**Running head**: Sex Differences in PsA

# Women with Psoriatic Arthritis Experience Higher Disease Burden than Men: Findings from a Real-World Survey in the USA and Europe

Laure Gossec, Jessica A. Walsh, Kaleb Michaud, Steve Peterson, Elizabeth A. Holdsworth, Chetan S. Karyekar, Nicola Booth, Soumya D. Chakravarty, Alexis Ogdie

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L. Gossec, MD, PhD[1,2], J.A. Walsh, MD[3], K. Michaud, PhD[4,5], S. Peterson[6], E.A. Holdsworth, MSc[7], C.S. Karyekar, MS, PhD[8], N. Booth, MChem[7], S.D. Chakravarty, MD, PhD[9,10], A. Ogdie, MD, MSCE[11]

[1]Sorbonne Université, INSERM, Institut Pierre Louis d'Epidémiologie et de Santé Publique, Paris, France; [2]Pitié-Salpêtrière Hospital, AP-HP. Sorbonne Université, Rheumatology

department, Paris, France; [3]University of Utah Health and Salt Lake City Veterans Affairs Medical Center, Salt Lake City, UT, USA; [4]University of Nebraska Medical Center, Omaha, NE, USA; [5]Forward Databank, Wichita, KA, USA; [6]Janssen Global Services, LLC, Horsham, PA, USA; [7]Adelphi Real World, Bollington, UK; [8]Janssen Research & Development, Spring House, PA, USA; [9]Janssen Scientific Affairs, LLC, USA; [10]Drexel University College of Medicine, Philadelphia, PA, USA; [11]Perelman School of Medicine, Penn Medicine, Philadelphia, PA, USA.

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Address for correspondence:

Pr. Laure Gossec
Orcid ID: 0000-0002-4528-310X
Hôpital Pitié-Salpétrière, Service de Rhumatologie, 47-83, boulevard de l'Hôpital - 75013 Paris, France
laure.gossec@aphp.fr

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# Abstract

## Objective

Although psoriatic arthritis (PsA) is equally present in men and women, sex may influence clinical manifestations and the impact of disease on patients' lives. This study assessed differences in clinical characteristics, disability, quality of life (QoL) and work productivity by sex in real-world practice.

## Methods

A cross-sectional survey of rheumatologists/dermatologists and their PsA patients, conducted in France, Germany, Italy, Spain, the UK and the USA between Jun-Aug 2018. Data collected included demographic, treatment use and clinical characteristics (Tender Joint Count, TJC; Swollen Joint Count, SJC; Body Surface Area, BSA, affected by psoriasis) and QoL (EuroQoL 5-Dimension questionnaire, EQ-5D; Psoriatic Arthritis Impact of Disease, PsAID12), disability (Health Assessment Questionnaire Disability Index, HAQ-DI) and work

productivity (Work Productivity and Impairment Index, WPAI). Outcomes were compared between men and women using parametric and non-parametric tests, as appropriate.

## Results

Of 2,270 patients (mean ±standard deviation (SD) age: 48.6 ±13.3 years, disease duration: 4.9 ±6.0 years), 1,047 (46.1%) were women. Disease duration, disease presentation and biologic use (mean 54.2%) were comparable between women and men. Women reported worse QoL (EQ-5D: 0.80 ±0.18 vs 0.82 ±0.17, p=0.02), greater disability (HAQ-DI: 0.56 ±0.60 vs 0.41 ±0.52, p <0.01) and work activity impairment (WPAI: 27.9% ±22.0 vs 24.6% ±22.4, p <0.01) than men. However, women had a lower burden of comorbidities (Charlson: 1.10 ±0.51 vs 1.15 ±0.58, p <0.01).

## Conclusion

In patients with similar PsA disease activity and treatment, women experienced greater disease impact than men. This represents a significant consideration for the therapeutic management of PsA.

# Introduction

Psoriatic arthritis (PsA) is a chronic inflammatory musculoskeletal disease associated with psoriasis and known to affect men and women in similar proportions (1). The presentation of PsA is heterogeneous, and includes peripheral arthritis with joint pain and stiffness, skin and nail psoriasis, spinal involvement, enthesitis, dactylitis and fatigue. PsA often leads to substantial alterations in health-related quality of life (QoL), including through its social and professional consequences (2), (3).

