Elaboration and validation of a questionnaire (Qualisex) to assess the impact of rheumatoid arthritis on sexuality with patient involvement

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Abstract

Objectives

Rheumatoid arthritis (RA) may have consequences on sexual life. The objective was to develop and validate a questionnaire assessing the impact of RA on sexuality.

Methods

First, 6 patients (5 women, 1 man) with RA, 2 rheumatologists and 1 sexologist elaborated during a one-day focus-group type meeting an exhaustive list of issues relating to impact of RA on sexuality. The list was reduced by merging similar issues, then according to the relative importance for patients of each issue. A questionnaire was developed with input from these patients, with particular attention on phrasing. Psychometric properties (missing data, correlations with other disease aspects, reliability) were assessed in a multi-centre study.

Results

The list of 33 issues related to impact of RA on sexuality included psychological issues (9), couple/relationship issues (9), physical issues (7), and general aspects (5). A 10-question numeric rating scale questionnaire was constructed. Preliminary validation was obtained on 53 patients (44 women, mean age 50.7 years; mean disease duration 14.4 years). The mean score was 3.3±2.5, missing data were acceptable (13%). Qualisex results were correlated with disease activity and symptoms ($r=0.50$–0.65, $p<0.001$); but not with demographics, depression or coping. Qualisex was reliable in 40 patients: the intra-class correlation coefficient was 0.83 (95% CI: 0.70–0.91).

Conclusion

A simple (10 questions) and valid tool investigating impact of RA on sexuality has been developed with the involvement of patients. This tool can be useful to assess this important aspect of quality of life.

Key words

rheumatoid arthritis, sexuality, outcome measure, questionnaire, validity

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Introduction

Rheumatoid arthritis (RA) is traditionally assessed by physical examination, laboratory tests and radiographs, keeping with a "biomedical model" the dominant paradigm of 20th century medicine. However, since the start of the new millennium, there has been growing interest in assessment of RA from the patient's perspective (1). RA leads to various degrees of disability with multiple physical social and psychological consequences. Impairment of quality of life in RA is well recognised and its evaluation is recommended in trials (2). Current standard assessment of RA includes some dimensions or domains assessed by patient-reported outcomes, namely patient assessment of pain, functional disability and/or patient global assessment. (3-5). However, other domains of health such as sexuality appear important from the patient's perspective (1, 6, 7). The consequences of RA on sexual life can be due to physical or psychological problems such as pain, fatigue, morning stiffness, disability, hip and knee involvement, but also depression and altered body image (8-9). However, impairment of quality of life by sexual problems is not being evaluated in clinical trials or in clinical practice (10-12).

In clinical trials, one important element explaining the non-assessment of sexual issues is the paucity of validated questionnaires, which have been assessed in terms of psychometric properties (6, 13). Biologics improves several aspects of quality of life (14) and may have an impact on the sexual consequences of RA also; this has however never been demonstrated to date.

In clinical practice, the sexual problems in RA are not being addressed by physicians for several reasons (11, 15). Sexuality remains an area that many feel unable to discuss, and rheumatologists may be unsure whether such problems are or not within their domain of care (15). Similarly, patients may not feel confident enough to discuss with their physicians the sexual impact of RA (12). On the other hand, a questionnaire might give the opportunity to start a discussion with RA patients about their sexual life (16) and appears to be an acceptable mode of communication on this sensitive issue (6, 8).

Thus, there is a need both for clinical studies and potentially also for clinical practice, for a questionnaire to assess sexuality in RA.

The objective of the present study was the elaboration and the validation of a new questionnaire assessing the impact of RA on sexuality: 'Qualisex'. The objective was to elaborate this questionnaire with input from people with rheumatism, so that the issues would be relevant for patients (1, 17-19). The questionnaire was also validated in terms of psychometric properties, according to modern standards for patient-reported outcomes (13, 20).

Patients and methods

Identification and selection of candidate aspects of sexuality: initial choice of domains

Six people with RA met in Paris in September 2009. These people all had definite RA according to the American College of Rheumatology 1987 criteria (21), and were selected by the principal investigators (AP and LG) based on their willingness to participate in a one-day meeting to communicate on impact of RA on sexuality. They had varying experience in research partnership; 1 had extensive experience (GvK) and 2 had some experience in teaching RA to medical students.

