (RA), psoriatic arthritis (PsA), spondyloarthritis (SpA), systemic lupus erythematosus (SLE), vasculitis, juvenile idiopathic arthritis (JIA), and, more recently, interstitial lung diseases associated with rheumatic conditions [8]. All patients included in RRBR have been exposed to at least one course of bDMARDs or tsDMARDs. The RRBR, a national electronic database, operates under the umbrella of the Association "Romanian Registry of Rheumatic Diseases," a non-profit organization initiated by the Romanian Society of Rheumatology [8].

We are presenting an analysis of the demographic characteristics of patients included in the RRBR in 2022, closely monitoring the dynamic utilization patterns of different therapeutic options. This offers valuable insights into the evolving landscape of PsA management in Romania.

Materials and methods

As presented in the previously published article regarding the situation in 2019, the data is added to the RRBR by the attending rheumatologist [9]. It is mandatory to enter patient data into RRBR in order to prescribe biologic therapy, and this is done after the patient has signed an informed consent covering both treatment options and the scientific use of their data. Details related to the obtained and entered data, statistical analysis, national criteria for prescribing innovative therapies, and the monitoring of these patients were outlined in the previously mentioned publication [9]. Additionally, the three types of electronic files — initiation, continuation, and switches — were also introduced.

The objective of this observational study is to present characteristic data from the RRBR concerning the PsA population undergoing bDMARDs and tsDMARDs treatment in Romania during 2022.

Results

The number of visits introduced in the RRBR in 2022 was 965, which indicates a minor increase compared to previous years: 861 in 2020 (+ 4.5%) and 900 in 2021 (+ 7.2%), marking the highest growth over the past 6 years (Figure 1).

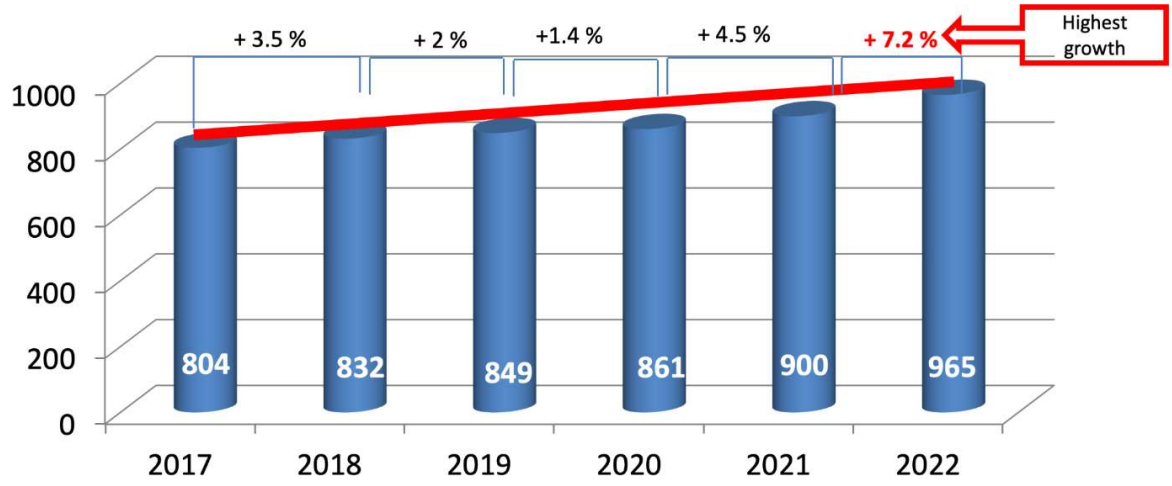

Figure 1 – The number of visits introduced in the RRBR in the last 6 years.

PsA patients characteristics

Demographic data are presented in Table 1. The distribution by gender showed a slight predominance of women (54%), representing a female-to-male ratio of 1.1/1, with an average age of 56.9 years. The population was slightly overweight, with a body mass index of 28,6, which is characteristic for PsA patients [10].

The majority of patients reside in urban areas (71.2%) and have a moderate level of education. The percentage of smokers is relatively low (9%), although there is an increase compared to previous years. It is noteworthy that the percentage of employed patients has seen a 5% increase in the last 4 years.

Table 1 – ***Characteristics of PsA patients from RRBR in 2022 (n = 965).***

Sex: women (n, %)	518 (54%) F / M = 1.1 / 1
Age (years, mean)	56.9 F= 57.2; M = 56.5

Body Mass Index (kg/m²)		28.6
Residence	urban	[illegible]
Education	illiterate	6 (<1%)
	elementary	158 (16%)
	high school	532 (55%)
	university	269 (28%)
Professional activity	employed	443 (46%)
	PsA-retired	[illegible]
	age-retired	[illegible]
Smokers		86 (9%)

The presence of comorbidities holds significant importance in PsA, a factor that may also be linked to the relatively elevated percentage of elderly patients (Figure 2). As per the 2022 data entries, 41% (392) of PsA patients exhibited comorbidities. Among these, the majority were associated with cardiovascular diseases (hypertension, coronary ischemic disease, heart failure, stroke, or peripheral vascular disease), dyslipidemia 19%, and diabetes 15%. It is noteworthy that no new cases of neoplasia were reported in 2022. Regarding infectious screening, in 2022, 54 cases of latent tuberculosis (TB), 5 cases of viral hepatitis B, and 12 cases of viral hepatitis C were detected.

