Research protocol: Follow-up with patient-reported outcome measures for improved health related quality of life – Construct validity and responsiveness of EQ-5D-3L in patients with rheumatic disease

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Table of contents

Brief summary

The aim of this study is to investigate the construct validity (convergent and known-groups) and responsiveness of EQ-5D-3L in patients with rheumatoid arthritis, polyarthritis, psoriatic arthritis, and ankylosing spondylitis. The study is based on retrospective registry data from the Swedish Rheumatology Registry (SRQ).

Background

Patient-reported outcome measures (PROMs) are used to measure how patients themselves experience their health and health related quality of life (HRQoL) [1]. One of the most commonly used PROMs is EQ-5D, which is a generic instrument used to measure, value and compare health across symptoms and diagnoses [2]. When choosing a PROM to follow-up care from the patient perspective and to assess HRQoL in patients with rheumatic disease, it is important to know that the instrument is valid and responsive. An instrument with low validity and responsiveness might not capture and describe patients' health and changes in their health accurately. The aim of the study is therefore to investigate the validity and responsiveness of EQ-5D-3L. The research questions are:

1. What is the construct validity of EQ-5D-3L in patients with rheumatic disease?
2. What is the responsiveness of EQ-5D-3L in patients with rheumatic disease?

Methodology

Study design and data collection

This study will assess the construct validity and responsiveness of EQ-5D-3L among patients with rheumatoid arthritis (RA), polyarthritis, psoriatic arthritis (PsA), and ankylosing spondylitis (AS) based on retrospective registry data. The design of the study will follow the established guidelines from COSMIN of how to assess validity and responsiveness of PROMs [3].

Construct validity refers to the degree to which an instrument measures the constructs it intends to measure [4]. Construct validity will be assessed in two ways, convergent validity and known-groups validity. Convergent validity refers to how well the instrument under study (EQ-5D-3L and EQ VAS) correlates with other outcome measures [4]. According to these

guidelines, convergent validity should be assessed by formulating and testing hypotheses regarding the expected direction and magnitude of the correlation between the measurement being studied (EQ-5D-3L and EQ VAS) and other outcome measures measuring the same or similar constructs [3]. The constructs measured by the other outcome measures should be clearly described [3].

Known-groups validity refers to how well the instrument can find differences between groups known to differ. Known-groups validity should be assessed by formulating and testing hypotheses regarding expected directions and magnitude of the differences between subgroups [3]. There should be an adequate description of important characteristics of the subgroups, such as disease characteristics [3].

Responsiveness refers to the ability of the instrument to capture change over time in the construct that is measured [5]. According to Cosmin, responsiveness can be assessed by comparing changes in EQ-5D-3L and EQ VAS, with changes in other outcome measures, similar to convergent validity explained above [3]. The hypotheses should include the expected direction and magnitude of the correlations, and the constructs should be clearly described. Responsiveness can also be assessed by analysing weather EQ-5D-3L and EQ VAS can discriminate between patients who have improved and those that have not, based on changes in another outcome, such as changes in disease activity or functional ability [3].

The analyses will be conducted independently for the different patient groups. To support construct validity and responsiveness of EQ-5D-3L and EQ VAS in each patient group, 75% of the hypotheses will need to be supported [6-9]. Historical registry data from the Swedish Rheumatology Register (SRQ) will be used to assess the construct validity and responsiveness of EQ-5D-3L and EQ VAS. Data on EQ-5D-3L has been collected since 2008 [10] and the study will include data from 2008 until the time of data extraction.

Ethical approval has been granted for the project (2023-04394-01).

Study population
Inclusion criteria are:

- 18 years and older at the time of first included measurement
- A diagnosis of RA, polyarthritis, PsA, or AS
- Complete registration of responses in the EQ-5D-3L descriptive system or EQ VAS on at least one time point in SRQ
- For patients with RA: At least one measurement with Disease Activity Score 28 (DAS28) reported in relation to the same visit as EQ-5D-3L
- For patients with polyarthritis: At least one measurement with DAS28 reported in relation to the same visit as EQ-5D-3L
- For patients with PsA: At least one measurement with DAS28 or Disease Activity in Psoriatic Arthritis (DAPSA) reported in relation to the same visit as EQ-5D-3L
- For patients with AS: At least one measurement with the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) reported in relation to the same visit as EQ-5D-3L

For the analyses of construct validity, the latest measurement will be used if the individual patients have multiple complete registrations with EQ-5D-3L and the other required measure. The hypotheses for responsiveness will be tested in patients with newly diagnosed disease (having the diagnosis for ≤12 months), as changes in disease activity are likely to be present in this group. For the analysis of responsiveness, the two first measurements during the first year will be used.

