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ORIGINAL RESEARCH

# Psoriatic Arthritis in Males and Females: Differences and Similarities

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## ABSTRACT

***Objective***: To assess any differences and similarities in psoriatic arthritis (PsA) between sexes. Any possible differences of psoriasis and its potential impact on disease burden between sexes with PsA were also evaluated.
***Methods***: Cross-sectional analysis of two longitudinal PsA cohorts. The impact of psoriasis on the PtGA was evaluated. Patients were stratified in four groups based on BSA. The median PtGA was then compared between the four groups. Moreover, a multivariate linear regression analysis was performed in order to evaluate associations between PtGA and skin involvement, split by sexes.
***Results***: We enrolled 141 males and 131 females: PtGA, PtPnV, tender, swollen joint count, DAPSA, HAQ-DI, PsAID-12 were statistically significant higher in females ($p \leq 0.05$). PASS "yes" was deemed more in males than in females and BSA was higher in males. MDA was present more in males than females. When the patients were stratified on BSA, median PtGA was not different between males and females with BSA = 0. Instead, in females with BSA > 0, a higher PtGA was observed compared to males with BSA > 0. There was not a statistically significant association between skin involvement and PtGA at linear regression analysis, even if a trend seems to be present in female.
***Conclusions***: Psoriasis is more present in males, but it seems to be related to a worse impact in females. In particular, a possible role of psoriasis as an influencing factor the PtGA was found. Moreover, female PsA patients tended to have more disease activity, worse function, and higher disease burden.

**Keywords:** Psoriatic arthritis; Psoriasis; Gender medicine; Sex differences; Assessment; Outcome

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**Key Summary Points**

Understanding the different expression of disease in males and females is of fundamental importance in the management of this condition.

Our study shows that BMI and BSA were higher in males, while PtGA, PtPnV, TJC, SJC, DAPSA, HAQ-DI, and PsAID-12 were higher in females.

Prevalence of psoriasis is higher in males but it seems to have a higher impact on PtGA in females, suggesting the importance to take into account sex differences in the management of PsA patients.

## INTRODUCTION

Psoriatic arthritis (PsA) is a chronic inflammatory disease characterized by a variable clinical course [1, 2]. The achievement of the best possible disease control, such as disease remission or low disease activity, has been proposed as a treatment target, and is shown to be an achievable goal for PsA patients [3, 4]. In particular, the Disease Activity Score for Psoriatic Arthritis (DAPSA) [5] and Minimal Disease Activity (MDA) [6] are the two composite indices identified as treatment response criteria to capture the various disease states.

Beyond the real possibility to achieve good disease control in PsA patients, evidence suggests a different burden of disease and response to treatment between sexes in patients with spondyloarthritis [7–9] and PsA [10–12]. Although PsA is considered equal in prevalence between males and females, evidence showed that the burden of the disease is higher in females when compared to males [13, 14]. In particular, psoriasis, as a clinical feature of PsA, seems to be more prevalent in males, but with less impact on disease burden [15, 16]. Previous studies focused on differences between males and females in PsA, in terms of disease activity, functional impairment, and/or response to treatment [10–14]. However, to the best of our knowledge, few studies have investigated the differences in psoriasis and its impact on disease burden between sexes in PsA patients. Therefore, the aim of the present study was to assess any differences and similarities between sexes observed in two groups of PsA patients, as a further contribution to this intriguing topic. Moreover, a secondary aim was to evaluate any differences of psoriasis on disease burden between sexes with PsA.

## METHODS

The study protocol was carried out in compliance with the declaration of Helsinki; written consent was obtained from each participant. The study was approved by the Institutional Review Board of the University of Molise (protocol n. 0001-017-2021).

### Patient Selection

In this cross-sectional analysis of two longitudinal cohorts, patients were enrolled at the Rheumatology Unit, Department of Medicine and Health Science-University of Molise, and at the Rheumatology Unit of University of Rome Tor Vergata. From February 1, 2022 until July 31, 2022, all PsA patients consecutively attending the rheumatology units were considered potentially eligible for the study.