The patients were presented with an explanation on aspects of sexuality by a sexologist (CS), *e.g.* desire, arousal, orgasm (22). Then, during a "focus group" type meeting, and in 2 successive sessions, in the presence of 2 rheumatologists as moderators (LG and AP) and one sexologist (CS), the participants identified aspects of sexuality impacted by RA, based on their personal experience. Each patient was asked to write 3 key terms relating to their own assessment of impact of RA on sexual life. These items were copied on a blackboard and discussed extensively.

Reduction of the list of items

Through group discussion, similar notions were merged into 6 major aspects of the impact of RA on sexuality. The relative importance of each aspect was obtained from each of the patient participants.

Qualisex questionnaire: drafting of the questionnaire

Based on the relative importance of each of the main aspects of impact of RA on sexuality, the number of questions for each of these aspects was decided within the working group during the same day. It was decided arbitrarily that the final questionnaire should include 5 to 15 questions, for feasibility issues (13). A preliminary questionnaire with 10 questions was developed the same day with input from the patients, and with particular attention paid on phrasing so as to avoid missing data in this sensitive field of research.

Finalisation of the questionnaire

The questionnaire was assessed by 5 external reviewers (2 physicians, 1 sexologist, 2 allied health professionals) for face validity.

Then the questionnaire was pre-tested in face-to-face meetings with 10 patients.

The final questionnaire was then translated and cross-culturally adapted into English. The process included 2 separate translations, simple consensus, back-translation and cross-cultural validation by a multidisciplinary consensus committee (23-24).

Psychometric properties

Psychometric properties were examined according to the OMERACT filter (13), which checks that a potential outcome measure is (1) feasible, (2) truthful, *i.e.* reflects what it is supposed to reflect (validity), and (3) discriminant, which includes reliability and sensitivity to change. However, sensitivity to change was not assessed here.

Patients

Outpatients seen for RA in the rheumatology departments of the participating tertiary-care centres (in Grenoble, Paris, Rennes and Strasbourg) were included between December 23 2009 and March 30 2010. Selection criteria were: definite RA according to the American College of Rheumatology (21), ability to fill in a questionnaire, and signed informed consent (convenience sample). We aimed for heterogeneity in terms of demographic characteristics (age, sex, disease duration). There were no criteria regarding marital status, for inclusion in the study.

Table I. Aspects of sexuality on which RA has an impact according to 6 people with RA participating in a focus group.

Domain	Number of items	Items
Psychological issues / self-esteem	9	- Self-esteem - Image of self, image projected to others - Culpability - Depression - Fatigue influencing desire - Pain influencing desire - Feeling a burden - Being very self-centred (around the disease), fixation on disease - Feeling weak
Couple / relationship issues	9	- Complicity - Getting along well - Tenderness - Communication within the couple - Reciprocal feelings - Getting along well intellectually - The partner's attention, too much attention from the partner, inequality in the couple - Image sent back by the partner - Comprehension of the disease by the partner
Physical issues	7	- Pain during intercourse - Fatigue - Sexual performances, erection for man - Fear on the partner's part to hurt physically - Possibility of having / of taking care of children - Physical deformities - Difficulties with certain sexual positions
General aspects	5	- Effects of medications (or perceived effects) on libido/desire - Duration of disease - Duration of the relationship - Coping - The way one feels perceived by partner / by society

Design

Cross-sectional study with a longitudinal component for reliability. This multi-centre observational study was conducted in 5 centres. All applicable regulations were respected, informed consent was obtained from each patient and the project was in accordance with ethical standards in France.

