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The Fertility Quality of Life Questionnaire (FertiQoL) Relational subscale: psychometric properties and discriminant validity across gender

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STUDY QUESTION: Is the Fertility Quality of Life Questionnaire (FertiQoL)—Relational Scale a valid measure to assess the relational domain regarding quality of life in women and men undergoing infertility treatment?

SUMMARY ANSWER: The FertiQoL-Relational scale (FertiQoL-REL) showed good psychometric properties and captured core aspects of couple relationships.

WHAT IS KNOWN ALREADY: FertiQoL has become a gold standard for the assessment of infertility-related quality of life in patients undergoing assisted reproduction treatment (ART). Despite its growing importance, no previous studies have examined the convergent validity of the FertiQoL-REL and its discriminant validity across gender.

STUDY DESIGN, SIZE, DURATION: Baseline cross-sectional data as part of a longitudinal study of infertile couples undergoing an ART between February 2013 and January 2015.

PARTICIPANTS/MATERIALS, SETTING, METHODS: Five hundred and eighty-nine patients (301 females and 288 males), prior to starting an ART in a private clinic, filled in the Fertility Quality of Life Questionnaire (FertiQoL) and several measures of the marital relationship (Dyadic Adjustment Scale, Marital Commitment Inventory and ENRICH Marital Satisfaction Scale) and infertility-related distress (Fertility Problem Inventory).

MAIN RESULTS AND THE ROLE OF CHANCE: Confirmatory factor analysis showed that the FertiQoL four-factor solution provided a good fit for the observed data. Reliability of the FertiQoL-REL was higher for women than men. Significant correlations between the FertiQoL-REL scores and all the other measures of marital relationship were found for both women and men. FertiQoL-REL scores did not differ significantly in women and men. The FertiQoL-REL was able to differentiate subjects as regards the Dyadic Adjustment Scale and ENRICH Marital Satisfaction Scale threshold.

LIMITATIONS, REASONS FOR CAUTION: Findings are limited because the data were obtained from only one Italian private clinic.

WIDER IMPLICATIONS OF THE FINDINGS: FertiQoL-REL threshold scores are useful for identifying those patients undergoing ART who are more likely to report poor or good relationship quality. Clinicians should tailor their counselling strategies to the positive qualities in a couple's relationship, so as to reinforce the overall quality of life, especially among women, and to support patients in tackling the psychological burden, so that they can either continue treatment or choose discontinuation.

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Introduction

Previous research has consistently demonstrated that dealing with infertility and assisted reproductive treatment (ART) has a significant impact on a person's well-being and life satisfaction (Verhaak *et al.*, 2007; Greil *et al.*, 2011; Matthiesen *et al.*, 2011) and can trigger relational difficulties in couples who have to adjust to a highly stressful condition (Peterson *et al.*, 2003). Furthermore, research evidenced that infertile patients, apart from the physical burden, experience two core infertility-related stress domains associated with their clinical condition; the first one is related to patients' interpersonal (social, relational and marital) experience, and the second one is connected to the importance of parenthood in a couple's life (Moura-Ramos *et al.*, 2012; Donarelli *et al.*, 2015). Interpersonal and relational aspects also became core domains of the assessment of infertility-related quality of life (QoL) (Boivin *et al.*, 2011a,b).

The QoL construct in infertility embeds several core dimensions (physical, emotional, social, relational and sexual; Boivin *et al.*, 2011a,b), which impact differently on women and men's lives (Chachamovich *et al.*, 2010). Although the impact of infertility on an individual's QoL is still a matter for debate (Luk and Loke, 2015), there is substantial evidence on infertile patients' decreased scores on QoL tools (Chachamovich *et al.*, 2009) as well as on the association between infertile couples' QoL and their emotional distress (anxiety and depression), low self-esteem and marital satisfaction (Aarts *et al.*, 2011; Keramat *et al.*, 2014).

In recent years, QoL specific (infertility-related) assessment questionnaires were developed, which were shown to capture the key life domains in people suffering from infertility better than generic QoL tools such as the SF-35 or the WHO-QOL (Mousavi et al., 2013). The Fertility Quality of Life (FertiQoL) questionnaire (Boivin et al., 2011a,b) is a multi-dimensional instrument that aims to evaluate QoL in individuals experiencing infertility problems, and it has quickly become a gold standard for the specific measurement of QoL in theoretical and clinical infertility issues. FertiQoL includes two forms: the Core FertiQoL and the (optional) treatment module, which assesses QoL during treatment. The Core FertiQoL measures four domains of fertility problems: emotional, mind-body, relational and social (Boivin et al., 2011a,b). The emotional domain measures the extent to which the infertility condition impacts on an individual's emotions (e.g. to what extent infertility may cause sadness, grief, resentment); the mind-body domain measures the impact of the infertility condition on physical health (e.g. pain, fatigue), cognition (e.g. poor concentration) and behaviour (e.g. disrupted daily activities); the social domain measures the impact of infertility condition on social aspects (e.g. social inclusion, friend support, dealing with other pregnant women); the relational domain measures the extent to which components of the marital partnership have been affected by fertility problems (e.g. difficulties in communication, commitment, a satisfying sexual relationship, affection). The relational domain, which will be specifically investigated in the current study, underlies a particular area of individual QoL that is specific for the infertility condition and that differs from generic assessment of marital relationship or social distress. Whereas the marital relationship measurement is usually focused on the assessment of factors such as spousal support, reciprocity, emotional expression, parenting (Bradbury et al., 2000), the FertiQoL is the only QoL scale which provides a specific assessment of the extent to which the burden due to the infertility condition impacts on a partnership. Certain widely-used QoL assessment instruments, such as the WHOQOL-Bref (WHOQOL group, 1998), provide a social relation-ship domain, which includes items tapping social support, interpersonal relationships and sexual life (Chachamovich et al., 2009). A specific infertility-related QoL measure, such as the FertiQoL, provides different scores for the relational and social domains, the former assessing the impact of the infertility burden on a couple's relationship, communication, commitment, sexual satisfaction, and the latter assessing the impact of the infertility burden on perceived support from family and friends, social isolation and stigmatization, shame and embarrassment in the presence of pregnant women.