Outcome measures
EQ-5D-3L and EQ VAS
The EQ-5D-3L measures HRQoL and consists of two parts. The first part contains five questions about mobility, daily activities, self-care, pain/discomfort, and anxiety/depression [11, 12]. Each question can be answered with no problem (1), some/moderate problem (2) unable to perform certain activities/having extreme problems (3). The answers can be summarized in an index value based on an existing preference-based value set. In this study, the EQ-5D-3L value set by Dolan [13] will be used for the main analyses and a Swedish experience-based value set in a sensitivity analysis [14]. For the EQ-5D-3L index, 1 represents full health and 0 represents a value equal to being dead. EQ VAS measures the persons

health today on a visual analogue scale (VAS) from 0 (worst imaginable health) to 100 (best imaginable health) [11, 12].

Disease activity

DAS28 was developed for patients with RA and contains questions about tender and swollen joints, disease activity and inflammation [15]. DAPSA was developed for patients with PsA and contains questions about tender and swollen joints, disease activity, pain, and inflammation [16, 17]. BASDAI was developed to measure disease activity in patients with AS and contains questions about fatigue, pain, swelling and stiffness [18, 19]. ASDAS was developed to measure disease activity in patients with AS and contains questions about pain, swelling, stiffness, disease activity and inflammation [20].

For all these measures, a higher value indicates higher disease activity.

Functional ability

The Health Assessment Questionnaire Disability Index (HAQ-DI) and the Bath Ankylosing Spondylitis Functional Index (BASFI) measure functional ability through questions about mobility, daily activities, and self-care [19, 21]. For both scales, a higher value indicates more problems with functional ability.

VAS questions

The SRQ also contains three questions about pain, fatigue, and general health (global score), measured on a VAS. The questions ask who much pain the person has had, how fatigue they have been and how their general health has been in the last week due to their rheumatic disease. The scale ranges from no problem (0) to as bad as it can be (100) [22].

Hypotheses

To assess the validity and responsiveness a priori hypotheses for convergent validity, known-groups validity, and responsiveness have been formulated. The hypotheses for EQ-5D-3L are presented first followed by the hypotheses for EQ VAS.

Convergent validity EQ-5D-3L

Convergent validity will be assessed by testing hypotheses regarding the expected direction and magnitude of correlation between the EQ-5D-3L

and the other outcome measures. Constructs that are considered to be related are expected to have at least a moderate correlation and constructs that are considered to be similar are expected to have a strong correlation [8]. A moderate correlation is defined as ≥0.3 and a strong correlation is defined as ≥0.5 [8]. The hypotheses for all patient groups are presented in the text below.

VAS pain

- VAS pain and EQ-5D-3L **index**: a moderate negative correlation is expected.

- VAS pain and EQ-5D-3L **mobility**: a moderate positive correlation is expected.

- VAS pain and EQ-5D-3L **self-care**: a moderate positive correlation is expected.

- VAS pain and EQ-5D-3L **daily activities**: a moderate positive correlation is expected.

- VAS pain and EQ-5D-3L **pain/discomfort**: a strong positive correlation is expected.

VAS global score

- VAS global score and EQ-5D-3L **index**: a strong negative correlation is expected.

VAS fatigue

- VAS fatigue and EQ-5D-3L **index**: a moderate negative correlation is expected.

- VAS fatigue and EQ-5D-3L **mobility**: a moderate positive correlation is expected.

- VAS fatigue and EQ-5D-3L **self-care**: a moderate positive correlation is expected.

- VAS fatigue and EQ-5D-3L **daily activities**: a moderate positive correlation is expected.

- VAS fatigue and EQ-5D-3L **anxiety/depression**: a moderate positive correlation is expected.

DAS28/DAPSA/BASDAI/ASDAS

- Disease activity measured with DAS28/DAPSA/BASDAI/ASDAS and EQ-5D-3L **index**: a moderate negative correlation is expected.