The patients filled in a questionnaire comprising Qualisex and additional information: demographic data (age, sex), the RA impact of disease scale (RAID) (25), which assesses impact of RA on 7 domains of health and includes a pain and a fatigue numeric rating scale, NRS (scores are 0–10, high values reflect high impact of RA), the modified health assessment questionnaire (mHAQ) (26, 27), a score to assess anxiety and depression, the Hospital Anxiety and Depression Scale (28) (scored 0–21 for anxiety and depression), a coping questionnaire, the Arthritis Helplessness index, AHI (29) scored 0–25, patient global assessment of disease activity by visual analogue scale (VAS), and the SF-36 (30). The SF-36 is a widely used, self-administered, generic instrument for the assessment of health status, and comprises eight subscales (low values reflect poor health) (31). In parallel, demographic and disease variables were collected by the physician (rheumatoid factor and anti-cyclic citrullinated protein status, current treatment), and also joint counts and laboratory tests that allowed calculation of the Disease Activity Score (DAS28 with erythrocyte sedimentation rate, ESR) (32).

Table II. Qualisex questionnaire.

The following questions are about how rheumatoid arthritis affects your sex life. Please circle the number which best reflects your experience over the last 3 months.

1. Over the last 3 months: has your sex life suffered as a result of your health condition?

Not at all	0	1	2	3	4	5	6	7	8	9	10	Very much so

Not applicable ☐

2. Over the last 3 months: has your sex life suffered as a result of the treatment that you have received for rheumatoid arthritis?

Not at all	0	1	2	3	4	5	6	7	8	9	10	Very much so

Not applicable ☐

3. Over the last 3 months: have you experienced a loss of libido (sex drive) as a result of your health condition?

Not at all	0	1	2	3	4	5	6	7	8	9	10	Very much so

Not applicable ☐

4. Over the last 3 months: has your sexual performance suffered as a result of your health condition ?

Not at all	0	1	2	3	4	5	6	7	8	9	10	Very much so

Not applicable ☐

5. Over the last 3 months: has your relationship with your partner become more difficult as a result of your health condition?

Not at all	0	1	2	3	4	5	6	7	8	9	10	Very much so

Not applicable ☐

6. Over the last 3 months: have you felt a loss of self-esteem within your relationship?

Not at all	0	1	2	3	4	5	6	7	8	9	10	Very much so

Not applicable ☐

7. Over the last 3 months: has your health condition made you feel less sexually attractive?

Not at all	0	1	2	3	4	5	6	7	8	9	10	Very much so

Not applicable ☐

8. Over the last 3 months: has your sex life suffered as a result of the pain caused by rheumatoid arthritis?

Not at all	0	1	2	3	4	5	6	7	8	9	10	Very much so

Not applicable ☐

9. Over the last 3 months: has your sex life suffered as a result of being tired (fatigue)?

Not at all	0	1	2	3	4	5	6	7	8	9	10	Very much so

Not applicable ☐

10. Over the last 3 months: has your sex life been satisfactory overall?

Not at all	0	1	2	3	4	5	6	7	8	9	10	Very much so

Not applicable ☐

The Qualisex score is calculated as follows:
A. Sum = result question 1 + result question 2 + result question 3 + result question 4 + result question 5 + result question 6 + result question 7 + result question 8 + result question 9 + (10 - result question 10).
B. Qualisex = Sum / 10
Thus Qualisex is the mean of the results for the 10 questions (but question 10 is scored on an opposite scale). The final Qualisex is on a 0-10 scale where higher scores indicate more impact of RA on sexuality.
Missing data: if only 1 of the 10 questions is unanswered (or answered as not applicable), the Qualisex score is the mean of the other 9 questions: proceed as above but ignoring the missing result and divide the Sum by 9. If 2 or more questions are unanswered, the score cannot be calculated.

Assessment of validity ('truth') of Qualisex

Face and content validity was assessed cross-sectionnally by correlations with other disease aspects, in the absence of a gold standard assessment for sexuality. We hypothesised there would be moderate correlations with disease activity (RAID, pain NRS, fatigue, patient global, DAS28) and with functional status (mHAQ), less so with quality of life (SF36) and possibly with helplessness (AHI) and/or anxiety/depression (HADS). Scores were also compared according to sex.

Assessment of reliability

Patients for whom RA treatment was not changed and who were considered in a stable state by the physician were included in the reliability arm of the study. For that purpose, they filled in the questionnaire at home a second time 2–7 days after the baseline assessment.

Feasibility

Feasibility was assessed by missing data.