The FertiQoL has been validated in various countries (see www. fertiqol.org), showing good overall psychometric characteristics (e.g. Aarts et al., 2011). For example, Melo et al. (2012) reported good evidence for the construct validity of the FertiQoL Portuguese version and its invariance across gender, by examining the associations between FertiQoL scores and other QoL measures, psychological wellbeing assessment, as well as intentions to persevere with ART.

Nevertheless, to our knowledge no previous studies have examined the psychometric properties of the FertiQoL relational subscale (FertiQoL-REL) with in-depth analysis. Despite the fact that previous factorial analyses on the structure of the FertiQoL confirmed its construct validity (Boivin et al., 2011a,b; Melo et al., 2012), with items conceptualized to tap into the concepts with high factor loadings (>0.30) on their designated factor (Boivin et al., 2011a,b), the internal consistency values of the FertiQoL-REL ranged between 0.20 and 0.80 across studies (Boivin et al., 2011a,b; Melo et al., 2012; Hsu et al., 2013), and they were generally lower than the values for the other Core-FertiQoL scales (Aarts et al., 2011; Pedro et al., 2013). Moreover, no studies specifically examined the correlation between the FertiQoL-REL and wellvalidated measures of a couple's relational functioning. Most previous studies only reported the association between FertiQoL-REL and the individual's psychosocial distress. Aarts et al. (2011) found a weaker correlation between the FertiQoL-REL domain and emotional distress (anxiety and depression) than the other FertiQoL subscales in a sample of patients attending ART. Also Melo et al. (2012) found lower, albeit significant, correlations between FertiQoL-REL and depression and anxiety than the other FertiQoL subscales. Some studies reported the association between the FertiQoL subscales and social domains measures. In the Lopes et al. (2014) study, the FertiQoL-REL was positively correlated with social support and acceptance cognitions measured by the SCREEN-IVF, whereas in the Pedro et al. study (2013) the FertiQoL-REL (as well as the other FertiQoL subscales) was associated with the communication and respect scores of the patient-centred care (PCC). However, data on the concurrent validity of the FertiQoL-REL are still lacking.

The quality of a couple's relationship, with individuals experiencing stress due to their condition of infertility, is still a matter for debate.

Despite there being evidence that infertility impacts differently on women than on partners, there is actually a dearth of research regarding the intra-couple effects of infertility on relationship issues. Only two previous studies examined infertile couples' relational and social QoL domains from a dyadic perspective. Chachamovich *et al.* (2009) found a discrepancy between partners in the social relationships domain, whereas Huppelschoten *et al.* (2013) reported no differences in FertiQoL-REL across gender. All other studies on the FertiQoL did not report FertiQoL-REL scores across gender because samples mainly included female participants. Considering these mixed findings, the current study investigated whether both members in infertile couples, experience different relational QoL when undergoing infertility treatment.

The first aim of the current study was to examine the psychometric properties of FertiQoL-REL and its relationship with measurements of marital functioning (dyadic adjustment, marital satisfaction and marital commitment) and sexual infertility-related stress in infertile couples. We offered the following hypotheses:

- (a) the FertiQoL-REL scores fit well with the original model, supporting the soundness of the four factor solution of the measure (emotional, mind-body, social and relational) through a confirmative factor analysis (CFA); it was also expected that the FertiQoL-REL scale would show adequate internal consistency values.
- (b) given that the items of the FertiQoL-REL relate to intimacy, commitment, communication and satisfaction, it was hypothesized that the FertiQoL-REL scores would be associated with the other marital relationship measures, which tap into each of these constructs.

Secondly, the study aimed to test the discriminant validity of the FertiQoL-REL scale with regard to the patient's gender. It was hypothe-sized that:

- (a) couples experiencing infertility and undergoing ART would not report different levels of impairment in FertiQoL-REL across gender, given that the infertility condition impacts on the quality of marital relationship in women as well as men.
- (b) moreover, we expected no gender differences in the correlations between the FertiQoL-REL and the other selected measurements of a couple's relationship.

Finally, both partners' average in FertiQoL-REL scores, which corresponds to the threshold of poor or high marital quality, will be provided.

Materials and Methods

Participants

Participants were recruited as a part of a larger longitudinal study that involved infertile couples undergoing intrauterine insemination (IUI) or in vitro fertilization (IVF) treatment at ANDROS Day Surgery Clinic, Reproductive Medicine Unit (Italy), between February 2013 and January 2015. For this cross-sectional study, the eligibility criteria were as follows: starting an ART (IUI or IVF), primary infertility, and adequate understanding of Italian language. The final sample comprised 589 subjects (301 females and 288 males). Table I shows the sample participants' socio-demographic, clinic and treatment characteristics.