Inclusion criteria were:

(1) PsA classified with the ClASsification criteria for Psoriatic ARthritis (CASPAR) criteria [17],
2) Age $\geq$ 18 years,
3) Stable treatment with a conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs) or biological DMARDs (bDMARDs) for at least 6 months.

### Data Collection

Patients' data collection included a detailed medical history, physical examination, current use of medications, and laboratory assessment. Demographics and disease characteristics, including age, sex, body mass index (BMI) and disease duration, were recorded. The clinical assessment encompassed the number of tender (TJC) and swollen joints (SJC) (68/66), enthesitis by the Leeds Enthesitis Index (LEI) [18], and dactylitis. Psoriasis was quantified by the body surface area (BSA) [19]. The psoriasis onset age was also recorded, dividing patients in early onset psoriasis (EOP) (onset $< 40$ years) and late onset psoriasis (LOP) ($\geq 40$ years) [20].

The patient-reported outcomes (PROs) collected were: Health Assessment Questionnaire-Disability Index (HAQ-DI) [21], Patient Global Assessment (PtGA) [22], patient's pain (PtPnV) assessed on numerical rating scale (NRS: 0–10 cm) and the Psoriatic Arthritis Impact of Disease 12-item (PsAID-12) [23]. PtGA was collected on NRS and comprises the global evaluation of psoriatic disease, with high values indicating worse status.

The Physician Global Assessment of disease activity (PGA), [22] and C reactive protein (CRP) were also collected.

We also collected the Patient Acceptable Symptom State (PASS) [24]. The global question assessing PASS was formulated as the following: 'Think about all the ways your PsA has affected you during the last 48 h. If you were to remain in the next few months as you were during the last 48 h, would this be acceptable to you?' The yes/no response was collected.

Finally, the DAPSA [5] and the MDA [6] were calculated as disease activity index and treatment target, respectively, and the presence of fibromyalgia (as a comorbidity) was also recorded. For the purpose of this study, no gender differences (referred to the characteristics of women, men, girls and boys that are socially constructed) were considered.

The study protocol was carried out in compliance with the Declaration of Helsinki; written consent was obtained from each participant. The study was approved by the Institutional Review Board of the University of Molise (protocol n. 0001-017-2021).

### Statistical Analysis

Statistical analysis was performed using SPSS (version 27). All demographical and clinical characteristics were summarized by using descriptive statistics. Normally distributed variables were summarized by mean ± standard deviation (SD) and non-normally distributed variables by median and inter-quartile range (IQR).

Patients were divided into two groups according to sex. To compare these two groups, independent-sample $t$ test, Mann–Whitney $U$ test and $\chi$-square test were performed, according with the data distribution. Moreover, to assess any changes of PtGA based on sex and BSA, patients were stratified in four groups as follow: females with BSA = 0, females with BSA > 0, males with BSA = 0, males with BSA > 0. The median PtGA was then compared within the four groups by using Kruskal–Wallis test.

Furthermore, each MDA domain (as categorical variable) was compared between males and females by using $\chi$-square test. Finally, multivariate logistic regression analysis was performed in order to evaluate any association between the HAQ-DI and disease duration, also evaluating potential confounders, split by sexes. Goodness-of-fit was estimated using the adjusted $R^2$. Odds ratio (OR) and confidence interval (CI) 95% were calculated when appropriate. Fibromyalgia was used as a control factor in the regression model n.2, only for female patients, due to its lower prevalence in male patients. A statistical significance level was defined as a two-tailed $p$ value accepted at $p \leq 0.05$.

## RESULTS

### Descriptive Results

During the study period, 272 PsA (male 141, female 131) patients satisfying the inclusion criteria were enrolled.

There were not statistically significant differences, in terms of clinical and demographic features, between patients from the two centers (data not shown).