Statistical analyses

For the preliminary validation of the score, the objective was to include 50 patients, 10 per centre. SAS version 9.1 was used for statistical analyses.

Truth

Internal consistency was evaluated in the cross-sectional study using Cronbach's alpha coefficient. A Cronbach's value >0.7 is generally regarded as satisfactory (33). Construct validity was determined in the cross-sectional study by Spearman's correlation between Qualisex and the other measures detailed above.

Reliability

Evaluation of reliability used the intra-class correlation coefficient (ICC) (two-way model, single measure) with a 95% confidence interval (CI). An ICC of more than 0.8 is usually considered to be indicative of excellent reliability (34).

Results

Important aspects of impact of RA on sexuality

The patients who participated in the

focus group were 5 women and one man. Ages ranged from 29 to 71 years and RA duration ranged from 7 to 35 years.

An exhaustive list of issues relating to impact of RA on sexuality was obtained (Table 1). The list of aspects related to impact on sexuality included 30 aspects, categorised into psychological issues/self-esteem (n=9), couple/relationship issues (n=9), physical issues (n=7), and general aspects (n=5).

Qualisex

The list was brought down to 10 items according to the relative importance of the aspects. A 10-question questionnaire was constructed, with assessment by numeric rating scales (NRS) from 0 (no impact of RA) to 10 (full impact of RA) (Table II and III). The questionnaire contains 2 general questions, one question on negative aspects of medication, 2 on self-perception, 2 on couple/relationship, 2 on RA related physical difficulties and 1 on performance. A time frame of 3 months was chosen since the usual time frames for questionnaires (2–7 days) seemed too short to our patient partners, due to the irregular frequency of sexual events. An answer modality 'not applicable' was added to allow this questionnaire to be distributed to all patients, whatever their situation (single or with a partner); this question should be analysed as a missing answer. The finalisation process of the questionnaire led to some changes in wording and anchor points which appear in the final version which was then validated (Table II).

Psychometric properties

Preliminary validation was obtained on 53 patients (Table IV). The validation population was mostly female with long disease duration and moderate disease activity: 44 women, mean age 50.7±11.5 years; mean disease duration 14.4±8.6 years, mean DAS28: 3.5±1.5; 74% were rheumatoid factor or anti-cyclic citrullinated protein positive, 77.5% were taking methotrexate, 67.9% were on biologics (mainly tumour necrosis factor inhibitors, n=16, rituximab, n=8, or abatacept, n=6), 58.8% on corticosteroids, with a mean

Table III. French version of the Qualisex questionnaire.

Questionnaire de sexualité dans la PR

Ces questions concernent les conséquences de votre polyarthrite rhumatoïde sur votre vie sexuelle. Merci d'entourer le chiffre qui correspond le mieux à votre état, au cours des 3 derniers mois.

1. Au cours des 3 derniers mois: votre état de santé a-t-il été responsable d'une dégradation de votre vie sexuelle?

Pas du tout	0	1	2	3	4	5	6	7	8	9	10	extrêmement

Je ne suis pas concerné(e) ☐

2. Au cours des 3 derniers mois: les traitements que vous prenez pour votre polyarthrite ont-ils été responsables d'une dégradation de votre vie sexuelle?

Pas du tout	0	1	2	3	4	5	6	7	8	9	10	extrêmement

Je ne suis pas concerné(e) ☐

3. Au cours des 3 derniers mois: votre état de santé a-t-il été responsable d'une diminution de votre désir sexuel?

Pas du tout	0	1	2	3	4	5	6	7	8	9	10	extrêmement

Je ne suis pas concerné(e) ☐

4. Au cours des 3 derniers mois: votre état de santé a-t-il été responsable d'une diminution de vos performances sexuelles?

Pas du tout	0	1	2	3	4	5	6	7	8	9	10	extrêmement

Je ne suis pas concerné(e) ☐

5. Au cours des 3 derniers mois: votre état de santé a-t-il été responsable d'une dégradation de votre entente avec votre partenaire?