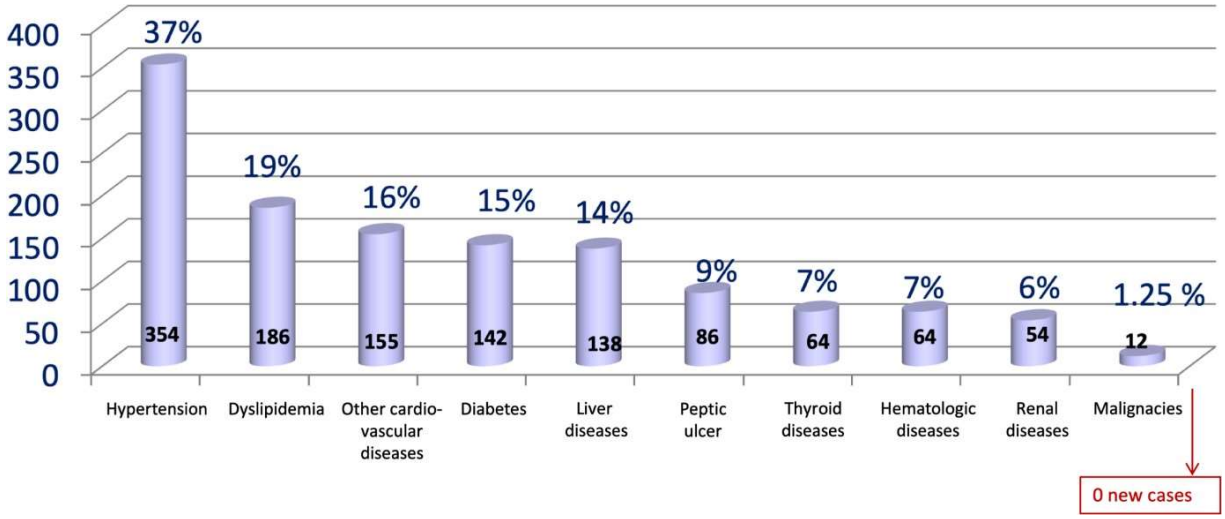

Figure 2 – ***The frequency of comorbidities of PsA patients in 2022 from the RRBR. Reported values represent the percent from the total sample.***

The mean disease duration was extended to 12.7 years. All patients enrolled in RRBR exhibit some form of peripheral arthritis. Moreover, 10.5% of them associated axial involvement and 20% sacroiliitis. Both enthesitis and dactylitis were detected in 6% of patients, while ocular involvement was identified in 1.65%. It is noteworthy that, due to the approval criteria for innovative therapies, the dedicated PsA section in RRBR predominantly includes forms characterized by peripheral involvement, with axial manifestations being associated to the peripheral ones.

The literature data indicates that axial involvement appears in 25% of patients at presentation, but this percentage increases during the course of the disease [11-13]. Among patients who do not have axial disease at the initial visit, 15% develop it over a 10-year follow-up period [11]. Severe peripheral arthritis and HLA-B27 positivity are risk factors for axial Psoriatic Arthritis (axPsA). Patients with Psoriatic Arthritis (PsA) and axial involvement experience a more severe disease course, as evidenced by the CorEvitas Psoriatic Arthritis Registry [14]. This group tends to present with moderate/severe psoriasis, more severe nail psoriasis, a higher likelihood of enthesitis, a greater number of painful joints, and higher scores for BASDAI, BASFI, and ASDAS-CRP [13].

Treatment regimens of PsA patients in 2022

At the end of 2022, the majority of patients (709, 73.5%) are undergoing combination therapy, representing a decrease compared to 2021 (77.5%) (Figure 3). There is evidence suggesting that the concomitant use of methotrexate (MTX) can reduce immunogenicity, which is one of the reasons why many rheumatologists prefer combination therapy [15-16].

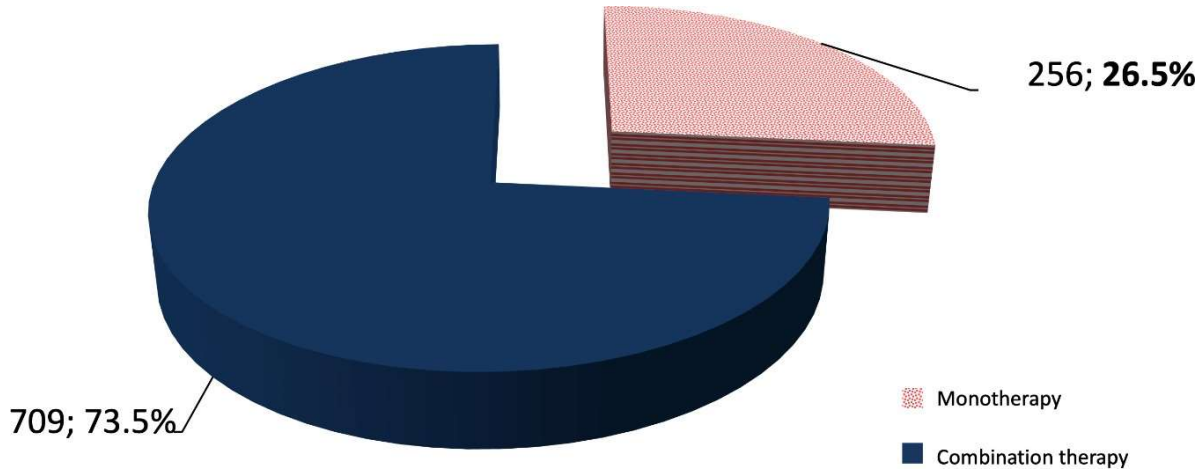

Figure 3 – ***Monotherapy vs. combination therapy with csDMARDs in PsA in 2022.***

Recently data from SEAM-PsA study, showed that the combination of methotrexate and etanercept did not improve the effectiveness of etanercept [17]. Similarly, data from the British Society for Rheumatology Biologics Register (BSRBR) did not demonstrate significant differences in treatment persistence between patients who received combination therapy with methotrexate and TNFi compared to TNFi monotherapy.

Regarding csDMARDs used in combinations with bDMARDs, the data from 2022 are similar to those recorded in the last 4 years. Methotrexate (MTX) remains the most frequently chosen option (63%), with an average dose of 15 mg per week, followed by leflunomide (LEF) (33%) and sulfasalazine (SSZ) (14%), cyclosporine (CSA) and azathioprine (AZA) (Figure 4).

