

CONCISE REPORT

Health-related quality of life in patients with psoriatic and rheumatoid arthritis: data from the prospective multicenter NOR-DMARD study compared with Norwegian general population controls

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ABSTRACT

Objectives

To compare 1) Short Form-36 (SF-36) Physical (PCS) and Mental (MCS) Component Summaries, scale scores and Short Form-6 dimensions (SF-6D) between rheumatoid (RA) and psoriatic arthritis (PsA) patients and Norwegian general population controls and 2) improvements in these measures between RA and PsA patients.

Methods

ANCOVA analyses were performed to compare SF-36 measures between first-time enrolled RA (n=3898) and PsA (n=1515) patients from the prospective observational multicenter NOR-DMARD study (6 months follow-up) and general population controls (n=2323).

Results

In age and gender-adjusted analyses PsA compared to RA patients had similar PCS, MCS and SF-6D ($p \geq 0.14$), worse vitality and general health, but better physical functioning at 0/6 months ($p \leq 0.03$). With additional DAS28-adjustment as a proxy for joint inflammation, PCS, most scale scores and SF-6D were worse in PsA than RA patients at 0/3/6 months ($p \leq 0.01$). PCS was more impaired than MCS both in RA and PsA compared with general population controls ($p \leq 0.001$). Mean 3- and 6-month improvements after DMARD treatment were larger in RA than PsA patients for bodily pain, vitality and mental health ($p \leq 0.02$).

Conclusions

HRQoL was overall similar in RA and PsA patients- with a tendency to worse scores in PsA- and worse compared with Norwegian general population controls.

INTRODUCTION

Health-Related Quality of Life (HRQoL) is part of the core set of data to be collected in patients with psoriatic arthritis (PsA) and recognized to be of major importance also in other rheumatic diseases, including rheumatoid arthritis (RA).^{1, 2} HRQoL has been found to be impaired in patients with inflammatory arthritides compared with the general population.³⁻⁶ In smaller observational studies performed 1-2 decades ago similar HRQoL in RA and PsA patients were described,^{7, 8} but also differences in Short Form-36 (SF-36) scale scores.⁵ To our knowledge no large, prospective observational study has compared HRQoL between RA and PsA patients and the general population using the widely recognized SF-36. The aim of this study was to compare SF-36 Physical and Mental Component Summaries (PCS, MCS), scale scores as well as short form-6 dimensions utility score (SF-6D) between RA and PsA patients from a large prospective observational study, as well as with general population controls. Furthermore, we aimed to compare improvements in PCS, MCS and scale scores between RA and PsA patients from baseline to 3 and 6 months follow-up after initiation of treatment with disease-modifying anti-rheumatic drugs (DMARDs).

METHODS

Patients

We included first-time enrolled RA and PsA patients from the prospective longitudinal observational multicentre NORwegian-Disease Modifying Anti-Rheumatic Drug (NOR-DMARD) study,^{9, 10} starting synthetic and/or biologic DMARDs between 1 December 2000 and 6 November 2012 and followed until 1 May 2013 or until stopping DMARD medication. The RA and PsA diagnoses were given by the treating rheumatologist after clinical judgement. Analyses included baseline, 3- and 6-month follow-up. Written informed consent was obtained from each patient. The study was approved by the National Data Inspectorate and by the Regional Committee for Medical and Health Research Ethics in Eastern Norway. For comparison, we included SF-36 Norwegian normative data from 2323 individuals collected in 1996.¹¹

Short Form-36 and short form-6 dimensions

The Norwegian translation of SF-36 version 1, used in this study, is validated in Norwegian RA patients.¹² PCS and MCS were calculated as described by Ware et al.¹³ Norm-based scale scores were computed by subtracting the general population's respective mean scale score from the 0-100 scale scores, divided by the standard deviation of the data from the general population. Each of these values were multiplied by 10 and 50 was added, as described by Ware et al.¹⁴ SF-6D was calculated from SF-36 according to the algorithm developed by Brazier et al.¹⁵