Sex may play an underlying role in driving the mechanisms of PsA, leading to different clinical manifestations of the disease (1). For example, men are more affected by the axial disease, whilst women suffer more from peripheral polyarticular disease (4) (5). Women with PsA may also experience greater disability and impact on their QoL than men (1). However, there is limited research available on these differences in a real-world setting. Therefore, the aim of this study was to assess key sex differences in terms of clinical characteristics, disability, QoL and work productivity in patients with PsA in real-world clinical practice.

# Methods

## Study Design and Ethical Considerations

Data were drawn from the Adelphi PsA Disease Specific Programme™ (DSP), a point-in-time survey of rheumatologists, dermatologists and their consulting patients with PsA conducted

in France, Germany, Italy, Spain, the United Kingdom (UK) and the United States of America (USA) between June and August 2018. DSPs are large, multinational, point-in-time surveys designed to investigate current disease management and patient- and physician-reported disease impact in real-world clinical practice; this study methodology has been published and validated (6). The survey collected data using a non-interventional market research approach; no identifiable protected health information was collected. Patients and physicians gave informed consent to participate in the survey, and patients provided written informed consent for the publication of analysed, aggregated data. The study was conducted in accordance with the relevant legislation at the time of data collection, including the US Health Insurance Portability and Accountability Act 1996, and Health Information Technology for Economic and Clinical Health Act legislation. The DSP complied with all relevant market research guidelines and legal obligations according to the European Pharmaceutical Marketing Research Association guidelines. This research obtained ethics approval from the Western Institutional Review Board (study number 1183030) in the US, and Freiberg Ethics Committee in Europe (study number 02018/1077).

## Patients and Methods

Data were collected via physician-completed patient record forms and patient self-reported questionnaires, with the main patient inclusion criterion being a physician-confirmed diagnosis of PsA. Physicians were instructed to complete a patient record form for the next 3 to 6 consecutive patients with active PsA who visited for diagnosis or routine care. These physician-completed patient record forms included patient demographics, clinical characteristics including prevalence of enthesitis, dactylitis, inflammatory back pain and

sacroiliitis, as well as medication use and treatment history. The 68 Tender Joint Count [TJC] and 66 Swollen Joint Count [SJC] scores were calculated. Body Surface Area [BSA] affected by psoriasis and a Charlson Comorbidity Index score were also determined.

These same patients were then invited to voluntarily complete a self-reported questionnaire, which collected a range of patient-reported outcome measures (PROs). These included the EuroQoL 5-Dimension questionnaire (EQ-5D), which is an instrument for measuring generic health status, with a maximum score of 1 indicating the best health state, as well as the EQ-5D visual analogue scale (VAS), which ranges from 0 to 100, with 100 indicating the best health status (7). The Health Assessment Questionnaire Disability Index (HAQ-DI) was included as an assessment of disability; scores range from 0 to 3, with 3 representing the most severe disability. Furthermore, PROs encompassed the Psoriatic Arthritis Impact of Disease (PsAID12), which assesses 12 different numerical rating scales, giving an overall score in the range 0-10, where a higher figure indicates worse status (8), and the Work Productivity and Impairment Index questionnaire (WPAI), which ranges 0-100%, where a greater percentage represents greater work impairment and reduced productivity.

## Data analysis

Bivariate analysis comparing outcomes between women and men were conducted using parametric tests (Student's T-test) and non-parametric tests (Wilcoxon Rank Sum, Fisher's exact test, Chi-square) as appropriate. In order to determine the effect of sex on PROs, a series of ordinary least squares linear regression models were employed. In separate models, each PRO (outcome) was compared among men vs women (exposure) and adjusted

for intragroup correlation across physicians, and age, body mass index (BMI), time since diagnosis, employment (except the WPAI model) and advanced therapy use (targeted synthetic disease-modifying antirheumatic drugs, DMARDs, and biologic DMARDs). The coefficients and associated p-values outputted in the regressions indicated the effect of sex on each PRO and the significance of this within the model, with the coefficient interpreted as the difference in men compared to women (i.e., negative score meaning score lower in men than women). Statistical significance in all cases was set to $p < 0.05$. Analyses were conducted in Stata Statistical Software version 15 (StataCorp LP, College Station, TX).

# Results

## Patient demographics and clinical characteristics

In total, data were collected for 2,270 patients (USA, n= 595; Spain, n= 369; Italy, n= 360; Germany, n= 360; UK, n= 309; France; n= 277), recruited by 382 rheumatologists and 190 dermatologists.