- Disease activity measured with DAS28/DAPSA/BASDAI/ASDAS and EQ-5D-3L **mobility**: a moderate positive correlation is expected.

- Disease activity measured with DAS28/DAPSA/BASDAI/ASDAS and EQ-5D-3L **self-care**: a moderate positive correlation is expected.

- Disease activity measured with DAS28/DAPSA/BASDAI/ASDAS and EQ-5D-3L **daily activities**: a moderate positive correlation is expected.

- Disease activity measured with DAS28/DAPSA/BASDAI/ASDAS and EQ-5D-3L **pain/discomfort**: a moderate positive correlation is expected.

HAQ-DI/BASFI

- Functional ability measured with HAQ-DI/BASFI and EQ-5D-3L **index**: a moderate negative correlation is expected.

- Functional ability measured with HAQ-DI/BASFI and EQ-5D-3L **mobility**: a moderate positive correlation is expected.

- Functional ability measured with HAQ-DI/BASFI and EQ-5D-3L **self-care**: a moderate positive correlation is expected.

- Functional ability measured with HAQ-DI/BASFI and EQ-5D-3L **daily activities**: a moderate positive correlation is expected.

- Functional ability measured with HAQ-DI/BASFI and EQ-5D-3L **pain/discomfort**: a moderate positive correlation is expected.

Known-groups validity EQ-5D-3L

In the assessment of known-groups validity, patients will be divided into groups for which there is an expected difference in HRQoL. The groups represent patients with different levels of disease activity or functional ability. Patients with lower disease activity (<3.2 measured with DAS28, ≤14 measured with DAPSA, <2.1 measured with ASDAS and <4 measured with BASFI) are expected to have better health and HRQoL compared to patients with higher disease activity (≥3.2 measured with DAS28, >14 measured with DAPSA, ≥2.1 measured with ASDAS and ≥4 measured with BASDAI). Likewise, patients with better functional ability (<1 measured with HAQ-DI and <4 measured with BASFI) are expected to have better health and HRQoL compared to patients with worse functional ability (≥1 measured with HAQ-DI and ≥4 measured with BASFI). The cut of values for disease activity (DAS28 [23], DAPSA [24], ASDAS [25, 26], BASDAI [25-27]) and functional ability (HAQ-DI [28, 29], BASFI [27]) were taken from the literature.

To assess the magnitude of the differences in the proportions of reported problems in the EQ-5D-3L dimensions between groups, the effect size (r) will be calculated. The effect size is considered small if it is ≥ 0.1, medium if it is ≥0.3 and large if it is ≥0.5 [30-32]. To support the hypotheses for the dimensions, at least a small effect size will be required.

To estimate whether there is a difference in the EQ-5D-3L mean index value between groups, cut-off values for minimally important differences (MID) will be used. Minimal important differences represent the smallest improvement considered worthwhile by a patient [33]. The MID values used in this study will be based on the literature.

The hypotheses for known-groups validity of EQ-5D-3L are presented in the text below.

DAS28/DAPSA

- Lower EQ-5D-3L **index** values are expected in patients with moderate/high disease activity compared to patients in remission/with low disease activity.

- More reported problems in EQ-5D-3L **mobility** are expected for patients with moderate/high disease activity compared to patients in remission/with low disease activity.

- More reported problems in EQ-5D-3L **self-care** are expected for patients with moderate/high disease activity compared to patients in remission/with low disease activity.

- More reported problems in EQ-5D-3L **daily activities** are expected for patients with moderate/high disease activity compared to patients in remission/with low disease activity.

- More reported problems in EQ-5D-3L **pain/discomfort** are expected for patients with moderate/high disease activity compared to patients in remission/with low disease activity.

ASDAS

- Lower EQ-5D-3L **index** values are expected in patients with high/very high disease activity compared to patients with inactive disease/low disease activity.

- More reported problems in EQ-5D-3L **mobility** are expected in patients with high/very high disease activity compared to patients with inactive disease/low disease activity.

- More reported problems in EQ-5D-3L **self-care** are expected in patients with high/very high disease activity compared to patients with inactive disease/low disease activity.

- More reported problems in EQ-5D-3L **daily activities** are expected in patients with high/very high disease activity compared to patients

with inactive disease/low disease activity.

- More reported problems in EQ-5D-3L **pain/discomfort** are expected in patients with high/very high disease activity compared to patients with inactive disease/low disease activity.