Statistics

Demographic and baseline characteristics are shown as medians (25th, 75th percentiles) for non-normally and means (SD) for normally distributed data. Continuous variables were

compared using independent t-test, Mann-Whitney U-test or ANOVA, as appropriate. Prespecified age and gender-adjusted ANCOVA analyses were performed to compare PCS, MCS, scale scores and SF-6D between RA, PsA patients and general population controls at baseline, and between RA and PsA patients with and without additional adjustment for the respective 28-joint disease activity scores (DAS28) at baseline and after 3- and 6-month follow-up. Prespecified ANCOVA analyses were performed to compare changes in PCS, MCS, scale scores and SF-6D from baseline to 3 and 6 months follow-up, adjusted for age, gender and the respective baseline values. Radar diagrams were made to visualize differences in scale scores (0 worst, 100 best) between RA/PsA patients and the Norwegian general population. Statistical tests were performed using SPSS V.23.0 for Windows. The analyses were performed as completer analyses and without adjustment for multiple comparisons.

RESULTS

RA patients (n=3898), PsA patients (n=1515) and general population controls (n=2323) had mean (SD) age 55.9 (31.6)/ 48.1 (12.6)/ 44.9 (16.5) years and 71.4/ 50.3/ 51.3% were females, respectively. Baseline mean (SD) DAS28 was worse in RA (4.9 (1.4)) than PsA (4.2 (1.3)) patients (online supplementary Table S1).

Analyses adjusted for age and gender

SF-36 PCS, MCS, scale scores and SF-6D were worse in RA and PsA patients compared with the general population (Table 1), but improved during follow-up (online supplementary Table S2).

Table 1 Unadjusted analyses and analyses adjusted for age and gender of baseline SF-36 component summaries, norm-based scale scores and SF-6D utility scores

| Baseline | | | | | | | | |
|--------------------------------|--------------------------------|-------------------------|-------------------------|---|---|---------------------|---------------------|---|
| Component summary/ scale score | Unadjusted analyses, mean (SD) | | | p-value | Adjusted analyses, estimated marginal means (95%CI) | | | p-value |
| | General population | RA | PsA | | General population | RA | PsA | |
| PCS | 50.0 (10.1) (n=2012) | 29.7 (9.9) (n=3898) | 30.5 (9.5) (n=1515) | <0.001 ^{1,2} 0.02 ³ | 49.7 (49.2-50.1) | 30.5 (30.2-30.8) | 30.4 (29.9-30.9) | <0.001 ^{1,2} 0.69 ³ |
| MCS | 50.0 (10.2) (n=2012) | 46.8 (11.3) (n=3898) | 47.1 (11.4) (n=1515) | <0.001 ^{1,2} 0.59 ³ | 50.0 (49.5-50.5) | 47.1 (46.8-47.5) | 47.1 (46.5-47.6) | <0.001 ^{1,2} 0.90 ³ |
| SF-6D | 0.80 (0.14) (n=2071) | 0.60 (0.12) (n=3787) | 0.61 (0.12) (n=1491) | <0.001 ^{1,2} 0.17 ³ | 0.80 (0.80-0.81) | 0.61 (0.60-0.61) | 0.60 (0.60-0.61) | <0.001 ^{1,2} 0.45 ³ |
| Physical Functioning | 49.4 (10.8) (n=2235) | 27.7 (14.5) (n=3898) | 30.5 (13.5) (n=1515) | <0.001 ^{1,2,3} | 48.9 (48.3-49.4) | 29.0 (28.5-29.4) | 30.2 (29.6-30.9) | <0.001 ^{1,2} 0.001 ³ |
| Role Physical | 49.6 (10.3) (n=2207) | 32.9 (9.1) (n=3898) | 34.0 (9.9) (n=1515) | <0.001 ^{1,2} 0.001 ³ | 49.4 (49.0-49.8) | 33.5 (33.2-33.8) | 33.9 (33.4-34.4) | <0.001 ^{1,2} 0.16 ³ |