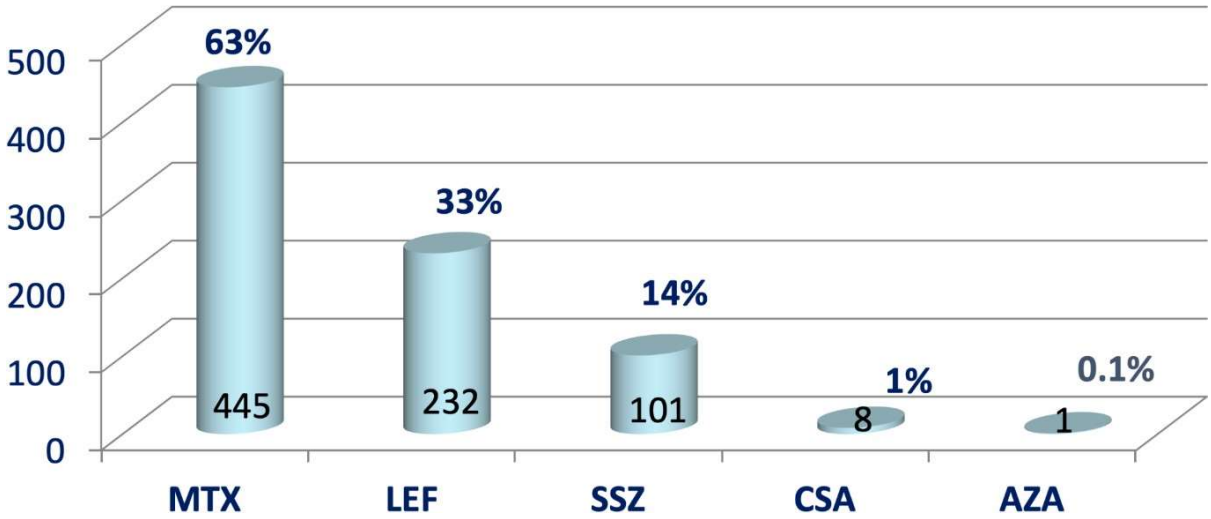

Figure 4 – The frequency of treatment with csDMARDs of PsA patients from the RRBR in 2022. Reported values represent the percent from the total entire cohort.

A number of 78 patients (11%) continue to use a combination of more than 2 csDMARDs, with MTX being the most frequently included in these combinations as well. (Figure 5).

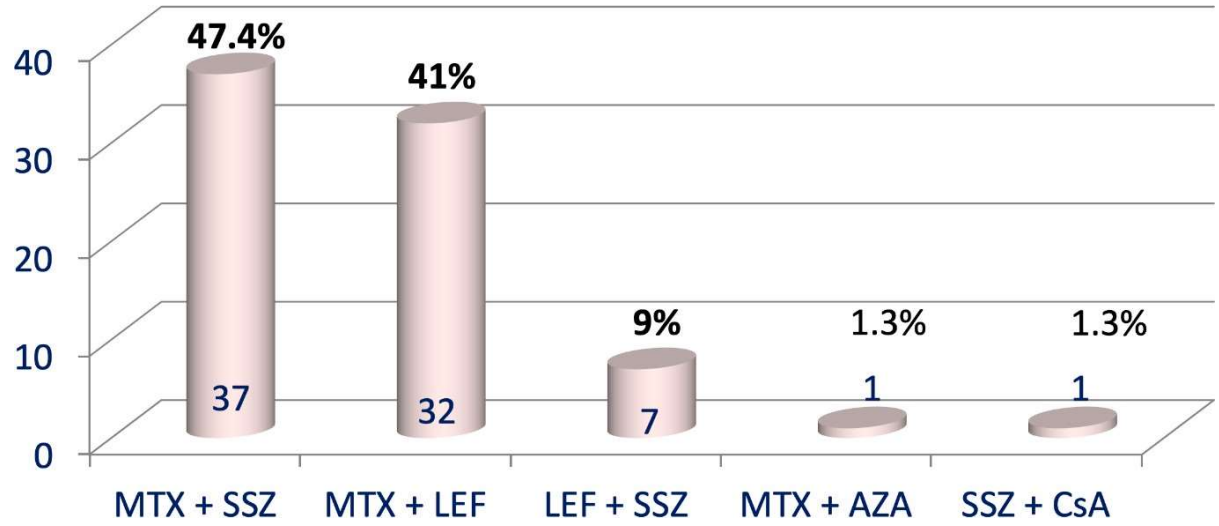

Figure 5 – The frequency of treatment with several csDMARDs of PsA patients from the RRBR in 2022. Reported values represent the percent from the entire cohort.

Systemic glucocorticoid therapy is rarely associated, being registered in only 17 cases (2.3%) of patients, while local steroids were administered in 67 cases (7%).

There is a slight tendency to initiate biologic treatment earlier, with 40% of patients receiving biologic therapy within the first 2 years, 28% between 2-5 years, 18% between 6-10 years, and only 14% after 10 years (Figure 6).

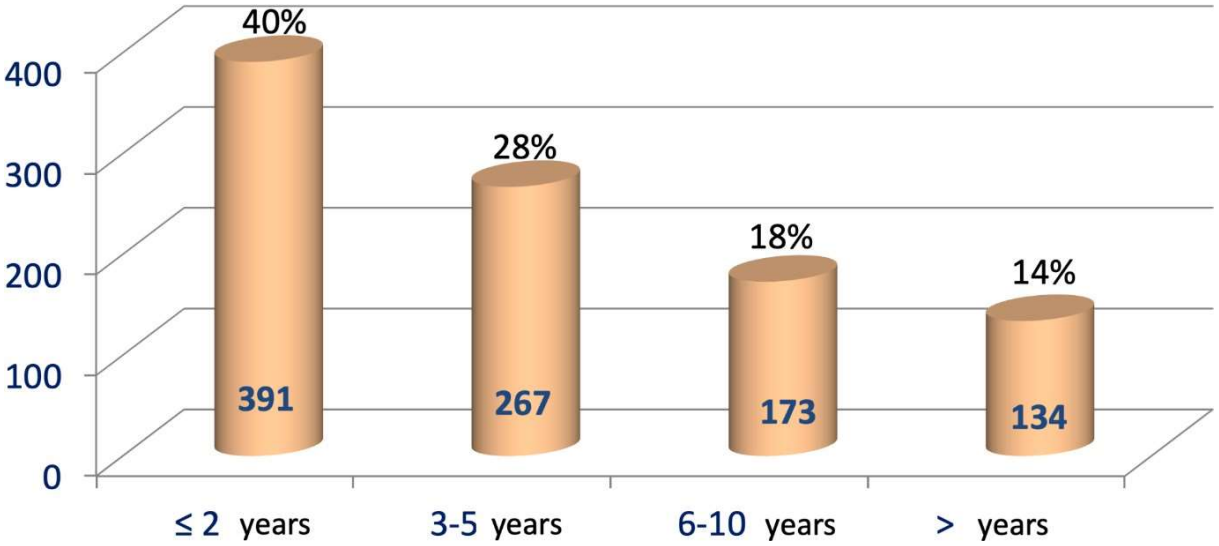

Figure 6 – The distribution of PsA patients starting bDMARDs in 2022 according to disease duration sub-groups.