BASDAI

- Lower EQ-5D-3L **index** values are expected in patients with high disease activity compared to patients with low disease activity.

- More reported problems in EQ-5D-3L **mobility** are expected in patients with high disease activity compared to patients with low disease activity.

- More reported problems in EQ-5D-3L **self-care** are expected in patients with high disease activity compared to patients with low disease activity.

- More reported problems in EQ-5D-3L **daily activities** are expected in patients with high disease activity compared to patients with low disease activity.

- More reported problems in EQ-5D-3L **pain/discomfort** are expected in patients with high disease activity compared to patients with low disease activity.

BASFI/HAQ-DI

- Lower EQ-5D-3L **index** values are expected in patients with less functional ability compared to patients with more functional ability.

- More reported problems in EQ-5D-3L **mobility** are expected in patients with less functional ability compared to patients with more functional ability.

- More reported problems in EQ-5D-3L **self-care** are expected in patients with less functional ability compared to patients with more

functional ability.

- More reported problems in EQ-5D-3L **daily activities** are expected in patients with less functional ability compared to patients with more functional ability.

- More reported problems in EQ-5D-3L **pain/discomfort** are expected in patients with less functional ability compared to patients with more functional ability.

Responsiveness EQ-5D-3L

Responsiveness will be assessed in two ways. One way is by assessing the relationship between individual changes in EQ-5D-3L index value and dimensions over time with changes in other outcome measures over the same time period. The second way is to assess whether EQ-5D-3L can discriminate between patients who have improved over time and those that have not, based on changes in disease activity or functional ability.

Correlation between changes in EQ-5D-3L with changes in other outcome measurement instruments

The relationship between changes in the EQ-5D-3L and changes in other outcome measures will be assessed by analysing the correlation between the changes in the variables between the two first measurements of each individual during the first year after diagnosis. The hypotheses for expected correlations are presented in the text below.

VAS pain

- VAS pain and EQ-5D-3L **index**: the changes in scores are expected to have a moderate negative correlation.

- VAS pain and EQ-5D-3L **mobility**: the changes in scores are expected to have a moderate positive correlation.

- VAS pain and EQ-5D-3L **self-care**: the changes in scores are expected to have a moderate positive correlation.

- VAS pain and EQ-5D-3L **daily activities**: the changes in scores are expected to have a moderate positive correlation.

- VAS pain and EQ-5D-3L **pain/discomfort**: the changes in scores are expected to have a strong positive correlation.

VAS global score

- VAS global score and EQ-5D-3L **index**: the changes in scores are expected to have a strong negative correlation.

VAS fatigue

- VAS fatigue and the EQ-5D-3L **index**: the changes in scores are expected to have a moderate negative correlation.

- VAS fatigue and EQ-5D-3L **mobility:** the changes in scores are expected to have a moderate positive correlation.

- VAS fatigue and EQ-5D-3L **self-care**: the changes in scores are expected to have a moderate positive correlation.

- VAS fatigue and EQ-5D-3L **daily activities**: the changes in scores are expected to have a moderate positive correlation.

- VAS fatigue and EQ-5D-3L **anxiety/depression**: the changes in scores are expected to have a moderate positive correlation.

DAS28/DAPSA/BASDAI/ASDAS

- Disease activity measured with DAS28/DAPSA/BASDAI/ASDAS and the EQ-5D-3L **index**: the changes in scores are expected to have a moderate negative correlation.

- Disease activity measured with DAS28/DAPSA/BASDAI/ASDAS and EQ-5D-3L **mobility**: the changes in scores are expected to have a moderate positive correlation.

- Disease activity measured with DAS28/DAPSA/BASDAI/ASDAS and EQ-5D-3L **self-care**: the changes in scores are expected to have a moderate positive correlation.

- Disease activity measured with DAS28/DAPSA/BASDAI/ASDAS and EQ-5D-3L **daily activities**: the changes in scores are expected to have a moderate positive correlation.

- Disease activity measured with DAS28/DAPSA/BASDAI/ASDAS and EQ-5D-3L **pain/discomfort**: the changes in scores are expected to have a moderate positive correlation.

HAQ-DI/BASFI

- Functional ability measured with HAQ-DI/BASFI and EQ-5D-3L **index**: the changes in scores are expected to have a moderate negative correlation.