	Females (n = 301) Mean <u>+</u> SD or n (%)	Males (n = 288) Mean <u>+</u> SD or n (%)
Age	34.9 ± 5.03	37.8 ± 5.7
Education		
6–8 years of school	68 (22.7)	79 (27.4)
9–13 years of school	141 (46.8)	144 (50.0)
College education	92 (30.5)	65 (22.6)
Professionally employed (YES)	180 (59.8)	265 (92.0)
	Couples ($n = 322$) Mean \pm SD or n	(%)
Duration of infertility (years)	4.0	<u>+</u> 3.37
Number of actual attempts	1.6	<u>+</u> 1.16
Cause of infertility		
Male factor	3	(40.7)

76 (23.6)

29 (9.0)

86 (26.7)

43 (13.4)

279 (86.6)

Table | Participants' socio-demographic, clinic and

treatment characteristics.

Ethical approval

Female factor

Unexplained

Type of ART

IUI

IVF

Male and female factor

The Research Ethics Committee of the ANDROS Day Surgery Clinic approved the study protocol and all couples were recruited voluntarily; they also gave their written informed consent to participate in the study.

Measures

Patients completed the following questionnaires prior to the beginning of the ART: the FertiQoL questionnaire, the Dyadic Adjustment Scale (DAS), the Commitment Inventory, the Fertility Problem Inventory-*Sexual Concern* Subscale (FPI-Sex) and the ENRICH Marital Satisfaction Scale (EMS).

The Core module of the FertiQoL (Boivin *et al.*, 2011a,b) was used to measure QoL in individuals experiencing fertility problems. Core FertiQoL consists of 24 items scored according to 5 response categories (range 0–4) and yields 4 subscales: mind-body (6 items), relational (6 items), social (6 items) and emotional (6 items). High scores on the total FertiQoL scale or any subscale mean a better QoL (Boivin *et al.*, 2011a,b). As previously mentioned, the FertiQoL showed good overall psychometric characteristics (e.g. Aarts *et al.*, 2011; Boivin *et al.*, 2011a,b; Melo *et al.*, 2012) with different clinical populations.

The DAS (Spanier, 1976) is a 32-item self-report measurement of global marital adjustment. For this study only two subscales were used: the Dyadic Consensus subscale and the Dyadic Cohesion subscale. The Dyadic Consensus subscale (13 items) evaluates the degree to which respondents agree with partners. The Dyadic Cohesion subscale (five items) evaluates the degree to which respondent and partner participate in activities together. The DAS has well-documented reliability and validity and had

good internal consistency in the present study (Cronbach's $\alpha = 0.85$ and 0.66 for Dyadic Consensus and Dyadic Cohesion, respectively).

The Marital Commitment Inventory (MCI; Stanley and Markman, 1992; it.tr. Maino and Resta, 1999) was used to measure the desire of the individual in each couple to maintain or improve the quality of his or her relationship. For the purposes of the present study only two subscales were used: the Relationship Agenda subscale and the Couple Identity subscale. The Relationship Agenda (six items) subscale evaluates the individual's desire that his/her relationship may continue into the future, which many researchers consider the essential component of commitment. The Couple Identity (six items) subscale evaluates the degree to which an individual thinks of the relationship as a team, instead of viewing it as two separate individuals. In the Italian version of the questionnaire, participants rate items on a four-point Likert scale ranging from 1 (*completely true*) to 4 (*completely false*). In the present study, Cronbach's α was 0.68 for the Relationship Agenda subscale and 0.62 for the Couple Identity subscale, respectively.

The Fertility Problem Inventory (FPI, Newton *et al.*, 1999) is a 46-item scale that evaluates perceived infertility-related stress and identifies domains of stress specific to infertility (e.g. sexual and social concerns). Participants rate items on a six-point Likert scale ranging from I (*Strongly disagree*) to 6 (*Strongly agree*). For this study only the Sexual Concerns subscale was used. The Sexual Concerns subscale (eight items) evaluates the degree to which sexual enjoyment or sexual self-esteem has changed (due to scheduled sex) and thus act as a stressor. In the present study, Cronbach's α was 0.76 for the Sexual Concerns subscale.

The ENRICH Marital Satisfaction Scale (EMS; Olson *et al.*, 1987; Fowers and Olson, 1993) was used to assess marital quality. This 15-item self-report questionnaire yields scores on 2 subscales: Marital Satisfaction (10 items) and Idealistic Distortion (5 items). Participants rate items on a scale ranging from I (*Strongly Disagree*) to 5 (*Strongly Agree*). In the current study the EMS revealed good internal reliability (Cronbach's α coefficient was 0.67 for the Marital Satisfaction subscale and 0.67 for the Idealistic Distortion subscale).