The dynamics of these patients compared to previous years (2018-2021) were as follows: the number of continuations increased by 8%, the number of initiations increased by 19%, and the number of treatment changes increased by 50%. It is noteworthy that during the period 2020-2021, the number of initiations and switches was lower than in previous years, a phenomenon explained by the COVID-19 pandemic (Figure 7).

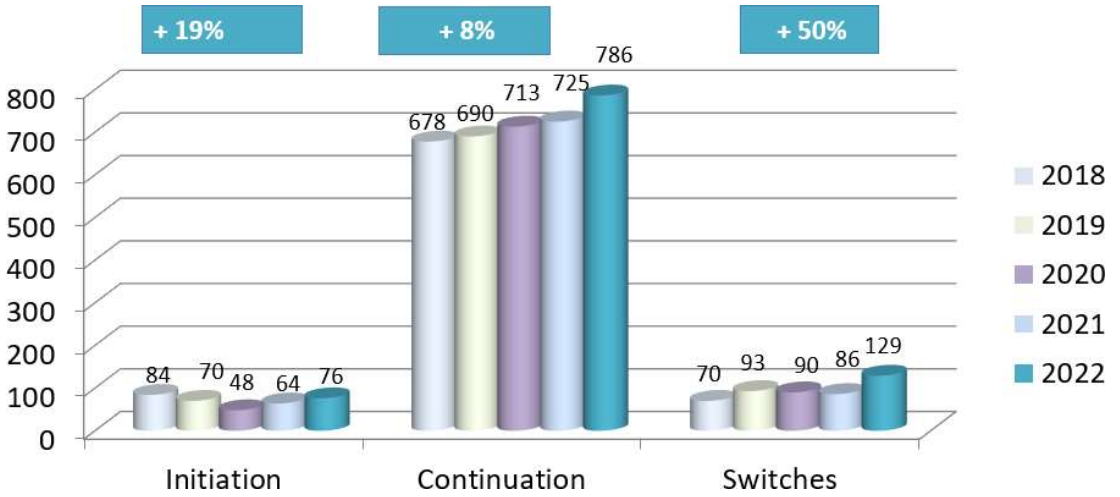

Figure 7 – The number of PsA patients from RRBR in 2022 compared to 2018-2021, regarding treatment decisions.

The distribution of innovative therapies used in 2022 has undergone some modifications compared to the previously presented data illustrating the situation in 2019 (Figure 8) [9]. It is noteworthy that TNF blockers, with etanercept (original + biosimilar) leading the way at 30.5%, continue to be the most commonly used, albeit with a slight declining trend. In the second position is adalimumab (original + biosimilar) at 28%, also exhibiting a descending trend.

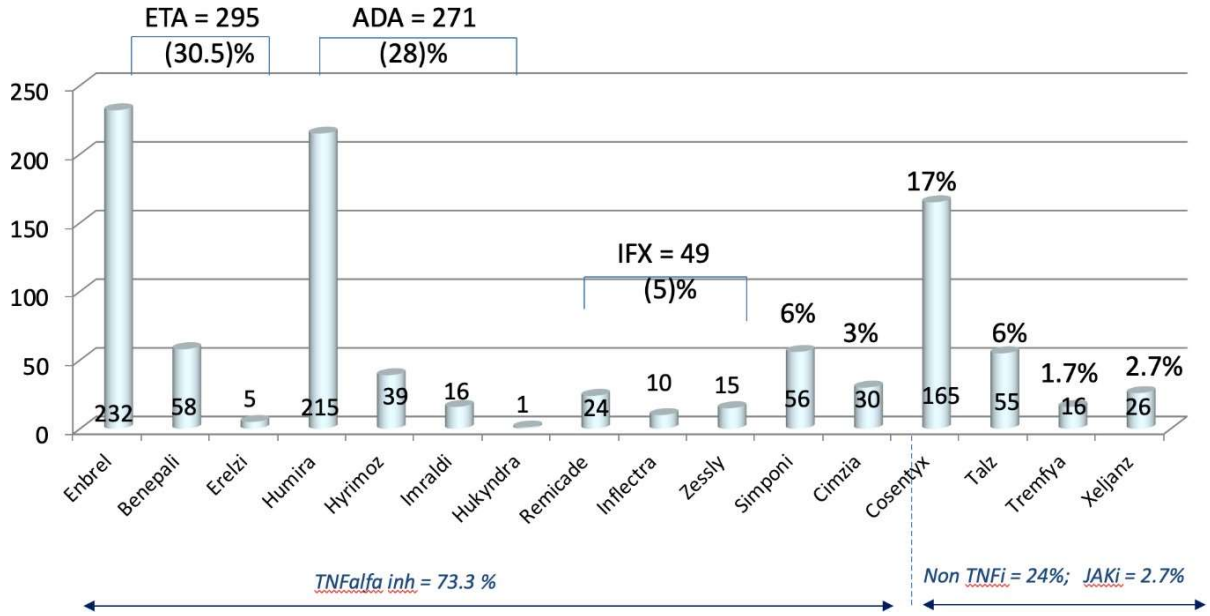

Figure 8 – The frequency of bDMARDs (originators and biosimilars) and tsDMARDs in PsA in 2022.

The implementation of biosimilars, in comparison to the previous year, has increased, accounting for 15% of the total prescriptions and 19% of those for which biosimilars are available on the market. This reflects a growth of 4% compared to the previous year (Figure 9).