Pas du tout	0	1	2	3	4	5	6	7	8	9	10	extrêmement

Je ne suis pas concerné(e) ☐

6. Au cours des 3 derniers mois: vous êtes-vous senti(e) dévalorisé(e) vis à vis de votre partenaire ?

Pas du tout	0	1	2	3	4	5	6	7	8	9	10	extrêmement

Je ne suis pas concerné(e) ☐

7. Au cours des 3 derniers mois: votre état de santé a-t-il été responsable d'une diminution de votre pouvoir de séduction?

Pas du tout	0	1	2	3	4	5	6	7	8	9	10	extrêmement

Je ne suis pas concerné(e) ☐

8. Au cours des 3 derniers mois: les douleurs de la polyarthrite ont-elles été responsables d'une dégradation de votre vie sexuelle?

Pas du tout	0	1	2	3	4	5	6	7	8	9	10	extrêmement

Je ne suis pas concerné(e) ☐

9. Au cours des 3 derniers mois: votre fatigue a-t-elle été responsable d'une dégradation de votre vie sexuelle?

Pas du tout	0	1	2	3	4	5	6	7	8	9	10	extrêmement

Je ne suis pas concerné(e) ☐

10. Au cours des 3 derniers mois: avez-vous eu une vie sexuelle globalement satisfaisante?

Pas du tout	0	1	2	3	4	5	6	7	8	9	10	extrêmement

Je ne suis pas concerné(e) ☐

Table IV. Description of the population participating in the validation of the Qualisex questionnaire.

	Whole population	Women	Men
n. patients	53	44	9
Age, years	50.7 (11.5)	50.0 (11.7)	54.1 (10.2)
RA duration, years	14.4 (8.6)	15.3 (8.9)	10.3 (5.5)
RAID score (0–10)	4.4 (2.3)	4.5 (2.5)	4.0 (1.1)
Pain NRS (0–10)	4.3 (2.4)	4.4 (2.6)	4.1 (1.4)
Fatigue NRS (0–10)	5.1 (2.7)	5.1 (2.9)	4.7 (1.9)
Disease activity VAS (0–100)	42.0 (28.6)	42.3 (29.5)	40.4 (25.0)
Modified HAQ (0–3)	0.7 (0.6)	0.7 (0.7)	0.6 (0.5)
Arthritis Helplessness Index (0–25)	17.8 (4.3)	17.9 (4.3)	17.4 (4.8)
Hospital Anxiety Depression Scale			
anxiety (0–21)	10.4 (2.4)	10.4 (2.2)	10.4 (3.2)
depression (0–21)	9.1 (1.8)	9.3 (1.8)	8.3 (1.2)
SF36 physical summary scale, PCS (0–100)	34.7 (6.9)	34.3 (7.3)	36.8 (3.8)
SF36 mental summary scale, MCS (0–100)	33.9 (6.6)	34.2 (6.8)	31.8 (5.3)
Qualisex score (0–10)	3.3 (2.5)	3.5 (2.4)	2.4 (2.6)

Results are presented as mean (standard deviation). RAID score: RA impact of disease (25). NRS: numeric rating scale. VAS: visual analogue scale.