Statistical analyses

Descriptive statistics (mean and standard deviations) and bivariate correlation coefficients between variables were examined. The internal consistency between items within each measure was determined by calculating Cronbach's a. Using AMOS version 18 (IBM, Crawfordville, FL, USA), a confirmatory factor analysis (CFA) was performed to assess the robustness of the four-factor model of the FertiQoL and particularly of its Relational subscale (Boivin et al., 2011a,b). The study has a participant per parameter ratio of 7:1. The model tested used maximum likelihood estimation (ML). The following indices were used to evaluate the overall goodness of fit of the model: the χ^2 test statistics (χ^2 /df ratios <3 indicate reasonable fitting models), the comparative fit index (CFI, with values of 0.90 or over indicating better fitting models) and the root-mean-square error of approximation (RMSEA, with values of 0.01 or less indicating an excellent fit, values of 0.05 or less indicating a good fit, and values greater than 0.08 are indicative of a poor fit) (MacCallum et al., 1996). Convergent validity was established using Spearman's correlation coefficient among FertiQoL-REL items and standardized measures of marital relationship (DAS, MCI and EMS) and sexual infertility-related distress (FPI-Sex). Gender subgroup analyses were conducted by Paired sample t-tests to examine differences between males and females on FertiQoL scores, and the r Pearson correlation coefficient; this was followed by partial correlation controlling for dyad effect (couples), to determine associations among variables. Effect sizes were calculated using Cohen's d to indicate the magnitude differences. Cohen's effect sizes are understood as negligible (≥ -0.15 and <0.15), small $(\geq 0.15 \text{ and } < 0.40)$, medium $(\geq 0.40 \text{ and } < 0.75)$ and large $(\geq 0.75 \text{ and }$ 1.10) (Cohen, 1988). All the screening, preliminary and convergent validity analyses were conducted by using PASW version 17.0.

Results

Participants

Of the 1472 consecutive subjects (736 couples) that were referred to the Clinic for an ART, 1028 subjects (514 couples) met the inclusion criteria for this study and were recruited and invited to participate in the research. One hundred and sixty-six subjects (83 couples) clearly declined to participate due to a lack of interest. Of the 862 subjects (431 couples) who received the questionnaires, only 58 subjects (7%) did not return the questionnaires. One hundred and eighty-eight subjects were subsequently excluded due to incomplete data (>30% missing items on the questionnaires; M = 106, F = 82; 23%); 27 subjects (3%) were outliers (M = 14, F = 13). The final sample comprised 589 subjects (F = 301; M = 288; response rate 68%), of whom 558 were the components of the 279 couples.

Psychometrics properties of FertiQoL-REL

- (a) Confirmatory factor analysis (CFA) was performed to assess the soundness of the FertiQoL four-factor model and the FertiQoL-REL subscale. The hypothesized model, shown in Fig. I, provided a good fit with the observed data across all the fit indexes for the total group (589 subjects) ($\chi^2 = 746.862$; df = 240; $\chi^2/df = 3.11$; CFI = 0.914; GFI = 0.900; RMSEA = 0.060). All the standardized factor loadings of the FertiQoL items were between 0.13 and 0.84 (mean = 0.58) (see Fig. 1). The amount of variation (AVE, Average Variance Extracted) explained by the Emotional, Mind/Body and Social constructs ranged between 0.51 and 0.37. As regards the FertiQoL-REL, the standardized factor loadings of the six items of the subscale in the corresponding, latent construct, ranged from 0.18 to 0.69 and were statistically significant (at least P < 0.01). The AVE value of the Relational domains was 0.25, which was below the critical threshold of 0.50 (Fornell and Larcker, 1981). The discriminant validity of the subscale was supported, as the AVE value was greater than the shared variance (squared correlation estimate) between FertiQoL-REL and each of the other FertiQoL subscales (square of the correlation ranged from 0.08 to 0.11). Moreover, the AVE value of the FertiQoL-REL was equal to or larger than the shared variance between the FertiQoL-REL and the other related observed variables (DAS, FPI, EMS, MCI; the square of the correlation ranged from 0.09 to 0.25) (Fornell and Larcker, 1981).
- (b) Reliability analysis of the FertiQoL-REL showed an internal consistency of 0.65, and a Composite Reliability (CR) value of 0.63, which indicates an acceptable construct reliability (Fornell and Larcker, 1981). All the corrected-item total correlations for the six items of the FertiQoL-REL and the correlations between the FertiQoL-REL subscale and its overall score are statistically significant (data not shown). Furthermore, the FertiQoL-REL showed higher internal consistency values for women than for men (Cronbach's α : 0.68 and 0.61 for women and men, respectively). Post hoc analyses revealed that internal consistency could be slightly increased by removing item Q15 'Have fertility problems strengthened your commitment to your partner?'. Furthermore, this item also showed lower correlation with the overall score (r = 0.16 versus range 0.25-0.50) and a lower average score (M = 2.7 versus range 3.3–3.9) than the other five items of the FertiQoL-REL scale. Reliability analysis of the other FertiQoL subscales revealed a good internal