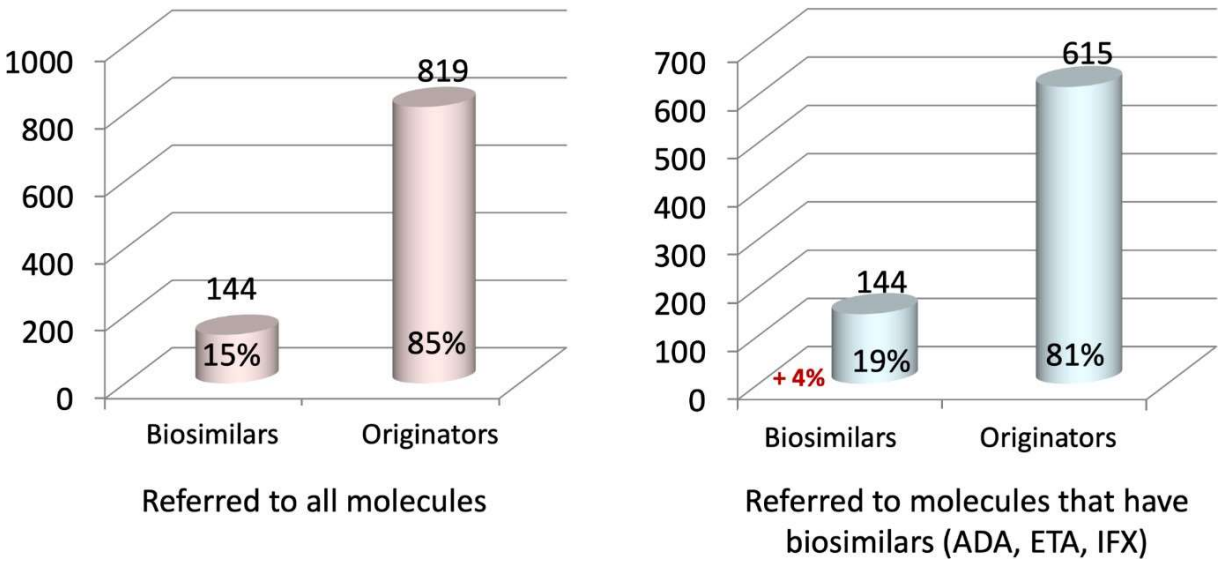

Figure 9 – Biosimilars vs originators.

In 2022, the number of reimbursed therapeutic agents has increased, with ixekizumab, guselkumab, and tofacitinib now available in addition to TNF inhibitors and secukinumab [18]. In 2019, the only biologic agent with a different mechanism of action reimbursed in Romania for PsA was secukinumab, and the percentage of patients treated with it was 11% [9]. It's important to note that only in the second half of 2019 patients who were non-responders to a TNF blocker could be switched to secukinumab, requiring a dose of 300 mg/4 weeks.

The increase of therapeutic options available in PsA is reflected in initiation data. Although TNF inhibitors continue to represent over half of the therapeutic agents used at initiation (51%), there has been an increase in initiations of IL-17 inhibitors (42%), guselkumab (4%), and tofacitinib (4%) (Figure 10).

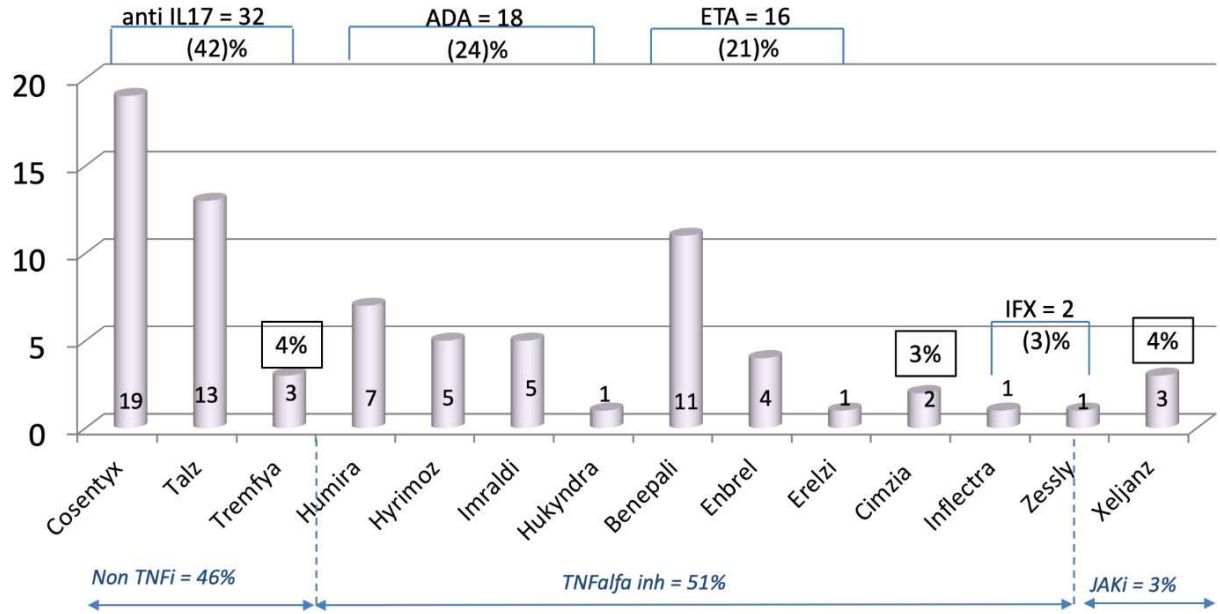

Figure 10 – The frequency of bDMARDs (originators and biosimilars) and tsDMARDs initiations in PsA in 2022.

The majority of patients (786 – 81%) continued their treatment in 2022 and the distribution of therapeutic agents used for these patients is represented in Figure 11. These data indicate a good treatment persistence, with the best results being recorded for etanercept, closely followed by adalimumab and secukinumab.