Of these patients, 1,223 were men (53.9%) and 1,047 women (46.1%). Overall patient demographics and clinical characteristics were comparable between men and women (Table 1). The mean age was 48.6 years and 90.4% of patients were white/Caucasian. The mean BMI was 26.8 kg/m$^2$, with 24.2% of patients classified as obese (BMI >29). The mean PsA duration time was 4.9 years, with a mean time from first symptoms to diagnosis of 1.3 years.

There were no significant sex differences in the reported frequencies of PsA manifestations such as BSA psoriasis involvement, enthesitis, dactylitis, inflammatory back pain and sacroiliitis. No differences were observed between men and women regarding TJC. Men had a higher mean SJC than women (4.5 vs 4.1, respectively, p= 0.03) (Table 1 and Figure 1), but more male patients experienced ≤1 swollen joint. A higher proportion of men than women were in full-time employment (68.6% vs 49.4%, respectively, p <0.01).

## Patient-reported outcome measures

A number of differences in PROs were observed (Table 2). Women reported worse QoL as defined by their EQ-5D score (0.80 vs 0.82, respectively, p= 0.02). Women also reported a greater level of disability and impaired physical functioning as defined by HAQ-DI (0.56 vs 0.41, respectively, p <0.01), as also demonstrated by the differences in the proportion of women and men classified with mild (78.7% vs 87.0%, respectively) and moderate (20.1% vs 12%, respectively) disease according to the HAQ-DI (p <0.01).

The impact of disease, as defined by PsAID12 score, was also greater in women than men (2.66 vs 2.27, respectively, p <0.01); both fatigue and pain were greater in women than men (p <0.01). Differences were observed in the proportion of women and men classified with acceptable PsAID12 score (0-4; 77.6% vs 84.0%, respectively). Women also reported a greater degree of overall activity impairment than men, as measured by the WPAI questionnaire (27.9% vs 24.6%, respectively, p <0.01). However, no differences were observed for work time missed in respondents who reported that they were in paid employment (Table 2).

When controlled for age, BMI, time since diagnosis, employment (excluding WPAI model) and targeted advanced treatment use, regression models indicated that men had significantly better HAQ-DI scores (coefficient -0.153, p <0.01) and experienced significantly less overall activity impairment than women (coefficient -3.078, p= 0.05). There were no statistical differences in EQ-5D, physical functioning as defined by PsAID12 and work time missed.

## Discussion

In this point-in-time survey of physicians and their patients with PsA, despite women and men presenting with similar levels of disease activity and receiving comparable levels of biologic treatments, women reported reduced QoL, a greater level of disability and higher work impairment than men, while experiencing a lower number of comorbidities. Other factors not assessed in the study are likely to be contributing to disease burden, and these unmeasured factors may impact men and women differently.

QoL in patients with PsA is affected both by the physical and the psychological impact of the disease (2). Previous studies have shown that, while the extent of physician's assessment of disease activity is similar between sexes, women had worse functional performance, lower complement levels, more frequent erosive disease, higher SJC and HAQ-DI scores, as well as more aggressive peripheral disease was reported for women than men (5). Men are more affected by axial disease, whilst women suffer more from peripheral polyarticular disease (4, 5). Our study demonstrated the finding that the mean SJC in male patients with PsA was

greater than that observed in their female counterparts, with the distribution of joint count scores favouring the extreme categories in male patients (≤1 or >10 joints); a finding which warrant further investigation in future research.

In another study of patients with PsA, disease activity, physical disability, functional limitation, depression and anxiety scores were all higher in female patients, while QoL was better and psoriasis area and severity index score were higher in male patients (9). This was further quantified in studies assessing the differences in work disability between sexes, where female patients experienced increased work disability (10, 11).

There are also differences in treatment outcomes between male and female patients with PsA. In this study, biologic use is similar between male and female patients, however, other literature suggests biologic use is more frequent in women than men (11). In a large observational cohort study which assessed outcomes of new tumour necrosis factor inhibitor (TNFi) treatments, women had worse patient-reported scores, and higher frequencies of hospital-diagnosed anxiety or depression and chronic pulmonary disease than men, with male sex associated with greater treatment effectiveness and higher odds of achieving response after 3 and 6 months from treatment initiation (12). Female patients more frequently reported side effects with TNFi and discontinued treatments earlier. Women were less frequently at treatment target than men, and had a greater life impact, including pain and fatigue (13). In another study, female patients showed a statistically lower response to TNFi in rheumatoid arthritis, spondylarthritis and PsA (14). It is evident, therefore, that there is unmet need in the female PsA patient population for effective

treatments to improve disease burden, and that life impact needs to be taken into consideration alongside physician-assessed disease activity measures when planning treat to target approaches.

