Comparison of the Quality of life in Patients with Early and Established Rheumatoid Arthritis

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Research

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Abstract

**Aim:** To compare the quality of life (QOL) in patients with early rheumatoid arthritis (RA) against patients with established RA.

**Methods:** The clinical study included 164 participants from Russia: 114 outpatients with early RA, and 50 outpatients with established RA. Assessment of QOL in RA patients detected impaired indicators of the HAQ, SF-36 questionnaires, QOL-RA Scale already during the first year of the disease.

**Results:** The HAQ test found a comparable frequency of severe functional disorders in patients with early and established RA. According to the SF-36 questionnaire, patients with early RA suffered from physical pain than patients with established RA. The QOL-RA Scale demonstrated that patients with initial stages of the disease process had the lowest scores for the "arthritis" and "joint pain", and participants with established RA additionally and on the "health".

**Conclusions:** A comparative study of the QOL in respondents with early and established RA has shown that patients have a decrease it already during the first year of the disease on many indicators, as patients with a long anamnesis, and even experience more pronounced physical pain. So, tested questionnaires can provide benefits for monitoring health status and comparison of the effectiveness of drugs and treatment methods.

Background

Rheumatoid arthritis (RA) is a chronic, immuno-inflammatory disease with erosive joint damage of unknown etiology (1, 2). It affects 0.5-1.0% of the adult population (3, 4). High disease activity, functional limitations, anxiety, and depression are negatively associated with QOL of RA patients (5). Pain and weak muscle strength additionally to disease activity has a maximum impact on disability especially in females with RA according to the Health Assessment Questionnaire (HAQ) (6). Higher HAQ values in RA patients with a newly established diagnosis predict the development of severe extra-articular manifestations during the first 2 years of follow-up (7). The differences between scales of the physical component summary (PCS) and mental component summary (MCS) according to Short Form 36 (SF-36) Health Survey are not statistically significant between the patients with RA aged 65 years or older and under 65 years of age (8). The English and Spanish versions of the Quality of Life-Rheumatoid Arthritis Scale (QOL-RA Scale) identified that interaction with family and friends in RA patients had the highest mean, whereas pain and arthritis had the lowest means (9). It is of interest to identify differences in the quality of life in patients with early RA and established RA according to the HAQ, SF-36 data and scores of the QOL-RA Scale in Russian version (10).

Methods

Participants
The clinical study included 164 participants: 114 outpatients with early RA, and 50 outpatients with established RA. The sampling technique was used to assign patients to the study and comparison groups. The group of patients with early RA was selected 114 out of 250 persons who had a clinical suspicion of the disease according to the EULAR criteria (2002) with duration of arthritis is not more than 1 year after excluding other rheumatic diseases. They fulfilled the EULAR criteria (2010) within the retrospectively analyze before the statistical processing the results. The comparison group with duration of the disease from 1,1 to 38 years was established by the RA criteria revised of the ACR (1987). As seen in Table 1, in both groups, there were 90% women, and the majority of patients had seropositive RA of the high activity according to Disease Activity Score 28 (DAS28), erosive changes in the metacarpal bones according to arthrosonography by the «Diasonics Ultrasound» device (USA), disorders of the II and III functional classes ($p < 0.05$). The group with early RA had predominantly stage I-X-ray, while the most of the comparison group had changes in the joints of the stage II-X-ray ($p < 0.05$). Patients of both groups did not suffer from complicated forms of cardiovascular diseases and did not have diabetes mellitus type 2, neoplasms or systemic osteoporosis.
Table 1
Characteristics of the groups of patients with early RA and established RA