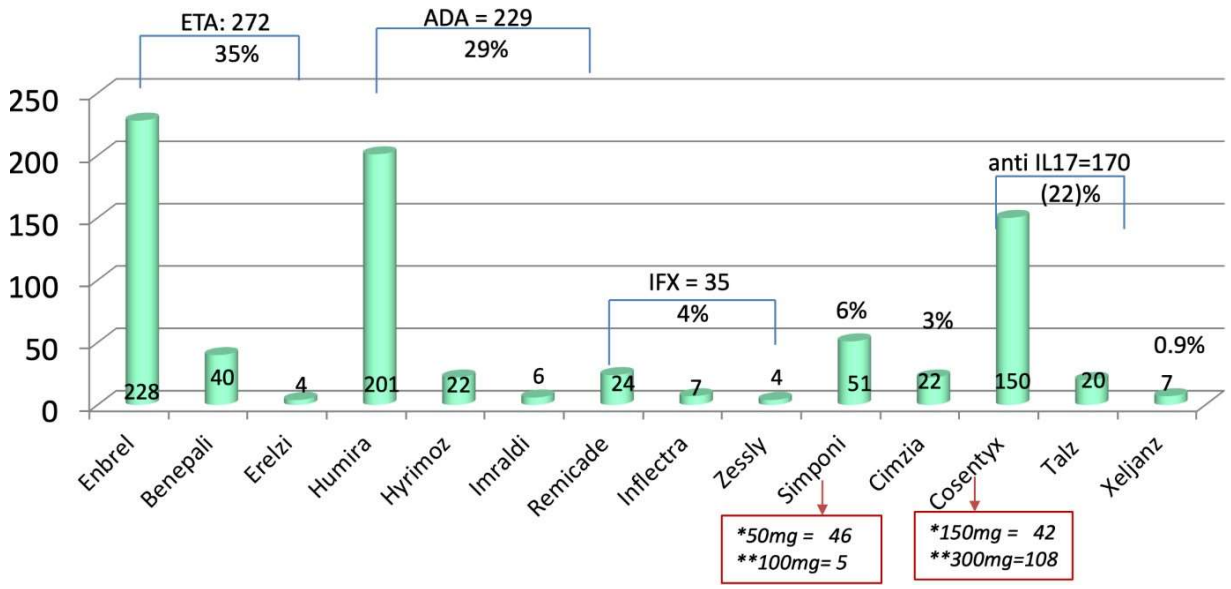

Figure 11 – The frequency of bDMARDs (originators and biosimilars) and tsDMARDs continuations in PsA in 2022.

Switches denote the count of patients who will discontinue a particular drug and initiate treatment with another medication. The overall number of switches in 2022 was 154, with the majority being done due to medical causes (single switches 84%, multiple switches 8.5%). 7.5% of them were attributed to non-medical causes, such as product unavailability in the market (Figure 12).

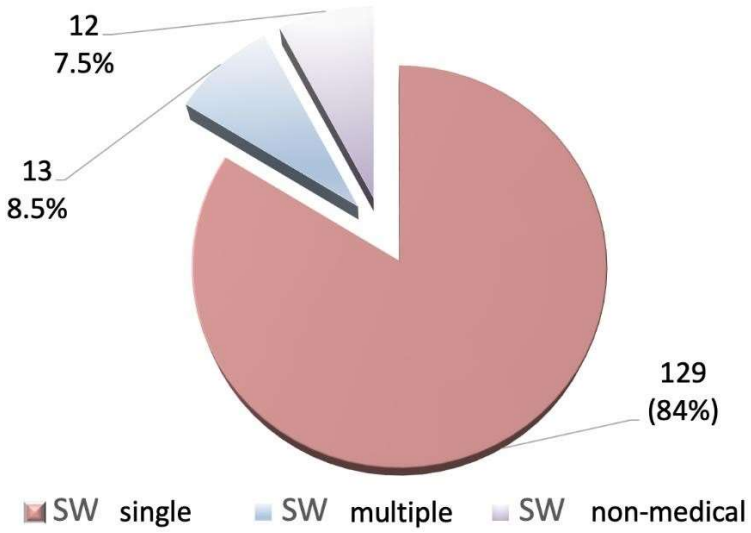

Figure 12 – The dynamic of switches in PsA in 2022.

The reasons for the medical switches were as follows: primary non-response (20%), secondary non-response (51.5%), occurrence of adverse effects (8.5%), and other reasons (20%).

The dynamics of entries and exits from various treatments are represented in Figure 13. From these data, a higher tendency to discontinue treatment is observed for original TNF inhibitors for which biosimilars are available on the market, while some of these biosimilars exhibit a positive trend (the number of entries is greater than exits). Medications more recently included in the reimbursement list (ixekizumab, guselkumab, tofacitinib) also show a positive dynamic.

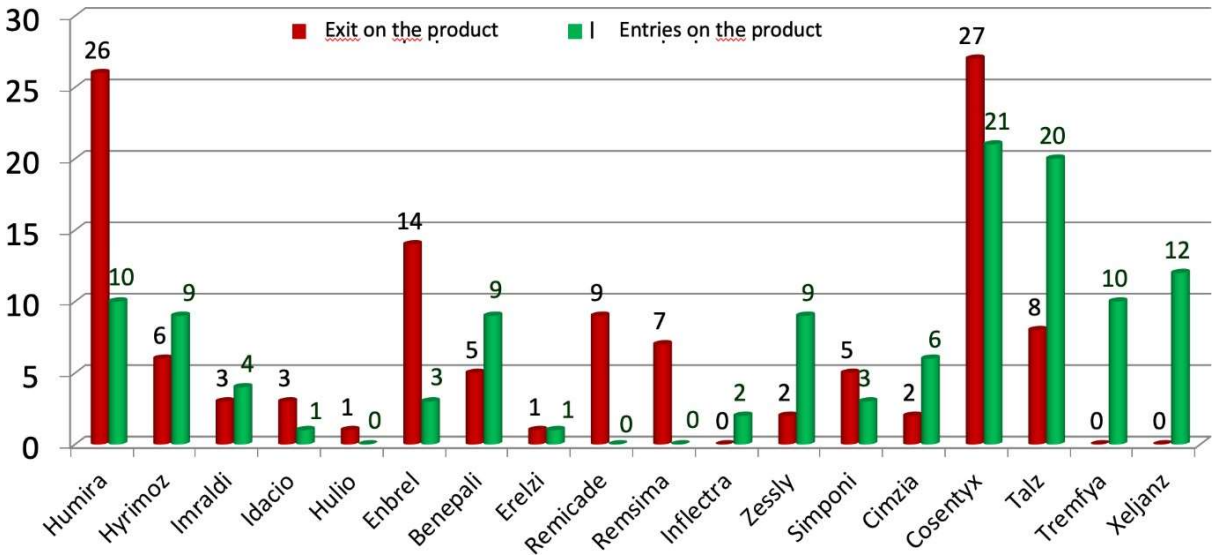

Figure 13 – The dynamics of entries and exits from various treatments.