| | | | | | | | | |
|---------------------------|-------------------------|-------------------------|-------------------------|---|---------------------|---------------------|---------------------|--|
| Bodily Pain | 49.6 (10.3) (n=2287) | 33.5 (7.5) (n=3898) | 33.6 (7.2) (n=1515) | <0.001 ^{1,2} 0.96 ³ | 49.4 (49.1-49.8) | 34.0 (33.7-34.2) | 33.5 (33.1-33.9) | <0.001 ^{1,2} 0.07 ³ |
| General Health | 49.6 (10.3) (n=2183) | 37.5 (9.5) (n=3898) | 36.8 (9.7) (n=1515) | <0.001 ^{1,2} 0.02 ³ | 49.5 (49.0-49.9) | 37.9 (37.6-38.3) | 36.7 (36.2-37.2) | <0.001 ^{1,2,3} |
| Vitality | 49.8 (10.3) (n=2270) | 39.6 (10.1) (n=3898) | 39.3 (10.3) (n=1515) | <0.001 ^{1,2} 0.69 ³ | 49.9 (49.5-50.3) | 40.4 (40.1-40.8) | 39.4 (38.9-39.9) | <0.001 ^{1,2,3} |
| Social Functioning | 49.5 (10.5) (n=2311) | 39.1 (12.6) (n=3898) | 39.5 (12.3) (n=1515) | <0.001 ^{1,2} 0.59 ³ | 49.4 (48.9-49.9) | 39.8 (39.4-40.2) | 39.5 (38.9-40.1) | <0.001 ^{1,2} 0.40 ³ |
| Role Emotional | 49.8 (10.2) (n=2182) | 40.2 (13.6) (n=3898) | 41.6 (13.6) (n=1515) | <0.001 ^{1,2} 0.002 ³ | 49.5 (49.0-50.0) | 40.6 (40.2-41.1) | 41.5 (40.8-42.1) | <0.001 ^{1,2} 0.03 ³ |
| Mental Health | 49.8 (10.3) (n=2255) | 44.3 (11.5) (n=3898) | 44.7 (11.1) (n=1515) | <0.001 ^{1,2} 0.63 ³ | 49.8 (49.4-50.3) | 44.8 (44.5-45.2) | 44.7 (44.2-45.3) | <0.001 ^{1,2} 0.76 ³ |

¹General population compared to RA patients; ²General population compared to PsA patients; ³RA patients compared to PsA patients. CI, confidence interval; MCS, mental component Summary; PCS, physical component summary; PsA, psoriatic arthritis; RA, rheumatoid arthritis; SF-6D, short form-6 dimensions utility score

PCS and MCS were not statistically different in RA compared to PsA patients, while physical functioning was better and general health and vitality worse in PsA patients at all time-points. Bodily pain was similar between RA and PsA patients at baseline, but slightly worse in PsA patients at 3 and 6 months (Table 1, online supplementary Table S2).

Analyses adjusted for age, gender and DAS28

In analyses adjusted for DAS28 in addition to age and gender, PsA patients had significantly worse PCS and SF-6D at all time-points compared to RA patients. Baseline MCS and all scale scores, except role emotional, were worse in PsA compared to RA patients. At 3 and 6 months bodily pain, general health, vitality, social functioning and mental health were worse and the remaining scale scores similar in PsA compared to RA patients (online supplementary Table S3).

Longitudinal analyses adjusted for age, gender and baseline values of the respective scores

RA and PsA patients had similar improvements in PCS, MCS, all scale scores and SF-6D at 3 and 6 months, except for larger improvements in bodily pain, vitality and mental health in the RA patients (Table 2, adjusted analyses and supplementary Table S4, unadjusted analyses).