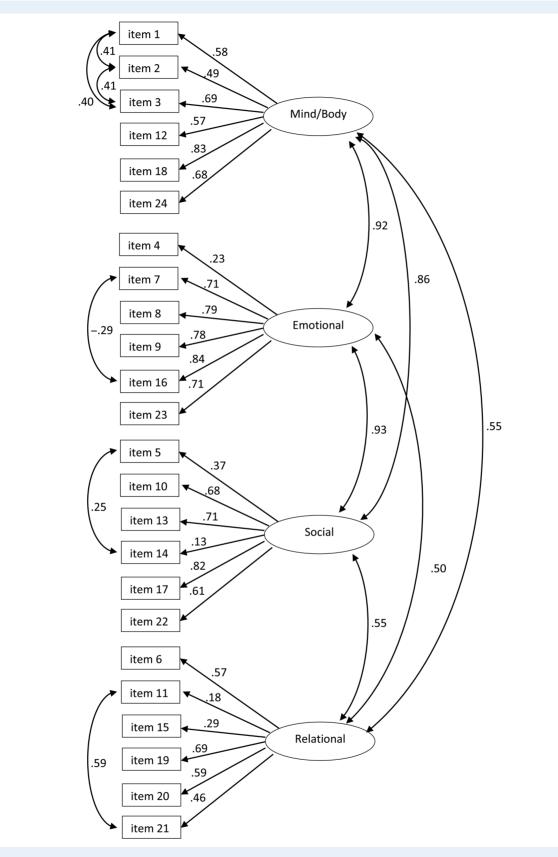


Figure 1 Fertility Quality of Life four-factor model. Numbers next to the arrows represent standardized factor loadings, correlations between factors and covariances between errors.

reliability (Cronbach's $\alpha = 0.83$, 0.70, and 0.83 for Mind/Body, Social and Emotional subscales, respectively).

(c) The correlations between the FertiQoL-REL and other measures of couple relationship (marital satisfaction_EMS, marital commitment_MCI, dyadic adjustment_DAS, and sexual stress_FPI-Sex) were all significant (P < 0.01) and in the expected direction for the overall sample (data not shown). The FertiQoL-REL showed positive associations with both the dyadic adjustment_DAS (r = 0.28 and 0.31, respectively for Consensus and Cohesion) and the marital satisfaction_EMS (r = 0.31 and 0.36, respectively for Idealistic Distortion and Marital Satisfaction) subscales. *Vice versa*, the FertiQoL-REL scores were negatively associated with the sexual stress FPI subscale (r = -0.48) and the two marital commitment_MCI subscales (r = -0.30 and -0.37, respectively for Relationship Agenda and Couple Identity).

Gender subgroup analyses on FertiQoL-REL scores

Both components of the couple (N = 558; 279 F and 279 M) were analysed to test the discriminant validity of the FertiQoL-REL across gender by controlling for dyadic effect. The partial correlations between the FertiQoL-REL and other measures of the couple's relationship all remained significant in the expected direction when the effect of the other component of the couple was partialled out (Table II). The same correlations were then carried out separately for women and men, and the results are in line with those of the overall sample, with the exception of the FertiQoL-Social scale, which was not associated with marital commitment (MCI_RA and MCI_CI) in men (Table III).

Table IV shows descriptive statistics and gender differences in Ferti-QoL, marital adjustment, marital satisfaction, sexual stress and marital

Table II Zero-order and partial correlations between Fertility Quality of Life Questionnaire (FertiQoL), Dyadic Adjustment Scale (DAS), ENRICH Marital Satisfaction Scale (EMS), Fertility Problem Inventory (FPI) and Marital Commitment Inventory (MCI) for total sample.

	Zero-orde FertiQoL	-			Partial [#] FertiQoL subscales						
	МВ	EMO	SOC	REL	тот	МВ	EMO	SOC	REL	тот	
DAS_CONS	0.328**	0.332**	0.237**	0.297**	0.375**	0.317**	0.347**	0.256**	0.311**	0.385**	
DAS_COHES	0.246**	0.203**	0.185**	0.326**	0.294**	0.240**	0.201**	0.185**	0.325**	0.291**	
ems_id	0.202**	0.214**	0.264**	0.468**	0.339**	0.196**	0.212**	0.265**	0.427**	0.336**	
EMS_MS	0.225**	0.228**	0.214**	0.504**	0.349**	0.225**	0.227**	0.214**	0.503**	0.349**	
FPI_SEX	-0.529**	-0.504**	-0.465**	-0.503**	-0.630**	-0.53I**	-0.504**	-0.465**	-0.503**	-0.630**	
MCI_RA	-0.211**	-0.185**	-0.190**	-0.379**	-0.290**	-0.204**	-0.183**	-0.190**	-0.378**	-0.286**	
MCI_CI	-0.225**	-0.213**	-0.196**	-0.396**	-0.308**	-0.220**	-0.211**	-0.196**	-0.396**	-0.306**	

FertiQoL subscales: MB, Mind/Body; EMO, Emotional; SOC, Social; REL, Relational; TOT, total score. DAS Dyadic subscales: CONS, Consensus; COHES, Cohesion. EMS subscales: ID, Idealistic Distortion; MS, Marital Satisfaction. FPI subscales: SEX, Sexual Concerns. MCI subscales: RA, Relationship Agenda; CI, Couple Identity. **P < 0.01

[#]Partialling out for couple.

Table III Correlations between Fertility Quality of Life Questionnaire (FertiQoL), Dyadic Adjustment Scale (DAS), ENRICH Marital Satisfaction Scale (EMS), Fertility Problem Inventory (FPI) and Marital Commitment Inventory (MCI) for females and males.