PsA treatment efficacy in 2022 in the RRBR database

The therapeutic objectives in PsA should include achieving remission or, alternatively, minimal/low disease activity [2,19]. The primary tool for assessing treatment efficacy used in RRBR is the Disease Activity Index for Psoriatic Arthritis (DAPSA), a validated and discriminative instrument [8]. DAPSA serves as a disease-specific and practical tool, particularly beneficial for rheumatologists, although constrained by the absence of skin evaluation. DAPSA is calculated simply by summing swollen + tender joint counts (using a total of 66/68 joints) + patient-reported pain + patient global assessments + C-reactive protein (CRP) [20]. For these reasons, national guidelines for PsA treatment and consequently RRBR utilize this composite index to evaluate treatment efficacy in PsA [8, 21-24].

Efficacy data from RRBR for patients initiating biologic treatment indicate a significant improvement in the average DAPSA value, decreasing from 49.91 to 22.13 after 6 months. (Figure 14).

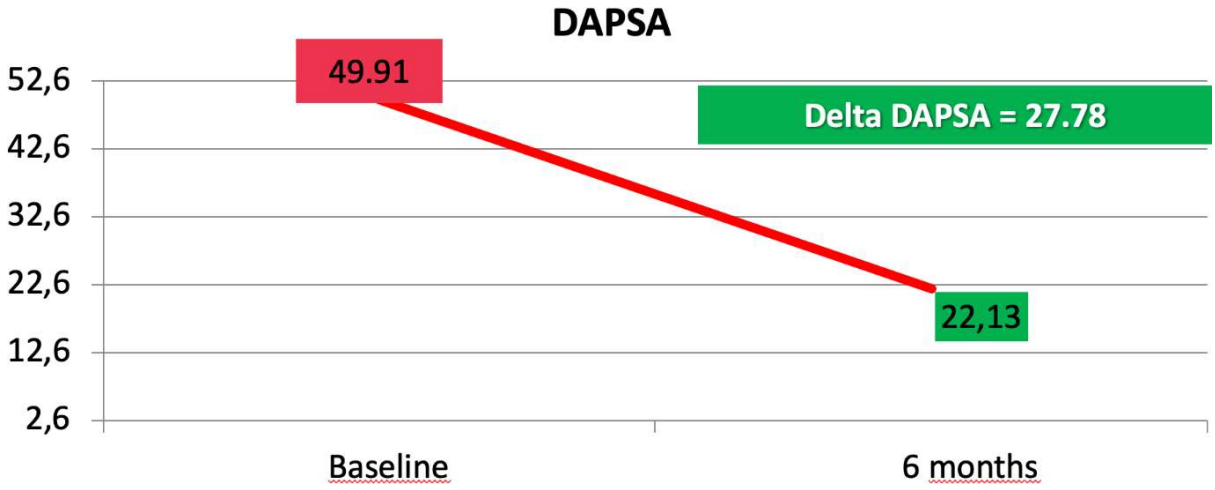

Figure 14 – The variation of mean DAPSA after the first 6 months of treatment with bDMARDs for patients who were initiated in 2022 and had their first 6-month evaluation in 2022.

For patients who underwent a treatment switch, positive outcomes are evident, with a reduction in DAPSA observed from an average of 23.19 to 10.6 after 6 months.

Moreover, the distribution of PsA patients who continued on treatment, assessed by DAPSA, reveals that 38.2% are in remission, while 53.3% exhibit low clinical activity (Figure 15). Merely 7% experience moderate disease activity, and a mere 1.5% present with high disease activity.

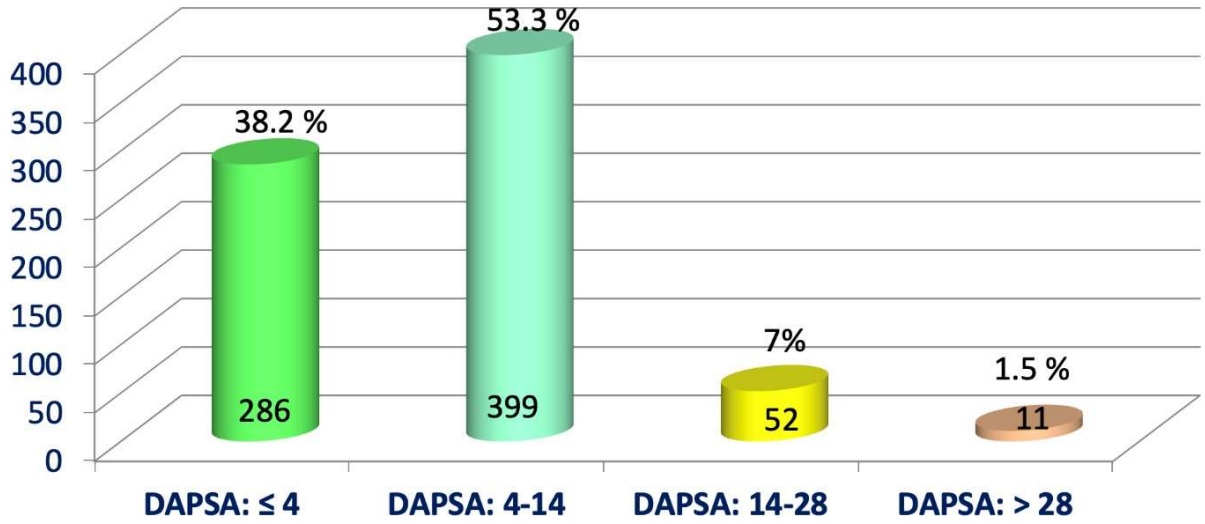

Figure 15 – The distribution of PsA patients according to DAPSA value in 2022 in RRBR.