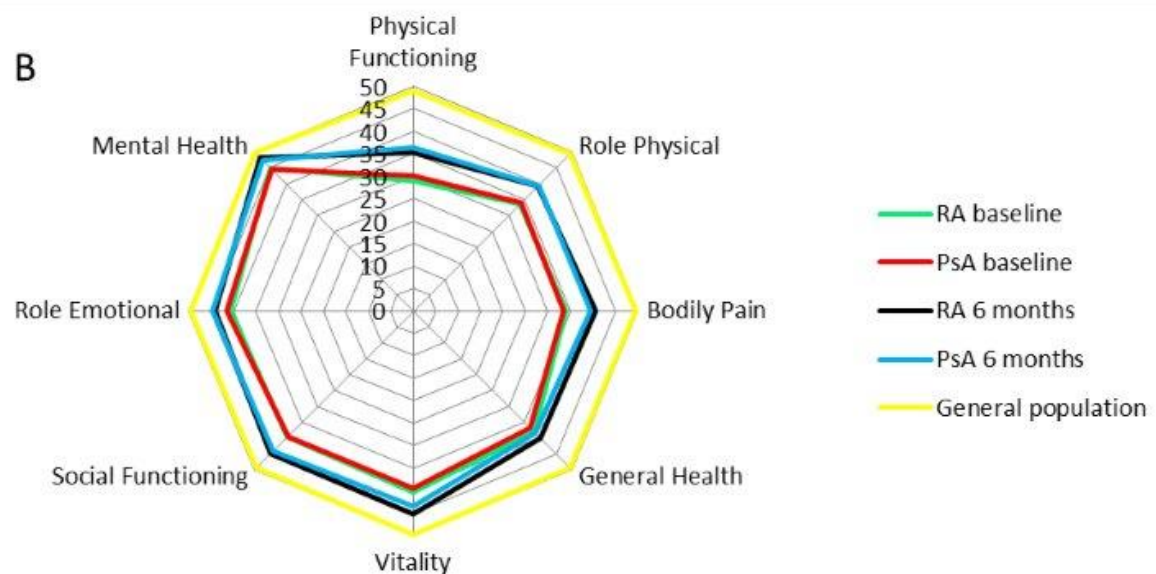
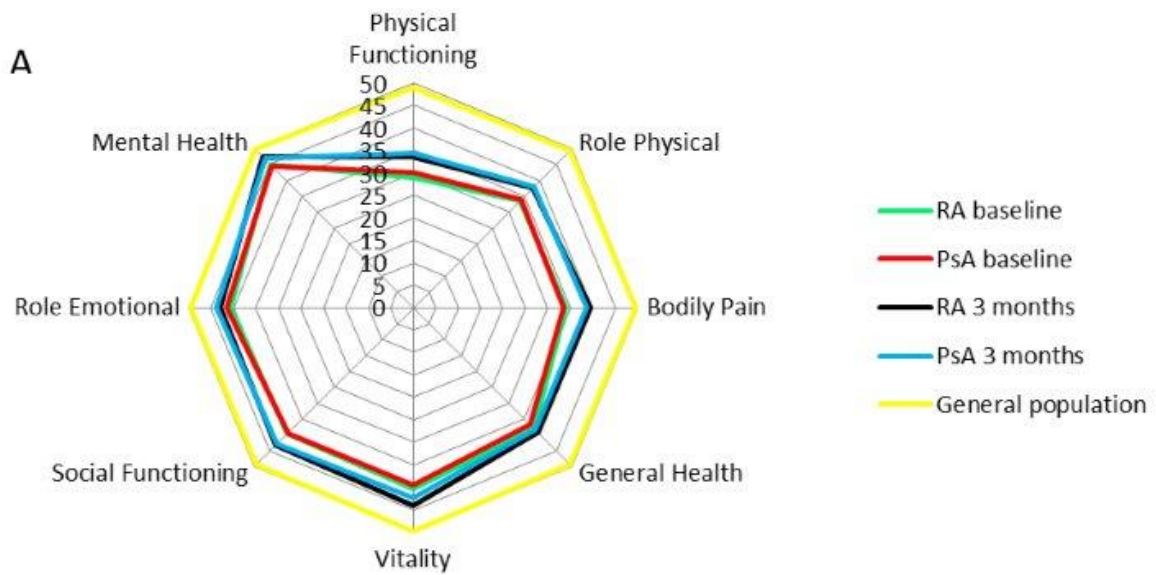
Table 2 Mean improvements from baseline until 3 and 6 months follow-up, adjusted for age, gender and the respective baseline values