| Parameters                                           | Number of patients |
|------------------------------------------------------|--------------------|
|                                                      | Group of patients with early RA (n = 114) | Comparison group (n = 50) |
|                                                      | abs. | %       | abs. | %       |
| Age, years                                           |      |         |      |         |
| Me (Q_{25}-Q_{75})                                   | 50.5 (47-54.75)   | –      | 53 (48-57) | –      |
| Women                                                | 103  | 90.4*   | 45   | 90*     |
| Seropositive RA                                      | 58   | 50.9*   | 33   | 66*     |
| Clinical stage:                                      |      |         |      |         |
| very early (<6 months)                               | 63   | 55.3    | –    | –       |
| early (6-12 months)                                  | 51   | 44.7    | –    | –       |
| expanded (>1 year)                                   | –    | –       | 23   | 46      |
| late (≥2 years + pronounced destruction)             | –    | –       | 27   | 54      |
| Disease activity                                    |      |         |      |         |
| 0 (DAS28<2.6)                                        | –    | –       | 1    | 2       |
| I (2.6<DAS28<3.2)                                    | 8    | 7       | 2    | 4       |
| II (DAS28 3.2-5.1)                                   | 44   | 38.6    | 15   | 30      |
| III (DAS28>5.1)                                      | 62   | 54.4*   | 32   | 64*     |
| Erosive RA (ultrasonic data)                         | 100  | 88*     | 49   | 98*     |
| Stage X-ray (Steinbrocker):                          |      |         |      |         |
| signs are absent                                     | 25   | 21.9    | –    | –       |
| I                                                     | 58   | 50.9*   | 10   | 20      |
| II                                                    | 31   | 27.2    | 33   | 66*     |
| III                                                   | –    | –       | 5    | 10      |
| IV                                                    | –    | –       | 2    | 4       |
| Functional class:                                    |      |         |      |         |
| I                                                     | 22   | 19.3    | 2    | 4       |
Measures

All participants were interviewed face-to-face in the ambulatory setting to assess their QOL using HAQ, SF-36 and QOL-RA Scale.

HAQ

A special questionnaire for assessment the functional status of the joints in RA patients was used. The questionnaire included 20 questions grouped into 8 scales of 2 or 3 questions (hygiene, dressing, grip, reach, eating, arising, walking, other activities). The answers to each of the questions were coded as follows: 0 points ("without difficulties"), 1 point ("with some difficulties"), 2 points ("with much difficulties"), 3 points ("unable to do"). The HAQ-Disability Index (HAQ-DI) was calculated as the arithmetic mean of the sum of the maximum scores on each scale. The values from 0 to 1 point were interpreted as minimal, from 1.1 to 2 points as moderate, from 2.1 to 3 points as severe disorders of daily functioning. During interview it became clear the patient’s need for assistive devices. The dynamics of the HAQ-DI were interpreted as minimal clinically significant changes if its values decreased at least on 0.22 points.

SF-36

General questionnaire assessed health status of the patient over the past four weeks. Each of the 36 items of the questionnaire, with the exception of one, was used in conversion of the estimates for one from eight scales: general health (GH), role limitations due to physical health (RP), physical functioning (PF), bodily pain (BP), vitality (VT), role limitations due to emotional problems (RE), mental health (MH), and social functioning (SF). The values on each scale were recoded from 0 to 100 points where 100 points represented complete health.

These scales were combined into PCS and MCS. The increase in the scores of individual summary components of SF-36 on 2.5-5 points was interpreted as minimal clinically significant changes.

In addition, the single-item measure of Health Transition (HT) evaluated the dynamics of health compared to what it was a year ago.
QOL-RA Scale

A specific questionnaire was used to obtain the patient's opinion about effects of RA on QOL. It included 8 questions (points) concerning physical ability, joint pain, tension, interaction with family and friends, health, arthritis, mood, support from family and friends. Each item was evaluated by the patient from 0 to 10 points, where 0 points corresponded to "very bad", and 10 points to "excellent" quality of life. The arithmetic mean of the sum of scores on 8 points was a "total QOL-RA Scale".

Statistical Analysis

Statistical analysis was performed using the software package "Statistica 6.0" (StatSoft, Inc., USA, 2001). The statistical hypothesis about the normality of distribution was tested for all quantitative parameters by the Kolmogorov-Smirnov criterion for equality of variances or the Shapiro-Wilk criterion for samples of less than 60 persons. The median (Me) and interquartile range between the first and third quartiles (Q1-Q3) were determined if distribution of the indicators was different from normal. The Chi-square test was applied to compare distributions of criteria in groups. The nonparametric Mann-Whitney U-test was used for comparison of the parameters between two groups. The Wilcoxon test was applied to compare two variables within the same group. Differences between the parameters were considered statistically significant at a value of $p < 0.05$.