	FertiQoL s Females	scales			FertiQoL scales Males						
	MB	EMO	SOC	REL	тот	МВ	EMO	SOC	REL	тот	
DAS_CONS	0.355**	0.349**	0.339**	0.500**	0.458**	0.229**	0.189**	0.132*	0.255**	0.260**	
DAS_COHES	0.249**	0.201**	0.187**	0.382**	0.303**	0.249**	0.210**	0.180**	0.259**	0.296**	
EMS_ID	0.257**	0.267**	0.337**	0.457**	0.401**	0.132*	0.153*	0.170**	0.491**	0.296**	
EMS_MS	0.288**	0.306**	0.259**	0.579**	0.418**	0.134*	0.122*	0.144*	0.401**	0.250**	
FPI_SEX	-0.557**	-0.512**	-0.509**	-0.563**	-0.650**	-0.450**	-0.448**	-0.366**	-0.445**	-0.568**	
MCI_RA	-0.262**	-0.210**	-0.312**	-0.486**	-0.370**	-0.150*	-0.162**	-0.028	-0.243**	-0.190**	
MCI_CI	-0.307**	-0.294**	-0.299**	-0.497**	-0.409**	-0.153*	-0.155**	-0.081	-0.278**	-0.216**	

Abbreviations as in Table II. *P < 0.05.

**P < 0.01

Table IV Mean. SDs and differences between females and males.

	Females		Males					
	м	SD	м	SD	t	df	Р	Cohen's d
FertiQoL_MB	75.6	19.6	84.1	16.2	5.58	556	<0.001	0.47
FertiQoL_EMO	68.1	19.7	79.1	16.8	7.06	556	< 0.001	0.59
FertiQoL_SOC	73.3	17.3	78.4	14.2	3.84	556	< 0.001	0.32
FertiQoL_REL	85.2	14.7	86.3	12.6	0.93	556	0.456	0.07
FertiQoL_TOT	75.5	14.8	82.0	11.3	5.83	556	< 0.001	0.53
DAS_CONS	55.8	6.4	67.2	12.7	13.30	556	< 0.001	1.09
DAS_COHES	19.4	3.6	19.6	3.5	0.53	556	0.683	0.03
FPI_SEX	16.8	7.9	14.6	6.5	-3.68	556	< 0.001	-0.27
ems_id	93.9	12.5	94.3	11.5	0.53	556	0.632	0.06
EMS_MS	90.9	13.8	91.7	11.7	0.48	556	0.464	0.08
MCI_RA	1.1	0.3	1.1	0.3	0.73	556	0.718	0.05
MCI_CI	1.2	0.3	1.2	0.3	-0.36	556	0.466	-0.06

Abbreviations as in Table II.

Table V Fertility Quality of Life Questionnaire-Relational scale and critical threshold for Dyadic Adjustment.

		DAS_C	ONS				DAS_COHES						
		< cut-off (n = 83)		> cut-off (n = 196)				< cut-off (n = 98)		> cut-off (n = 181)			
		Mean	SD	Mean	SD	t	Р	Mean	SD	Mean	SD	t	Р
Females	FertiQoL_MB	67.4	21.4	79.1	17.7	-4.74	<0.01	71.0	20.7	78.1	18.6	-2.92	< 0.0
	FertiQoL_EMO	59.4	20.3	71.8	18.2	-5.05	< 0.01	64.3	19.5	70.2	19.5	-2.43	0.0
	FertiQoL_SOC	66.0	18.5	76.4	15.8	-4.76	< 0.01	70.0	18.6	75.0	16.3	-0.35	0.
	FertiQoL_REL	76.2	18.3	89.0	10.8	-7.03	< 0.01	80.3	17.6	87.9	12.0	-4.26	<0.0
	FertiQoL_TOT	67.2	16.0	79.0	12.7	-6.52	< 0.0	71.2	15.9	77.8	13.6	-3.65	<0.0
		< cut-of (n = 79)		> cut-off (n = 200)				< cut-off (n = 87)		> cut-off (n = 192)			
		Mean	SD	Mean	SD	t	Р	Mean	SD	Mean	SD	t	Р
Males	FertiQoL_MB	81.0	18.1	85.3	15.2	- I.90	0.06	77.5	18.3	87.1	14.2	-4.73	<0.0
	FertiQoL_EMO	76.3	17.4	80.2	16.5	-1.73	0.08	73.7	17.4	81.6	16.0	-3-71	<0.
	FertiQoL_SOC	77.4	15.2	78.8	13.8	-0.76	0.45	75.3	15.6	79.8	13.3	-2.50	0.
	FertiQoL_REL	83.0	14.4	87.6	11.5	-2.80	0.01	82.0	13.5	88.2	11.6	-3.93	<0.
	FertiQoL_TOT	79.4	12.5	83.0	10.6	-2.41	0.02	77.1	12.1	84.2	10.2	-5.04	<0.

Abbreviations as in Table II.

commitment scores. Interestingly, males and females did not report significant differences in the FertiQoL-REL (t = 0.93, P = 0.456), whereas the women's scores on the other Core-FertiQoL scales and overall score were lower than men's scores. *Vice versa*, women reported significantly higher scores on the FPI-SEX than men.