Table 1 shows the main clinical characteristics of the total enrolled patients divided by sex. Generally, in terms of differences, BMI and BSA were higher in males, while PtGA, PtPnV, TJC, SJC, DAPSA, HAQ-DI, and PsAID-12 were higher in females. The latter had a higher prevalence of fibromyalgia (F 19.2 vs. M 2.2%, $p < 0.001$). Moreover, MDA and an acceptable symptom state (PASS yes) were less likely present in females than males.

In terms of similarities, age, disease duration, psoriasis onset age (EOP and LOP), PsA patterns, dactylitis, LEI, CRP, PGA, and the current therapy were not different between the two sexes. However, even if there were no statistically significant differences, a higher percentage of females were on csDMARDs and tumor necrosis factor inhibitors (TNFi), while a higher number of male patients were on anti-IL-12/23 treatment.

### *Disease Activity, Function, and Impact of the Disease*

Mean DAPSA was statistically significant higher in females. However, DAPSA is good for assessing peripheral arthritis, not other manifestations of PsA, and may not capture all the elements influencing disease reporting. Of note, when analyzing each DAPSA component, TJC, SJC, PtGA, and PtPnV were higher in females, despite CRP values were not different between the two groups, as previously mentioned.

Females, compared with males, reported higher mean pain [5 ($\pm$ 2.78) vs. 4 ($\pm$ 2.60), $p = 0.003$] and worst mean PtGA: [5.01 ($\pm$ 2.51) vs. 3.99 $\pm$ 2.45, $p < 0.001$].

These data are also in keeping with worst function assessed by HAQ-DI, worst impact of the disease assessed by PsAID-12, and less presence of PASS yes ([69.5% in males and 47% in females, respectively, $\chi^2$ (1, $n = 245$) = 11.88, $p < 0.001$].

Finally, MDA, considered in the total population was present in 83/239 (34.7%), but when calculated by dividing the two sexes, this percentage was significantly different: 44% in males vs. 24.6% in females, [$\chi^2$ (1, $n = 239$) = 9.10, $p = 0.003$]. Moreover, going deeper into MDA domains, females, compared with males, less likely had PtPnV $\leq$ 1.5, HAQ-DI $\leq$ 0.5 and TJC $\leq$ 1; on the other hand, males less likely had a BSA $\leq$ 3 when compared with females (Table 2, Fig. 1).

### *Relationship Between Skin and Disease Burden*

Mean (SD) BSA was higher in males: 2.16 ($\pm$ 3.74) vs. 1.22 ($\pm$ 2.26), $p = 0.015$. A possible role of psoriasis, measured as BSA, on the burden of the disease was analyzed in the two sexes. We found that PtGA was different in males and females with regard to BSA; in fact, when comparing median PtGA between males and females with BSA > 0, a statistically significant difference was found ($p = 0.038$), with females showing higher values of PtGA; therefore, when psoriasis was present, a sex difference in PtGA was observed. On the other hand, when comparing PtGA in females with BSA = 0 to males with BSA = 0, there was a trend to be worse in females, even if it was not statistically significant (median PtGA (IQR): 4 (3–6) and 3 (2–5), respectively). In the same way, when comparing PtGA in females with BSA = 0 to female with BSA > 0, there was a trend to be worse in females with BSA > 0, even if it was not statistically significant (median PtGA (IQR): 4 (3–6) and 6 (4–8), respectively). Moreover, males with BSA > 0 or BSA = 0 were also better than females with BSA > 0, and it was statistically significant in both cases (Fig. 2).

These results could have been influenced by the sample size; however, these trends could be of some importance to distinguish the role of skin involvement in PtGA between males and females.

Finally, to evaluate any association between BSA and PtGA, independently by others confounding factors, we performed two multiple linear regression analysis, for males and females, respectively.

In male patients, the association between BSA > 0 and PtGA was not statistically significant ($p = 0.169$), when adjusted for other confounding factors (Table 3, model 1) (adjuster $R^2$:0.21).