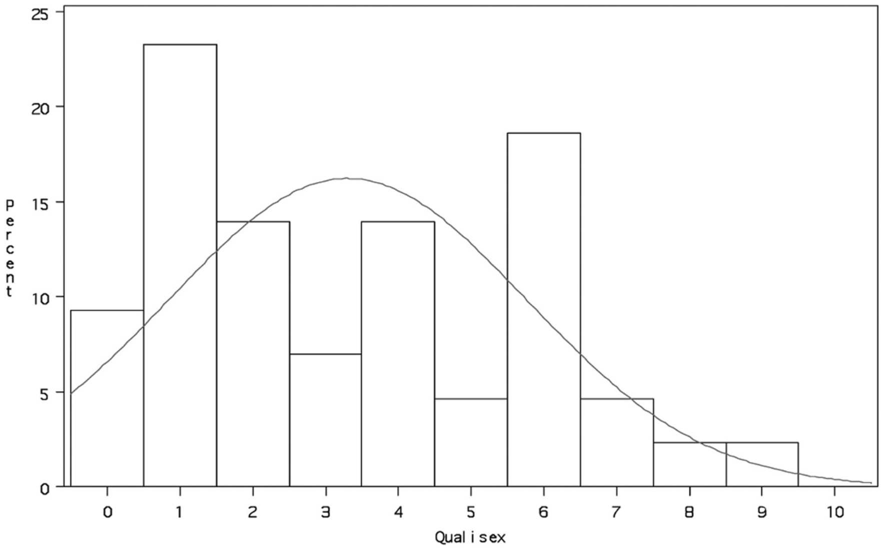

Fig. 1. Distribution of Qualisex scores in 53 patients. Higher scores indicate more impact of RA on sexuality.

dose of 6.7±4.2 mg/day. Of all patients, 8 (15.1%) had definite depression and 24 (45.2%) had definite anxiety according to the Hospital Anxiety and Depression Scale.

The Qualisex mean score was 3.3±2.5 and the distribution was similar in men and in women (Fig. 1). Cronbach's alpha was 0.93.

Missing data were acceptable (10 patients, 19%, had at least one missing answer, and 7 patients, 13%, had at least 2 missing answers; 'not applicable' being coded as a missing answer). The single question with highest missing answers was question 2 (8, 15%, missing). Missing data were stable for the second assessment (reliability). Furthermore, an imputation rule was devised and tested and results were similar (data not shown) (Table I).

Regarding correlations, Qualisex results were correlated with RAID (R=0.65, $p<0.0001$), DAS28 (R=0.55, $p=0.0004$), the physical summary scale of SF36 (-0.54, $p=0.0001$), fatigue numeric scale (R=0.55, $p<0.0001$), pain (0.53, $p=0.0001$) and mHAQ (R=0.50, $p=0.001$).

Correlations were less strong with disease duration (R=0.29, $p=0.0004$) and patient global assessment of disease activity (R=0.35, $p=0.017$). There was an inverse correlation with anxiety (R=-0.42, $p=0.007$).

There were no correlations with the mental summary scale of SF36, age, depression or helplessness and no association with sex (data not shown).

Qualisex was reliable in 40 patients (33 women, 7 men, mean age 51.6±11.3 years): the intra-class correlation coefficient was 0.83 (95% confidence interval: 0.70, 0.91). In these same patients, reliability of other scores was respectively 0.61 (0.38, 0.78) for the physical summary scale of SF36, 0.63 (0.41, 0.79) for the mental scale of SF36, 0.67 (0.45, 0.81) for HADS, 0.85 (0.73, 0.92) for RAID, and 0.92 (0.85, 0.96) for mHAQ.

Discussion

In the present study, a working group comprising 6 patients developed a simple (10 NRS) and valid tool investigating impact of RA on sexuality, Qualisex. The originality of Qualisex resides both in its elaboration and its scoring. As this questionnaire was elaborated with a group of patients, Qualisex reflects patient preferences in terms of aspects of sexuality assessed and wording. This is important particularly in a sensitive area of research such as sexuality. Furthermore, the quantitative scoring of Qualisex, from 0 (no impact of RA on sexuality) to 10 (maximal impact of RA on sexuality) will allow a quantitative evaluation of the impact of RA, and of RA treatment on the sexual life of patients. Qualisex has undergone preliminary validation and was shown to be reliable and correlated to disease activity; missing data were low indicating that this questionnaire was perceived as acceptable by people with RA.

The originality of this questionnaire is the implication of patients in the development of this outcome measure, which is a way to obtain better acceptability for the outcome measure and is in keeping with recent standards for development of patient reported outcomes (17, 19, 20). A weakness is the small sample size included in the validation of the questionnaire. However, the objective was to perform preliminary validation of the psychometric properties of this questionnaire, which has rarely been performed before in the field of sexuality (6, 9); and furthermore, we included the number of patients planned and reliability was obtained on 30 patients and was shown to be high. This study was a national study performed in France; this may impact the questionnaire since sexuality and its expression may vary across countries (35, 36). However, this limitation is one which can always be said of all qualitative studies with patient involvement (17, 37); and the validation of the questionnaire was performed in a multicentre study, thus heightening external validity. The timeframe chosen for the questions (3 months) is much longer than is usual for patient-reported outcomes (1, 26, 27) and may lead to memorisation bias (38). However, it was felt by the patients participating in the elaboration that a time frame of one week or so was not relevant for sexual activity. This long time frame may lead to lower sensitivity to change; this should be further assessed.