Results

A comparison of the results of a face-to-face interview of 114 patients with early RA (duration of arthritis < 1 year) and 50 patients with established RA found that all indicators of quality of life in both groups were reduced. The HAQ-DI in group with early RA corresponded to moderate functional status disorders compared with severe functional disorders in the comparison group according median and interquartile 1.8 (0.9–2.5) against 2.3 (1.6–2.8) points, respectively ($p < 0.05$). At the same time, this questionnaire established a comparable frequency of the severe functional limitations in patients with early and established RA (43 and 56% of cases, respectively) with more significant difficulties in "hygiene", "arising", "walking" and HAQ-DI in patients with long-term current disease ($p < 0.05$) (Fig. 1). The need for outside help and the use of devices reached 77.2% of early RA cases and 88.0% of cases in group of comparison.

The survey by the SF-36 revealed that all indicators of life quality in patients of both groups were reduced (Table 2). However, if in the group of patients with established RA scores of the RP most have been reduced relatively to other scales, in the comparison group the RP and FB scales were the worst. At the same time, the median of PF indicators in the group with established RA was inferior to the assessment for the same scale in the group with early RA: 15 points against 25 points, respectively ($p < 0.05$). The MH indicators were highest in both groups ($p < 0.05$).
Table 2
QOL indicators of patients with early and established RA according to the SF-36 questionnaire

| SF-36 scales and summary measures | Scale values in points Me (Q25-Q75) |
|----------------------------------|-------------------------------------|
|                                  | Group of patients with early RA (n = 114) | Comparison group (n = 50) |
| Physical functioning             | 25.0 (15.0-50.0) | 15.0 (10.0-35.0) * |
| Role limitations due to physical health | 0.0 (0.0-0.0) # | 0.0 (0.0-0.0) # |
| Bodily pain                       | 22.0 (12.0-32.0) # | 22.0 (0.0-32.0) |
| General health                    | 45.0 (20.0-55.0) | 35.0 (20.0-60.0) |
| Vitality                          | 30.0 (20.0-45.0) | 30.0 (15.0-40.0) |
| Social functioning                | 37.5 (12.5-50.0) | 31.3 (12.5-62.5) |
| Role limitations due to emotional problems | 0.0 (0.0-100.0) | 33.3 (0.0-66.7) |
| Mental health                     | 48.0 (28.0-68.0) | 52.0 (36.0-64.0) |
| Physical component summary        | 30.0 (26.0-35.5) | 26.0 (23.0-30.9) * |
| Mental component summary          | 37.2 (28.4-45.7) $ | 39.4 (31.6-47.0) $ |

* statistical significance of differences between indicators of groups of patients with early RA and established RA; # differences between indicators of other scales in the group; $ differences between indicators of summary measures in each group (p < 0.05)

A comparison of the summary components demonstrated that the PCS indicators in both groups were worse than the MCS values (p<0.05). At the same time, PCS indicators in RA patients with long-term medical history were lower than in persons with early RA (p<0.005).

The majority of respondents (62.3%) in the group with early RA at baseline rated their health as "much worse than a year ago" (p<0.001), which was a statistically significant difference from patients with established RA.

As seen from Table 3, the respondents of the both groups gave the higher estimates of life quality associated with RA for "support from family and friends" and "interaction with family and friends", the lower points to "arthritis" and "joint pain", additionally, in the group of the patients with established RA to "health" (p<0.05). No statistically significant differences were found in scores on the QOL-RA Scale between groups of study.
Table 3
QOL-RA Scale indicators for patients with early RA and established RA