**Table 1** Demographic and clinical features of all enrolled PsA patients, divided by sex

| | **Total population** ***N*** **= 272** | **Male** ***n*** **= 141 (51.8%)** | **Female** ***n*** **= 131 (48.2%)** | ***p*** **value** |
|---|---|---|---|---|
| Age (mean, SD) | 55.68 (12.43) | 56.62 (12.89) | 54.66 (11.89) | 0.200 |
| Weight (kg), mean (SD) | 76.26 (15.32) | 83.19 (14.54) | 68.74 (12.36) | < 0.001 |
| Height (m), mean (SD) | 1.67 (0.09) | 1.73 (0.09) | 1.62 (0.06) | < 0.001 |
| BMI, median (IQR) | 26.89 (23.5–29.7) | 27.66 (24.3–30.0) | 25.55 (22.2–29.3) | 0.004 |
| Disease duration (months), median (IQR) | 89 (45–163) | 94 (44–165) | 84 (48–156) | 0.728 |
| BSA, mean, (SD) | 1.71 (3.15) | 2.16 (3.74) | 1.22 (2.26) | 0.015 |
| EOP, *n* (%) | 141/215 (65.6) | 70/108 (64.8) | 71/107 (66.3) | 0.812 |
| LOP, *n* (%) | 74/215 (34.4) | 38/108 (35.2) | 36/107 (33.7) | |
| PtGA (0–10), mean (SD) | 4.5 (2.53) | 3.99 (2.45) | 5.01 (2.51) | < 0.001 |
| PtPnV (0–10), mean (SD) | 4.49 (2.73) | 4.00 (2.60) | 5.00 (2.78) | 0.003 |
| PGA (0–10), mean (SD) | 3.40 (2.47) | 3.19 (2.42) | 3.62 (2.52) | 0.552 |
| TJC/68, mean, (SD) | 3.7 (5.03) | 2.70 (3.52) | 4.78 (6.09) | < 0.001 |
| SJC/66, mean (SD) | 0.97 (2.07) | 0.71 (1.36) | 1.25 (2.6) | 0.033 |
| LEI, mean (SD) | 0.43 (0.81) | 0.38 (0.73) | 0.47 (0.89) | 0.393 |
| CRP (mg/dl), mean (SD) | 0.52 (0.76) | 0.53 (0.84) | 0.50 (0.67) | 0.687 |
| MDA 5/7 *n* (%) | 83/239 (34.7) | 55/125 (44.0) | 28/114 (24.6) | 0.003 |
| DAPSA, mean (SD) | 14.05 (10.41) | 11.95 (8.49) | 16.31 (11.77) | < 0.001 |
| HAQ-DI, median (IQR) | 0.625 (0.250–1.250) | 0.5 (0.125–1) | 1 (0.5–1.5) | 0.009 |
| PASS YES, *n* (%) | 144/245 (58.8) | 89/128 (69.5) | 55/117 (47.0) | < 0.001 |
| PsAID, mean (SD) | 2.67 (2.23) | 2.39 (2.12) | 2.98 (2.32) | 0.030 |
| Fibromyalgia, *n* (%) | 27/260 (10.4) | 3/135 (2.2) | 24/125 (19.2) | < 0.001 |
| THERAPY (actual) | | | | |
| NSAIDs, *n* (%) | 39/268 (14.6) | 20/138 (14.5) | 19/130 (14.6) | 1 |
| COXIB, *n* (%) | 32/267 (12) | 14/137 (10.2) | 18/130 (13.8) | 0.469 |
| Steroids (oral), *n* (%) | 30/268 (11.2) | 16/138 (11.6) | 14/130 (10.8) | 0.984 |
| MTX, *n*. (%) | 72/268 (26.9) | 33/138 (23.9) | 39/130 (30) | 0.324 |
| csDMARDS_others, *n* (%) | 31/262 (11.8) | 13/134 (9.7) | 18/128 (14.1) | 0.368 |
| TNFi, *n* (%) | 122/268 (45.5) | 58/138 (42) | 64/130 (49.2) | 0.289 |
| PDE4i, *n* (%) | 22/269 (8.2) | 9/138 (6.5) | 13/131 (9.9) | 0.284 |
| Anti-IL-17 | 53/272 (19.5) | 29/141(20.6) | 24/131(18.3) | 0.753 |