The impact of RA on sexual life is well recognised. In studies, sexual problems appear to affect 30 to 70% of RA patients (9). Various factors, such as physical, social or psychological problems, are susceptible to influence sexuality. Moreover, sexuality is complex, with different aspects, such as sexual ability, sexual satisfaction and sexual activity (39). Self-management also plays an important role, as recently shown by Helland *et al*. (40). In previous studies, there are discrepancies about which factors could influence sexuality of RA patients; this could be due to the phrasing of the questions in the absence of a validated questionnaire. In the first studies about sexuality problem in RA, importance was given to failure of women satisfaction during sexual intercourse (41) and to the importance of joint involvement and hip pain on sexual life (42). More recent works have explored the impact of various factors on sexual life. With a self report questionnaire given to 57 RA patients, Hill *et al*. found that fatigue had a major impact on sexuality, followed by pain and reduced physical function (6). The questionnaire used by Hill *et al*. explored various domains of sexual life, as does Qualisex, but with yes/no responses leading to loss of information. In the ORAR (Oslo RA Register) cohort of RA patients from Norway, the response of 830 patients to a postal questionnaire showed a significant correlation between sexual disability and disease (35). In that study, perceived impact on sexual activity was associated with male gender, younger age, fatigue, mental distress, and HAQ score. In a cohort of Egyptian RA (36), sexual disability was significantly correlated with the Disease Activity Score, HAQ, and hip pain, but not with psychological factors. In the same study, the loss of sexual desire or satisfaction was correlated with depression.

It is of interest to consider the difference in sexual difficulties, in patients and controls. The comparison of sexual satisfaction between patients with rheumatic diseases, (mostly RA), and controls did not show differences (7, 40). However, patients with rheumatic disease had more difficulties in their sexual life, in relation with pain, stiffness, and fatigue (7, 40). Qualisex is representative of different aspect of the sexual difficulties in RA, and could help to analyse which RA factors could impact the sexual life of the patients.

Validation of Qualisex among 53 RA patients showed a significant correlation between Qualisex and RA activity scores. The correlation of Qualisex with RAID is not surprising, since both of them are patient-derived, patient reported outcomes measuring disease impact. Correlations were also observed between Qualisex and fatigue, pain and disability (modified HAQ). Qualisex was also well correlated to the DAS28, which is considered as the gold standard for RA clinical activity. This result suggests that Qualisex could be a good indicator of disease activity, and possibly of treatment efficacy.

The relationship between fatigue and sexual problems is of interest. Both of these factors are associated with physical, psychological and social domains (44) and are often under evaluated by physicians and of first importance by the patients. Fatigue in RA has been associated with sleep disturbance, physical disability, pain depression (45) and it is considered as an important parameter in the evaluation of new treatments (20, 45).

On the other hand, in this preliminary validation of Qualisex, no significant correlation was observed with demographic data. This preliminary result needs to be confirmed, since differences between men and women have been observed in some studies. The absence of association with depression and coping suggests that the questionnaire assesses aspects of sexuality which are possibly more associated with the RA process than with psychological well-being.

Qualisex was elaborated with and for RA patients. Little is known about the characteristics of RA difficulties in sexual life compared to other inflammatory disorders (40). Sexual problems in spondyloarthritis have been associated with disability (47) and erection dysfunction (48). In adult with juvenile arthritis, self-esteem seems to be very important (49). In lupus patients, the severity of the disease was associated with more impairment in sexual function (50). As these different problems were also raised in RA, it could be interesting to test Qualisex in other rheumatic diseases.

In conclusion, Qualisex is a new questionnaire to assess impact of RA on sexuality. It will allow assessment of this important aspect of quality of life, both in observational studies and in trials, for example to assess the efficacy of oriented interventions or of biologics on sexual life. Future studies need to address sensitivity to change of Qualisex.

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