In accordance with current recommendations, for patients with sustained remission who have provided consent, tapering can be considered, either by dose reduction or by extending the dosing interval [1-2]. The percentage of patients undergoing tapering remained consistent compared to the previous year (7.2%), with these 70 patients being treated with etanercept (41 patients), adalimumab (25 patients), and infliximab (4 patients). This strategy proved effective, as only 5 patients needed to resume the initial treatment regimens.

Discussion

While randomized controlled trials (RCTs) stand as the primary data sources for evaluating the efficacy and safety of treatments, real-life data offer complementary insights with fewer constraints and without rigid inclusion and exclusion criteria. Registries, in this context, serve as invaluable tools encompassing real-life data, providing a more comprehensive view of the population as a whole [22-24]. However, registries come with certain drawbacks, including occasional incomplete data, a lack of control groups, and less stringent information entry. It's essential to acknowledge the distinct purposes of RCTs and registries; the latter primarily aim at evaluating demographics, clinical data, therapeutic strategies, and safety information related to therapies [25].

On an international scale, several registries focusing on PsA have been developed, although their number is comparatively smaller than those dedicated to other medical conditions [4-7, 21-25]. The Romanian Registry of Rheumatic Diseases (RRBR) stands out as a national registry encompassing all patients with immune-mediated rheumatic diseases undergoing treatment with a bDMARS or tsDMARD [8]. An analysis of the 2019 data was published in 2020, and the current analysis serves as an update to the previous one, incorporating data recorded in 2022 [9]. This analysis provides intriguing insights into demographic characteristics, the persistence and switching of bDMARDs/tsDMARDs, treatment strategies, as well as efficacy and safety data pertaining to Romanian PsA patients.

A first observation is the consistency of these data, with relatively minor differences between the results obtained in 2019 and those in 2022. The number of patients whose records were entered into RRBR recorded the highest increase compared to previous years (+7.2% vs 2021). Forty-one percent of PsA patients had comorbidities, with cardiovascular conditions being the most frequent. The majority of patients continue to receive combination therapy (73.5%), with methotrexate (MTX) being the most commonly used (63%), although the percentage is lower than the previous year (73.5% vs 77.5%). The use of systemic glucocorticoids is relatively low (2.3%). The number of treatment initiations was higher compared to 2021 (76 vs 64). The trend to initiate biologic treatment earlier persists, with 40% receiving biologic therapy within the first 2 years. TNF blockers remain the most prescribed biologics (73.3%). Biosimilar penetration is still low (14%), but it has increased compared to 2021 (12%). Non-TNFi biologics account for 46% of initiations (secukinumab 42%). The majority of patients have low disease activity (53.3%) or are in remission (38.2%). Tapering has decreased (7.2%), but it has proven to be a valid option for the majority of cases.

The analysis of demographic data reveals that the PsA patient population within the RRBR aligns closely with comparable registries, exhibiting an average age of around 55 years and a nearly equal distribution between genders [21-24, 26]. This average age slightly exceeds that observed in some RCTs. Furthermore, the prevalence of comorbidities in RRBR mirrors similar patterns found in other national registries, particularly with a notable presence of cardiovascular disease [27]. In contrast, the occurrence of dyslipidemia, diabetes, or malignancies appears to be comparatively lower in RRBR when compared to other databases [24, 27].

Notably, the utilization of systemic corticosteroids among RRBR patients is remarkably low, contrasting with findings in other datasets where up to 33% of patients are reported to be on corticosteroids [21, 24-25].

Consistent with many registries, RRBR observes that the majority of PsA patients are under a combination

therapy involving a csDMARD and a bDMARD, despite ongoing debates about the superior efficacy of this combination approach [28-29].

Up until seven years ago, TNF blockers stood as the sole reimbursed bDMARDs in Romania. The introduction of secukinumab in the Romanian market initially led to reimbursement exclusively for treatment-naive TNF blockers patients. It wasn't until the latter half of 2019 that secukinumab became reimbursed for all PsA patients meeting the criteria outlined in the national protocol [18]. Currently, other bDMARDs such as ixekizumab and guselkumab, along with tsDMARDs - tofacitinib, are reimbursed, and upadacitinib and apremilast are expected to be included in reimbursement in the coming months. Consequently, TNF blockers continue to be the most commonly prescribed bDMARDs for PsA patients in the RRBR. However, there is a discernible trend toward an increased prescription of therapeutic agents with alternative mechanisms of action, particularly during treatment initiation and switches—a trend noted in other studies as well [28, 30].

The efficacy data integrated into RRBR indicate that a substantial percentage of patients achieved the therapeutic targets recommended by the European Alliance of Associations for Rheumatology (EULAR) [2]. This aligns with information gleaned from both RCTs and other registries [29].

It is crucial to acknowledge the limitations of the present study, which primarily stem from the exclusive focus on data from the year 2022. Consequently, the study does not provide insights into treatment persistence and does not aim to analyze safety data.

Conclusions

Information related to baseline demographics, disease characteristics, medical history, medication regimens, therapeutic strategies and the effectiveness of disease control proves to be highly valuable in clinical practice. The results derived from real-world studies play a crucial role in guiding treatment decisions. Given the evolving landscape of treatment patterns in PsA, having data from a specific country or geographic region is essential for informing treatment decisions and pinpointing areas with unmet needs. The RRBR exhibits similarities with previously published registries, establishing its external validity. Some modifications in the protocol are needed, especially concerning the requirement for a highly intense biological inflammatory syndrome for initiating innovative therapies. Conversely, more comprehensive analyses are necessary to enhance our understanding and refine clinical insights further.

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Received: 08.03.2024

Accepted: 25.03.2024