**Table 1** continued

| | Total population*N* = 272 | Male*n* = 141 (51.8%) | Female*n* = 131 (48.2%) | *p* value |
|---|---|---|---|---|
| Anti-IL 12/23 | 18/268 (6.7) | 13/138 (9.4) | 5/130 (3.8) | 0.115 |

*BMI* body mass index, *BSA* body surface area, *PtGA* patient global assessment, *EOP* early onset psoriasis, *LOP* late onset psoriasis, *PGA* physician global assessment, *PtPnV* patient pain, *TJC* tender joint count, *SJC* swollen joint count, *LEI* Leeds enthesitis index, *CRP* C reactive protein, *MDA* minimal disease activity, *DAPSA* disease activity for psoriatic arthritis, *HAQ-DI* Health Assessment Questionnaire-Disability Index, *PASS* Patient Acceptable Symptoms State, *PsAID* Psoriatic Arthritis Impact of the Disease, *NSAIDs* non-steroid anti-inflammatory drugs; *COX2i* cyclooxygenase 2 inhibitors; *MTX* methotrexate; *csDMARDs* conventional synthetic anti rheumatic drugs, *TNFi* tumor necrosis factors inhibitors, *PDE4i* phosphodiesterase 4 inhibitors, *IL* interleukin

**Table 2** MDA domains stratified by sex

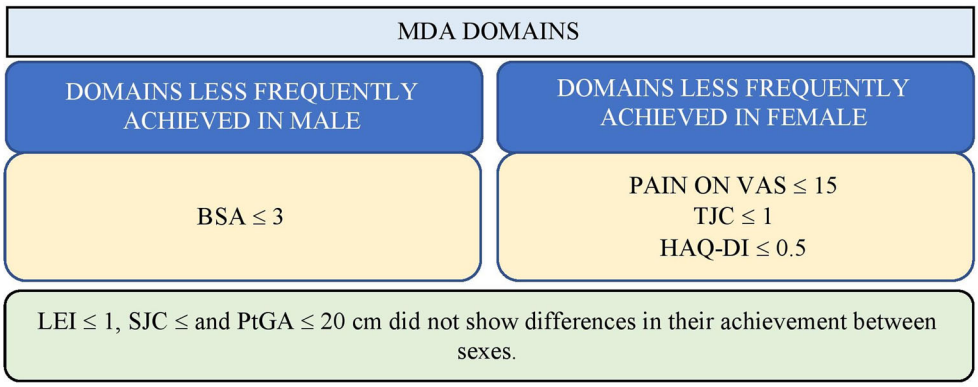
| MDA DOMAINS | Males | Females | *P* value |
|---|---|---|---|
| Patient pain $\leq$ 15 mm | 44/138 (31.9) | 22/128 (17.2) | 0.006 |
| PtGA $\leq$ 20 mm | 33/138 (23.9) | 22/128 (17.2) | 0.176 |
| HAQ-DI $\leq$ 0.5 | 70/131 (53.4) | 46/122 (37.7) | 0.012 |
| TJC $\leq$ 1 | 72/138 (52.2) | 43/128 (33.6) | 0.002 |
| SJC $\leq$ 1 | 114/138 (82.6) | 95/128 (74.2) | 0.096 |
| BSA $\leq$ 3 | 104/136 (76.5) | 115/125 (92.0) | 0.001 |
| LEI $\leq$ 1 | 119/133 (89.5) | 103/121 (85.1) | 0.297 |

*MDA* minimal disease activity, *PtGA* patient global assessment, *TJC* tender joint count, *SJC* swollen joint count, *BSA* body surface area, *LEI* Leeds enthesitis index

In female patients, the association between BSA > 0 and PtGA was not statistically significant, even if with a trend of significance ($p = 0.074$) was found (Table 3, model 2). Therefore, it could mean that when psoriasis is present in females, the mean value of PtGA tends to increase by 0.75, independently of articular involvement (TJC and SJC) and fibromyalgia (adjuster $R^2$:0.25).