| Component summary/ scale score | Adjusted analyses, mean change (95% CI) from baseline until 3 months* | | p-value |
|-----------------------------------|--|------------------------|---------|
| | RA | PsA | |
| PCS | 4.7 (4.3-5.0) n=3081 | 4.4 (3.9-4.9) n=1183 | 0.42 |
| MCS | 1.8 (1.4-2.1) n=3081 | 1.5 (1.0-2.0) n=1183 | 0.41 |
| SF-6D | 0.04 (0.03-0.04) n=2323 | 0.03 (0.03-0.04) n=872 | 0.06 |
| Physical Functioning | 4.6 (4.2-5.0) n=3197 | 4.6 (4.2-5.2) n=1217 | 0.93 |
| Role Physical | 4.2 (3.8-4.6) n=3178 | 4.3 (3.7-4.8) n=1208 | 0.83 |
| Bodily Pain | 5.8 (5.5-6.1) n=3187 | 5.1 (4.6-5.5) n=1214 | 0.004 |
| General Health | 1.4 (1.1-1.7) n=3149 | 1.3 (0.9-1.7) n=1203 | 0.61 |
| Vitality | 3.8 (3.5-4.2) n=3173 | 2.8 (2.3-3.4) n=1209 | 0.002 |
| Social Functioning | 3.7 (3.3-4.1) n=3201 | 3.3 (2.8-3.9) n=1216 | 0.31 |
| Role Emotional | 2.2 (1.8-2.7) n=3161 | 2.8 (2.1-3.4) n=1197 | 0.20 |
| Mental Health | 2.5 (2.2-2.8) n=3170 | 1.9 (1.4-2.4) n=1210 | 0.008 |
| Component summary/ scale score | Adjusted analyses, mean change (95% CI) from baseline until 6 months* | | p-value |
| | RA | PsA | |
| PCS | 5.6 (5.2-6.0) n=2605 | 5.4 (4.8-5.9) n=1034 | 0.49 |
| MCS | 2.5 (2.2-2.9) n=2605 | 2.1 (1.5-2.6) n=1034 | 0.18 |
| SF-6D | 0.04 (0.04-0.05) n=1832 | 0.04 (0.03-0.05) n=721 | 0.42 |
| Physical Functioning | 5.8 (5.4-6.3) n=2676 | 6.3 (5.6-7.0) n=1052 | 0.26 |
| Role Physical | 5.6 (5.2-6.1) n=2670 | 5.6 (5.0-6.2) n=1048 | 0.91 |
| Bodily Pain | 6.7 (6.3-7.0) n=2675 | 5.8 (5.3-6.3) n=1051 | 0.005 |
| General Health | 1.7 (1.4-2.1) n=2659 | 1.3 (0.9-1.8) n=1050 | 0.17 |
| Vitality | 4.7 (4.3-5.1) n=2668 | 3.9 (3.3-4.4) n=1051 | 0.02 |
| Social Functioning | 4.7 (4.3-5.1) n=2687 | 4.4 (3.8-5.0) n=1054 | 0.39 |
| Role Emotional | 3.1 (2.6-3.6) n=2657 | 3.4 (2.7-4.2) n=1045 | 0.44 |
| Mental Health | 3.2 (2.9-3.6) n=2665 | 2.5 (2.0-3.0) n=1052 | 0.02 |

*estimated marginal means; CI, confidence interval; SD, standard deviation; MCS, mental component summary; PCS, physical component summary; PsA, psoriatic arthritis; RA, rheumatoid arthritis; SF-6D, short form-6 dimensions utility score

Graphical comparisons of scale scores

Estimated marginal means of baseline, 3- and 6-month SF-36 scale scores adjusted for age and gender (Figure) as well as DAS28 (figure not shown) were impaired in RA and PsA patients compared with the general population, but showed only small differences between RA and PsA patients.