Biological factors, including the effect of sex hormones, gene expression, or differences in patient-reported perceptions of pain are thought to play a role in these sex differences (1). For example, the HLA-B27 antigen has been identified as a genetic risk factor for PsA (5), however this may be more relevant in male patients. Additionally, there may be differences in the way patients self-reported the impact of their disease. A cross-sectional study indicated that sex did not make a difference in composite psoriatic disease activity index (CPDAI) scores in patients with PsA; however, subjective disease scores were higher in female patients (15). Further research into the pathophysiologic difference between male and female patients could help to define the differing impact of disease male and female patients experience.

This study had some limitations. The survey design resulted in a geographically diverse sample of the PsA population; however, those presenting to their physician more frequently may have been overrepresented in this sample. The completion of patient self-reported questionnaires was voluntary; therefore, PROs were based solely on patients who agreed to participate. Recall bias is a common limitation of surveys; however, data in the study were collected at the time of the patient visit and thus recall bias was limited. Also, test scores were only collected if the physicians carried out the test at the visit; they were not required to do so. Hence, base sizes fluctuated across different variables. Another limitation is that

we did not collect data fibromyalgia using a validated score, but rather from a list of comorbidities. The prevalence observed in the present study for fibromyalgia (2.1%) is much lower than what has been reported in other studies (16, 17). The effect of fibromyalgia, and the difference between male and female patients has not been examined in this study, along with other impacting factors such as sleep disturbance, anxiety, joint erosion which could be examined in more detail in future studies.

In conclusion, despite women and men having similar levels of physician-assessed disease activity and receiving similar treatment regimens, women reported a reduced QoL and greater levels of disability and work impairment than men, while experiencing a lower comorbidity burden. Further research is needed to explore the additional burden experienced by women with PsA, and whether alternative treatment regimens would alleviate some of these differences.

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## Author contributions:

All authors were involved in 1) conception or design, or analysis and interpretation of data; 2) drafting and revising the article; 3) providing intellectual content of critical importance to the work described; and 4) final approval of the version to be published, and therefore meet the criteria for authorship in accordance with the International Committee of Medical Journal Editors (ICMJE) guidelines. In addition, all named authors take responsibility for the integrity of the work as a whole and have given their approval for this version to be published.

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# Figure Legends

Figure 1. Joint score distributions

Table 1: Patient demographics and clinical characteristics

| | Women* | | Men* | | p-value |
|---|---|---|---|---|---|
| | n | | n | | |
| n (%) | 1,047 | (46.1) | 1,223 | (53.9) | - |
| Age, years, mean (SD) | | 48.3 (13.7) | | 48.8 (12.8) | 0.42 |
| Employment, n (%) | 417 | | 510 | | |
| Working full-time† | | 206 (49.4) | | 350 (68.6) | <0.01 |
| Working part-time | | 36 (8.6) | | 26 (5.1) | |
| On long-term sick leave | | 6 (1.4) | | 18 (3.5) | |
| Homemaker | | 78 (18.7) | | 8 (1.6) | |
| Student | | 12 (2.9) | | 12 (2.4) | |
| Unemployed | | 24 (5.8) | | 24 (4.7) | |
| Retired | | 55 (13.2) | | 72 (14.1) | |
| | **n** | **Outcome** | **n** | **Outcome** | **p-value** |
| Charlson Comorbidity Index score, mean (SD) | 1,047 | 1.10 (0.51) | 1,223 | 1.15 (0.58) | <0.01 |
| Time from first symptoms to diagnosis, years, mean (SD) | 634 | 1.48 (3.53) | 707 | 1.14 (2.48) | 0.76 |
| PsA duration, years, mean (SD) | 832 | 4.87 (6.15) | 972 | 4.95 (5.79) | 0.42 |
| Currently receiving biologic treatment, n (%) | 1,047 | 557 (53.2) | 1,223 | 674 (55.1) | 0.38 |
| BSA psoriasis involvement, mean % (SD) | 819 | 5.5 (8.4) | 973 | 5.5 (8.1) | 0.87 |
| TJC, mean (SD) | 243 | 3.2 (7.0) | 276 | 3.5 (6.9) | 0.39 |
| SJC, mean (SD) | 243 | 4.1 (5.2) | 256 | 4.5 (8.0) | 0.03 |
| Enthesitis, n (%) | 1,047 | 59 (5.6) | 1,223 | 72 (5.9) | 0.86 |
| Dactylitis, n (%) | 1,047 | 79 (7.5) | 1,223 | 75 (6.1) | 0.21 |
| IBP, n (%) | 1,047 | 101 (9.6) | 1,223 | 127 (10.4) | 0.58 |
| Sacroiliitis, n (%) | 1,047 | 34 (3.2) | 1,223 | 49 (4.0) | 0.37 |