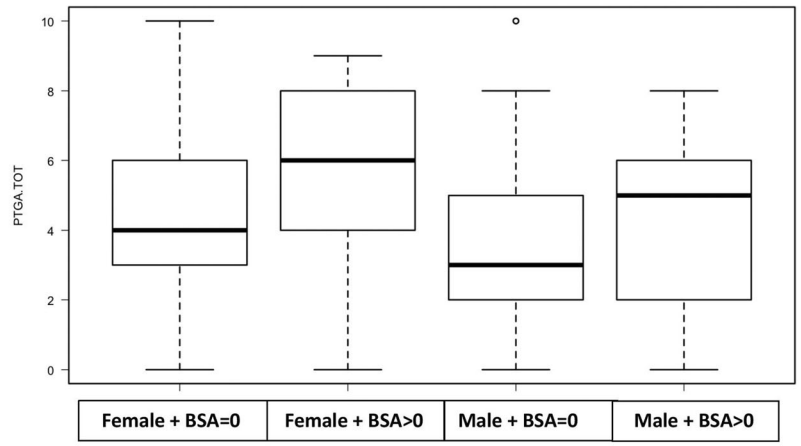
## DISCUSSION

The present study was aimed at evaluating the possible differences and similarities between males and females with PsA. The results of this study, based on two groups, showed that PsA might be similar in some characteristics while on some other aspects, such as disease burden, is different between male and female sexes. Among the various clinical manifestations of this multifaceted syndrome [2], we found that there is an unequal distribution of some clinical features such as dactylitis, enthesitis, and psoriasis onset age. On the other side, we found that TJC, SJC, disease activity level, and even the absence of achievement of MDA differed between the two sexes, being more prevalent in females [25]. These results are in keeping with previous data, reinforcing that the management of PsA between the two sexes is still un unmet need [26]. Consequently, a potential difference of the skin involvement between sexes could be one of the factors driving different choices in the management, even if psoriasis could be one of the "less problematic" features in rheumatological settings because it is generally not a major issue when compared to patients attending dermatological clinics and, possibly, perceived as not important as the musculoskeletal complaints [27]. Having said that, the presence of psoriasis may persist even in PsA patients achieving a condition of MDA, as previously




MDA: Minimal Disease Activity; PtGA: Patient Global Assessment; TJC: Tender Joint Count; SJC: Swollen Joint Count; BSA: Body Surface Area; LEI: Leeds Enthesitis Index.

**Fig. 1** Sex differences in the achievement of MDA domains




| PtGA | Female + BSA=0 | Female + BSA>0 | Male + BSA=0 |
|---|---|---|---|
| **Female + BSA>0** | 0.070 | - | - |
| **Male + BSA=0** | 0.083 | **<0.001** | - |
| **Male + BSA>0** | 1.000 | **0.038** | 0.124 |

**Fig. 2** Comparison of PtGA based on sex and BSA. Patients were stratified in four groups based on sex and BSA category. Females with BSA = 0; females with BSA > 0; males with BSA = 0; males with BSA > 0. PtGA was compared among these groups using Kruskal–Wallis test. The table shows the *p* values for each comparison

shown [28]. Therefore, the impact of psoriasis might be one of the choices for a change in the treatment strategy.