DISCUSSION

In this large prospective observational multicentre study SF-36 PCS, MCS as well as the utility measure SF-6D were comparable between RA and PsA patients at baseline and at 6 months follow-up in age and gender-adjusted analyses. Furthermore, PsA patients had worse general health and vitality, but better physical functioning at all time-points, as well as more bodily pain at 3 and 6 months. With adjustment for DAS28 in addition to age and gender, PsA compared to RA patients had worse PCS, SF-6D, general health, vitality, bodily pain, social functioning and mental health at all time-points.

Further, the study shows that levels of physical HRQoL were more impaired than mental HRQoL in patients with RA and PsA compared with Norwegian general population controls. Improvements in scale scores from baseline until 3 and 6 months were similar between RA and PsA patients during treatment with DMARDs, except for larger improvements in bodily pain, vitality and mental health in RA.

We have chosen to present norm-based scale scores to facilitate interpretation and comparison across different countries and populations.^{14, 16} Still, interpretation of the findings is not straight-forward; the statistically significant differences between RA and PsA patients may not always be clinically significant. As visualized in radar diagrams (Figure) the differences in scale scores between RA and PsA patients are small. Still, for e.g. general health the difference between RA and PsA patients at different time-points is of similar magnitude as the improvement in general health from baseline until 6 months both for RA and PsA patients and hence of probable clinical significance.

The study underlines the severe impact of both RA and PsA on HRQoL reflected through SF-36, which is in line with a smaller observational study³ as well as clinical trials.^{4, 17, 18}

Furthermore, the study highlights the relatively stronger impairment of HRQoL in PsA compared with RA patients, when also taking into consideration levels of joint inflammation, as measured by DAS28. Notably, also according to PsA patients' perspective HRQoL is of great importance.¹ The severe impact of PsA on HRQoL may possibly be explained by extra-articular inflammatory affection of e.g. skin or entheses. However, NOR-DMARD does not have data on these disease manifestations. We were therefore unable to identify which disease manifestations that contributed most to the reduced HRQoL in PsA. Of note, general health and vitality were worse in PsA compared with RA patients in all adjusted analyses at all time-points.

RA as well as PsA patients reported better mental than physical HRQoL, which is in line with smaller observational studies on SF-36,³ as well as with clinical trials.^{4, 17} Interestingly, the RA and PsA scale score profiles (Figure) were similar to the RA scale score profile found by Strand et al.¹⁷

Furthermore, the study is partly in line with two considerably smaller NOR-DMARD studies reporting better 6-month improvements in bodily pain and vitality, but not mental health in RA compared to PsA patients.^{19, 20} These studies did not include general population controls. The generic SF-36 facilitated comparison of HRQoL across diseases, although it might capture somewhat different aspects of HRQoL than disease-specific measures like e.g. the psoriatic arthritis quality of life (PsAQoL).²¹

Limitations of the study include lack of 66/68 joint count as well as lack of measures of PsA inflammatory activity other than arthritis (e.g. skin involvement, enthesitis, dactylitis and spondylitis), which may have led to underestimation of disease activity in PsA as used in the DAS28-adjusted analyses. Lack of adjustment for comorbidities may have biased the results, although partly corrected for by the age-adjustment. Furthermore, completer analyses may have affected the generalisability of the results.

The major strength of the study is the prospective observational multicentre design including large cohorts of RA and PsA patients over a long time span, as well as Norwegian general population controls. To our knowledge this is the largest prospective observational study comparing SF-36 between RA and PsA patients, and the first to compare SF-36

component summaries, scale scores as well as SF-6D between RA and PsA patients and general population controls in the same analyses.

In conclusion, HRQoL was overall similar in patients with RA and PsA- with a tendency to worse scores in PsA- and worse compared with Norwegian general population controls.

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Competing interests: None declared.

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