FertiQoL-REL and critical threshold for Dyadic Adjustment and Marital Satisfaction

Tables V and VI show the average FertiQoL scores that corresponded to the DAS (consensus and cohesion subscales) and EMS (idealistic distortion and marital satisfaction subscales) critical threshold. One hundred

and ninety-six (70.3%) females and 200 (71.7%) males met the DAS-Consensus cut-off (53.9 and 58.7 for females and males, respectively) and 181 (64.9%) females and 192 (68.8%) males met the DAS-Cohesion cut-off (18.3 and 18.4 for females and males, respectively). The average FertiQoL-REL scores of participants who met the DAS-Consensus critical threshold were 89.0 (SD = 10.8) and 87.6 (SD = 11.5) for females and males, respectively. The average FertiQoL-REL scores of participants who met the DAS-Cohesion critical threshold were 87.9 (SD = 12.0) and 88.2 (SD = 11.6) for females and males, respectively. When comparing patients with high and low dyadic adjustment, their FertiQoL-REL scores differed significantly. Females with high dyadic consensus and cohesion levels had significantly higher relational QoL (P < 0.01) and

		EMS_ID)					EMS_MS						
		< cut-off (n = 49)		> cut-off (n = 230)				< cut-off (n = 35)		> cut-off (n = 244)				
		Mean	SD	Mean	SD	t	Р	Mean	SD	Mean	SD	т	Р	
Females	FertiQoL_MB	65.5	20.1	77.7	18.8	-4.09	< 0.01	65.4	19.6	77.1	19.2	-3.37	< 0.0	
	FertiQoL_EMO	56.4	21.6	70.7	18.3	-4.79	< 0.01	56.1	20.1	69.9	19.0	-3.98	< 0.0	
	FertiQoL_SOC	62.1	19.7	75.7	15.8	-5.21	< 0.01	63.8	20.5	74.6	16.4	-3.53	< 0.0	
	FertiQoL_REL	71.4	19.6	88.1	11.4	-8.02	< 0.01	67.0	21.9	87.8	11.2	-8.87	< 0.0	
	FertiQoL_TOT	63.5	16.8	78.I	12.9	-6.78	< 0.0 I	63.1	17.0	77.3	13.5	-5.61	< 0.0	
		< cut-of (n = 59)		> cut-off (n = 220)				< cut-off (n = 50)		> cut-off (n = 229)				
		Mean	SD	Mean	SD	т	Р	Mean	SD	Mean	SD	т	Р	
Males	FertiQoL_MB	79.2	16.4	85.4	15.9	-2.62	0.01	80.4	16.2	84.9	16.1	— I.78	0.0	
	FertiQoL_EMO	73.6	18.3	80.6	16.1	-2.87	< 0.01	76.3	18.2	79.7	16.5	-I.28	0.2	
	FertiQoL_SOC	72.3	16.6	80.0	13.0	-3.81	< 0.01	74.9	17.8	79.2	13.2	— I.93	0.0	
	FertiQoL_REL	76.9	13.4	88.8	11.1	-6.98	< 0.01	77.2	16.3	88.2	10.7	-5.95	< 0.0	
	FertiQoL_TOT	75.5	12.5	83.7	10.3	-5.17	< 0.01	77.2	13.4	83.0	10.5	-3.34	< 0.0	

Table VI. Fertility Quality of Life Questionnaire-Relational scale and critical threshold for Marital Satisfaction.

also males with high dyadic consensus and cohesion levels reported significantly higher relational QoL (P = 0.01 and P < 0.01).

Two hundred and forty-four (87.5%) females and 229 (82.1%) males met the EMS-Marital Satisfaction critical threshold (36.5 and 39.7 for females and males, respectively). The average FertiQoL-REL score of participants who met the EMS-MS threshold was 87.8 (SD = 11.2) and 88.2 (SD = 10.7) for females and males, respectively. Patients with high versus low marital satisfaction reported significantly different scores on the FertiQoL-REL (P < 0.01).

Discussion

The current study is the first to examine the psychometric properties of the FertiQoL-REL scale in a paired sample of women and men attending ART. Consistently with the study's hypotheses, the current results supported the construct and discriminant validity of the FertiQoL-REL, even though one item (Q11) has a low factor loading and another one (Q15) has a low correlation with the overall score. Although the FertiQoL hypothesized four-factor model provided a good fit with the observed data, in accordance with previous research (Boivin *et al.*, 2011a,b; Melo *et al.*, 2012), four items of the FertiQoL had low factor loadings in their latent constructs. Previous studies regarding the structure of the questionnaire had been conducted by explorative factor analysis (Boivin *et al.*, 2011a,b) or by the CFA, combining items into parcels (Melo *et al.*, 2012); this limits comparability of the results of the current study, warranting further research on this important topic.

It is important to note that the internal consistency of the FertiQoL-REL scale was only partially satisfying, with higher α values for women than for men. Previous studies evidenced that the internal consistency of the FertiQoL-REL scale is generally lower than other Core-FertiQoL scales, and the Dutch and Portuguese samples reported only slightly better alphas (0.72) for the FertiQoL-REL than those reported in the current study (0.65). However, the item-total correlations of the six items of the FertiQoL-REL scale are quite good in the current sample.

Further international studies are needed to test whether, as suggested by the current findings, the deletion of poor-correlated items (i.e. the Q15) can be useful for reliably improving the internal consistency of this subscale.