The present article showed a worse psoriasis in males when compared to females in two PsA settings. This result has been previously reported [11], confirming that psoriasis could be more frequent in males. However, when evaluating the role of psoriasis in terms of disease burden, we found that psoriasis was a factor potentially influencing the PtGA, reinforcing that PtGA is able to capture differences between males and females when the skin involvement is present. In other words, the burden of

**Table 3** Model 1: linear regression analysis, in male patients

| **Male sex** | | |
|---|---|---|
| | **Dependent factors** | |
| | **PtGA** | |
| | **Coefficient regression (CI 95%)** | ***p* value** |
| Independent factor | | |
| BSA > 0 vs. BSA = 0 | 0.54 (− 0.23 to 1.33) | 0.169 |
| Age | − 0.01 (− 0.03 to 0.02) | 0.701 |
| BMI | − 0.01 (− 0.08 to 0.06) | 0.785 |
| TJC/68 | 0.29 (0.17–0.42) | < 0.001 |
| SJC/66 | 0.06 (− 0.25 to 0.39) | 0.673 |
| **Model 2: linear regression analysis, in female patients** | | |
| **Female sex** | | |
| | **Dependent factors** | |
| | **PtGA** | |
| | **Coefficient regression (CI 95%)** | ***p* value** |
| Independent factor | | |
| BSA > 0 vs. BSA = 0 | 0.75 (0.08–1.58) | 0.074 |
| Age | 0.02 (− 0.01 to 0.06) | 0.143 |
| BMI | 0.03 (− 0.05 to 0.12) | 0.426 |
| TJC/68 | 0.12 (0.04–0.21) | 0.004 |
| SJC/66 | 0.15 (− 0.03 to 0.34) | 0.103 |
| Fibromyalgia | 0.32 (− 0.75 to 1.41) | 0.552 |

*PtGA* patient global assessment, *BSA* body surface area, *BMI* body mass index, *TJC* tender joints count, *SJC* swollen joints count, *CI* confidence interval

psoriasis might have an impact on the global assessment, being higher in females and confirming other previous data. In fact, PtGA was already found as a reliable measure of patient's global assessment [29]. Of note, a clear trend was present in PtGA in male patients in respect to females, but this could be confirmed in a large sample of PsA patients. The present results might contribute to better understanding any clinical sex differences in PsA and, potentially, providing some practical insights in the global management of this multifaceted condition [2]. Moreover, as another factor showing any differences in disease burden between the two sexes, we found that the achievement of a condition of acceptable symptom state was more frequent in male PsA patients. Finally, all these differences—clinical, functional, disease activity and disease burden—may help the physicians on different treatment strategy toward a personalized approach, as also recently shown [3, 30]. This is in keeping with other previous results [31], paving the way to a

potential different treatment strategy sex driven.

PsA, per se, is not a sex-related disease but these results could support the concept that the burden of the disease is different when compared between the two sexes. However, as a potential weakness of the study, we evaluated only the extension of the skin disease more than severity one. In fact, BSA was the only assessment of psoriasis we performed, without evaluating other specific tools to assess the impact or the severity of psoriasis as usually dermatologist do.

Moreover, biological sex can influence PsA by affecting sex hormones, gene expression, immune function, pain mechanisms, and pharmacokinetics of medications, with treatment outcomes that may be influenced by behavior, adherence to medications, patient–physician interactions, pain reporting, social support, coping mechanisms, and access to care. This aspect is shared with other diseases such as rheumatoid arthritis and osteoarthritis [32, 33].

## CONCLUSION

In conclusion, the present study showed that there are some differences and similarities between males and females with PsA. Psoriasis is more present in males but, in terms of disease burden, has a worse impact in females. Female PsA patients tended to have more disease activity, worse function, and higher disease burden.

A future research agenda on these differences between the two sexes should be addressed, including this topic on larger population studies.

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

***Authorship Contributions.*** All authors have made substantial contributions to all of these sections: conception and design of the study, acquisition of data, analysis and interpretation of data, drafting the article, revising it critically for important intellectual content and final approval of the version to be submitted.

***Disclosures.*** Ennio Lubrano, Silvia Scriffignano, Mauro Fatica, Paola Triggianese, Paola Conigliaro, Fabio Massimo Perrotta and Maria Sole Chimenti have nothing to disclose.

***Compliance with Ethics Guidelines.*** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study. The study was approved by the Institutional Review Board of the University of Molise.

***Data Availability.*** The datasets generated during and/or analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

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