- Functional ability measured with HAQ-DI/BASFI and EQ-5D-3L **mobility**: the changes in scores are expected to have a moderate positive correlation.

- Functional ability measured with HAQ-DI/BASFI and EQ-5D-3L **self-care**: the changes in scores are expected to have a moderate positive correlation.

- Functional ability measured with HAQ-DI/BASFI and EQ-5D-3L **daily activities**: the changes in scores are expected to have a moderate positive correlation:

- Functional ability measured with HAQ-DI/BASFI and EQ-5D-3L **pain/discomfort**: the changes in scores are expected to have a moderate positive correlation.

Analysing EQ-5D-3L in patients who have improved versus patients who have not improved based on disease activity and functional ability

To assess whether EQ-5D-3L can discriminate between patients who have improved and those that have not, the area under the receiver operating curve ROC curve (AUC) will be calculated. Patients will be considered to have improved based on results from the measures of disease activity (DAS28, DAPSA, ASDAS or BASDAI) and functional ability (BASFI and HAQ-DI) using criteria for what is defined as a response from previous studies. To determine whether EQ-5D-3L can discriminate between patient groups, the AUC is required to be ≥ 0.70 [8]. The hypotheses for these analyses are presented in the text below.

DAS28/DAPSA/ASDAS/BASDAI

- The EQ-5D-3L **index** is expected to be able to discriminate between patients who have improved disease activity and patients who have not improved.

BASFI/HAQ-DI

- The EQ-5D-3L **index** is expected to be able to discriminate between patients who have improved functional ability and patients who have not improved.

Convergent validity EQ VAS

Convergent validity of EQ VAS will be assessed with the same analyses used for EQ-5D-3L (see the section about convergent validity EQ-5D-3L). The hypotheses are described in the text below.

- **VAS pain** and EQ VAS: a moderate negative correlation is expected.
- **VAS global score** and EQ VAS: a strong negative correlation is expected.
- **VAS fatigue** and EQ VAS: a moderate negative correlation is expected.

DAS28/DAPSA/BASDAI/ASDAS

- Disease activity measured with DAS28/DAPSA/BASDAI/ASDAS and EQ VAS: a moderate negative correlation is expected.

HAQ-DI/BASFI

- Functional ability measured with HAQ-DI/BASFI and EQ VAS: a moderate negative correlation is expected.

Known-groups validity EQ VAS

Known-groups validity of EQ VAS will be assessed for the same groups as the EQ-5D-3L index (see section about Known-groups validity EQ-5D-3L). To estimate whether there is a difference in EQ VAS, cut-off values for MID based on the literature will be used. The hypotheses described in text below are regarding the known-groups validity of EQ VAS.

DAS28/DAPSA

- Lower EQ VAS values are expected in patients with moderate/high disease activity compared to patients in remission/with low disease activity.

ASDAS

- Lower EQ VAS values are expected in patients with high/very high disease activity compared to patients with inactive disease/low disease activity.

BASDAI

- Lower EQ VAS values are expected in patients with higher disease activity compared to patients with lower disease activity.

BASFI/HAQ-DI

- Lower EQ VAS values are expected in patients with less functional ability compared to patients with more functional ability.

Responsiveness EQ VAS

Responsiveness for EQ VAS will be assessed with the same analyses used for EQ-5D-3L (see the section about responsiveness EQ-5D-3L). The hypotheses are described in the text below.

Correlation between changes in EQ VAS with changes in other outcome measures

- VAS pain and EQ VAS: the changes in scores are expected to have a moderate negative correlation.

- VAS global score and EQ VAS: the changes in scores are expected to have a strong negative correlation.

- VAS fatigue and EQ VAS: the changes in scores are expected to have a moderate negative correlation.

- Disease activity measured with DAS28/DAPSA/BASDAI/ASDAS and EQ VAS: the changes in scores are expected to have a moderate negative correlation.

- Functional ability measured with HAQ-DI/BASFI and EQ VAS: the changes in scores are expected to have a moderate negative correlation.

Analysing EQ VAS in patients who have improved versus patients who have not improved based on disease activity and functional ability

DAS28/DAPSA/ASDAS/BASDAI

- EQ VAS is expected to be able to discriminate between patients who have **improved** disease activity and patients who have not improved.

BASFI/HAQ-DI

- EQ VAS is expected to be able to discriminate between patients who have **improved** functional ability and patients who have not improved.

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