| Items of the QOL-RA Scale | Scale indicators in points, Me (Q_{25}-Q_{75}) |
|---------------------------|-----------------------------------------------|
|                           | Group of patients with early RA (n = 114)       | Comparison group (n = 50) |
| Physical ability          | 5.0 (3.0-5.0)                                 | 5.0 (4.0-5.0)            |
| Support                   | 7.0 (5.0-9.0) *                              | 6.0 (5.0-8.0) *          |
| Joint pain                | 4.0 (3.0-5.0) #                              | 3.5 (2.0-5.0) #          |
| Tension                   | 4.5 (3.0-5.0)                                 | 5.0 (3.0-5.0)            |
| Health                    | 5.0 (3.0-5.0)                                 | 4.0 (3.0-5.0) #          |
| Arthritis                 | 3.0 (3.0-5.0) #                              | 3.0 (2.0-5.0) #          |
| Interaction               | 8.0 (5.0-8.0) *                              | 8.0 (6.0-9.0) *          |
| Mood                      | 5.0 (3.0-6.0)                                 | 5.0 (5.0-7.0)            |
| Total QOL-RA Scale        | 4.8 (3.8-6.0)                                 | 4.9 (4.0-5.9)            |

* maximum scores, # minimum scores compared to other scales in each group (p < 0.05)

Discussion

Three instruments were used for a comparative analysis of the QOL in patients with early and established RA: special, general and disease-specific questionnaires.

According to the results obtained using the HAQ, 43% of respondents with early RA and 56% of respondents with established RA had severe functional disorders. It indicated that regardless of the duration of the disease, the active pathological process in most of them led to a significant decrease in functional abilities. Thus, a significant part of patients (77.2%) already in the early stages of RA needed outside help and the use of devices. With the increase in the duration of RA, restrictions in "hygiene", "arising", "walking" in patients were intensified.

The survey by the SF-36 revealed impairment of physical, psychological and social functioning starting from the early stages of RA. Regardless of the duration of RA, difficulties in work or other activities occurred mainly due to physical status, although in interviewed participants with early RA, the PCS indicators suffered less than in patients with long-term disease. At the same time, RA patients on early
stages were more likely to experience limitations due to physical pain. In 62.3% of cases initially they assessed the health as "much worse than a year ago".

The use of the QOL-RA Scale in this clinical study found that patients with early RA gave the worst scores for the "arthritis" and "joint pain", and participants with established RA for "health" also, but at any duration of the disease RA patients were satisfied with the support from family and friends. This specific questionnaire that assesses the impact of arthritis on QOL excludes the effects of the comorbidities if there are doubts when using a general questionnaire (SF-36 in our case). At the same time the use of three questionnaires meets the requirements for QOL studies.

Previous studies did not aim to compare the QOL of the RA patients with different disease duration using HAQ, SF-36, QOL-RA Scale. The application of these questionnaires for scientific purposes allows already in the early stages of the RA to identify the indicators that are most susceptible to deterioration of the quality of life, which means that they can be used as additional criteria for the effectiveness of treatment, primarily when testing new drugs or choosing a therapy strategy by drugs with proven effectiveness. This part of the scientific study has limitations in this publication due to the fact that it does not include comparative results of the effectiveness of drugs for the treatment of early RA, which are described in other articles.

**Conclusion**

A comparative study of the QOL in respondents with early and established RA has shown that patients have a decrease it already during the first year of the disease on many indicators, as patients with a long anamnesis, and even experience more pronounced physical pain. So, tested questionnaires can provide benefits for monitoring health status and comparison of the effectiveness of drugs and treatment methods.

**Abbreviations**

**RA:** rheumatoid arthritis

**HAQ:** Health Assessment Questionnaire

**QOL:** quality of life

**QOL-RA Scale:** Quality of Life-Rheumatoid Arthritis Scale

**SF-36:** Short Form 36 (SF-36) Health Survey

**HAQ-DI:** HAQ-Disability Index

**PF:** physical functioning
RP: role limitations due to physical health
BP: bodily pain
GH: general health
VT: vitality
SF: social functioning
RE: role limitations due to emotional problems
MH: mental health
PCS: physical component summary
MCS: mental component summary

Declarations

Ethics approval and consent to participate

The scientific research was ethically approved by the Academic Council of XXXX (protocol number 5, December 23th, 2005). All participants gave their written consent to participate in the study.

Consent for publication

Not applicable.

Availability of data and materials

All data generated and analyzed during comparative study of QOL are included in this published article.

Competing interests

The author declare that she has no conflict of interest. None commercial editing agencies involved in the translating the text.

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Authors' contributions

LS analyzed and interpreted the patient data regarding the QOL, and she wrote and translated this manuscript into English.

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