SD, standard deviation; PsA, psoriatic arthritis; BSA, body surface area; TJC, 68 tender joint count; SJC, 66 swollen joint count; IBP, inflammatory back pain.
*Percentages calculated on available data.
†In paid employment outside home.

Table 2: Quality of life, disability and work productivity compared between men and women with PsA

| | Women | | Men | | p-value |
|---|---|---|---|---|---|
| | n | Outcome | n | Outcome | |
| EQ-5D utility score, mean (SD) | 435 | 0.80 (0.18) | 508 | 0.82 (0.17) | 0.02 |
| Pain domain, n (%), no pain | 440 | 120 (27.3) | 515 | 158 (30.7) | 0.12 |
| EQ-5D utility score, n (%) | | | | | |
| Low (<0.65) | | 64 (14.7) | | 59 (11.6) | 0.02 |
| Medium (0.65-0.85) | | 203 (46.7) | | 216 (42.5) | |
| High (>0.85) | | 168 (38.6) | | 233 (45.9) | |
| HAQ-DI score, mean (SD) | 422 | 0.56 (0.60) | 493 | 0.41 (0.52) | <0.01 |
| HAQ-DI score, n (%) | | | | | |
| Mild (0-1) | | 332 (78.7) | | 429 (87.0) | <0.01 |
| Moderate (1-2) | | 85 (20.1) | | 59 (12.0) | |
| Severe (>2-3) | | 5 (1.2) | | 5 (1.0) | |
| PsAID12 score, mean (SD) | 419 | 2.66 (2.07) | 500 | 2.27 (1.98) | <0.01 |
| Pain NRS | | 2.97 (2.29) | | 2.53 (2.20) | <0.01 |
| Fatigue NRS | | 3.17 (2.53) | | 2.58 (2.40) | <0.01 |
| PsAID12 score, n (%) | | | | | |
| Acceptable (0-4) | | 325 (77.6) | | 420 (84.0) | 0.01 |
| Not acceptable (>4) | | 94 (22.4) | | 80 (16.0) | |
| WPAI percentage of activity impairment, mean (SD) | 423 | 27.9 (22.0) | 511 | 24.6 (22.4) | <0.01 |
| WPAI percentage of work time missed, mean (SD) | 210 | 4.0 (14.0) | 302 | 5.8 (19.2) | 0.62 |

PsA, psoriatic arthritis; EQ-5D, EuroQoL 5-Dimension questionnaire; SD, standard deviation; HAQ-DI, Health Assessment Questionnaire Disability Index; PsAID12, Psoriatic Arthritis Impact of Disease; NRS, numerical rating scale; WPAI, Work Productivity and Activity Impairment questionnaire.

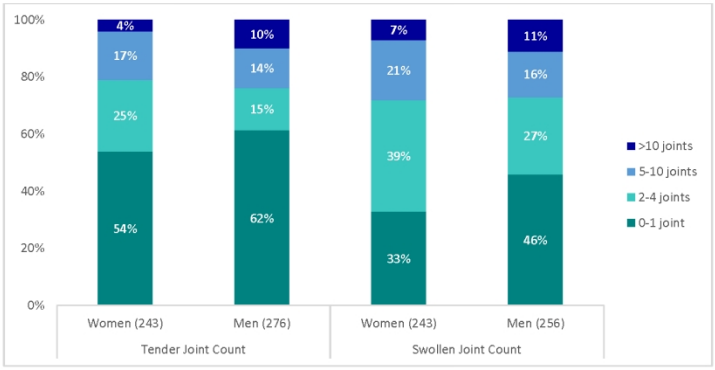


Figure 1

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