In relation to the convergent validity of the FertiQoL-REL, the correlational analysis of the current study showed that the FertiQoL-REL scores are strongly associated with other measures of couple relationship, such as marital satisfaction, couple adjustment, marital commitment and sexual stress. These results seem to support the validity of the FertiQoL-REL in tapping core aspects of couple relationship, such as commitment, communication, satisfaction and sexuality concerns, both for women and men.

In relation to the analysis of gender differences on the FertiQoL-REL some interesting results are worth discussing. First, no differences were found between women and men on the FertiQoL-REL scores. Although women reported lower QoL scores on all the other domains, the FertiQoL-REL scores were the only ones which did not differ across gender. Consistently with this finding, no differences were found on marital satisfaction, couple commitment and cohesion across gender. These findings are also in line with a previous study on infertile couples' QoL, measured by the FertiQoL, which found that the FertiQoL-REL scores did not differ across partners (Huppelschoten et al., 2013). Our study adds to this previous one in that both members of the couple did not also differ on marital satisfaction, cohesion and commitment, thus improving the validity of the FertiQoL-REL scores. It is also noteworthy that at the present time two independent studies on the FertiQoL with dyadic data showed the same pattern of results in different cultural contexts.

Moreover, the results of the current study evidenced that men reported higher overall QoL scores than women, and this finding seems consistent with previous literature which showed that women generally report a worse adjustment to the infertility condition and higher infertility-related stress than men (Donarelli *et al.*, 2012; Huppelschoten *et al.*, 2013; Lopes *et al.*, 2014). The perceived relationship quality seemed to move differently from other QoL domains. In accordance with previous studies (Aarts et al., 2011; Boivin et al., 2011a,b; Lopes et al., 2014), the FertiQoL-REL scores were higher than those of the other FertiQoL scales, showing that relational QoL did not seem to be impaired in either component of the couple. This finding seems to be in line with previous research which showed that the infertility condition affects the relationship of both members of the couple, and that both partners who initiate ART have a strong commitment to each other and a mutual desire for parenthood (Hammarberg et al., 2008). In a previous study with a paired sample (Chachamovich et al., 2009), it was shown that men reported worse scores on the social relationships QoL domain than women. The different measures adopted in the two studies could account for these different results; in the Chachamovic et al. study, the social relationship scale of a non-specific infertility-related QoL instrument was used (the WHOQOL-Bref), which includes items on interpersonal relationships, social support and sexual life, whereas the FertiQoL has two separate relational and social scales, differentiating the impact of infertility on partnership and other social aspects (i.e. social inclusion, expectations and support). The findings of the current study seemed to support the fact that infertility impacts differently on social and couple relationship domains, showing that men report slightly higher scores on the social domain than women, whereas both members of the couple reported good relationship quality. The use of a disease-specific instrument such as the FertiQoL seems to be more valuable for the purposes of this study.

However, although several studies have previously examined the influence of psychosocial variables on couples' adjustment to infertility, further research is needed to better investigate what other clinical variables may affect women's and men's QoL during the course of treatment differently. In the current study we only included couples when they were completing the initial steps of the ART procedure and we would speculate that the feeling of members of a couple addressing their needs for parenthood and the hope of successful treatment could improve their relationship quality, couple commitment and cohesion.

Moreover, further research on the development of congruence on relationship quality over the course of repeated ART attempts are warranted, given that there is evidence that the number of previous ART could affect women's and men's adjustment differently (Moura-Ramos *et al.*, 2016).

In the current study, we also found some promising findings regarding the FertiQoL-REL capability to discriminate between high and low quality in a couple's relationship. Our results provided an average FertiQoL-REL score (both for women and men) that corresponds to the DAS and EMS critical threshold, thus identifying couples with a low level of cohesion and consensus and low marital satisfaction. Since there are not yet any well-established cut-off values for the FertiQoL subscales, it was not possible to determine its accuracy in terms of specificity and sensitivity. Therefore, this only represents the first phase towards determining a FertiQoL-REL cut-off score. These findings are in line with previous studies, which identified the average total FertiQoL score that corresponded to the HADS clinical threshold on anxiety and depression (Aarts et al., 2011). Determining specific Ferti-QoL cut-off values can provide an advantage in using the FertiQoL in clinical practice. Furthermore, the current study was the first to determine these cut-off scores for both women and men; this is needed especially when assessing couple relationship quality and to improve the processes of psychological counselling.

Strengths and limitations

A major contribution from the present study is the examination of the psychometric characteristics of the FertiQoL-REL scale in a paired sample of women and men who were going to start an ART. The inclusion of both couple members to test the validity of the FertiQoL scale was also an important contribution, as it consents the studying of similarities and differences in women and men's relationship quality at the time of facing a high stressful situation such as an ART. The identification of average FertiQoL-REL scores, which correspond to the marital relationship threshold, was an important finding because it allows clinicians to be easily alerted on specific areas of a patient's life that need to be addressed in the assessment phase or in the psychological counselling process.

Certain limitations of the current study should also be mentioned. Firstly, only Italian patients attending a single private clinical site were recruited in the current study, and more studies on the validity of the FertiQoL-REL should be conducted in different sites. The FertiQoL is an international instrument and its psychometric properties were tested in the international context, but contextual and social variables can influence the relationship quality construct assessed by the questionnaire. Secondly, incomplete data account for a large portion of the sample (23%), and the representativeness of the sample analysed may be called into question. In the current study, we excluded from the final sample only subjects with more than 30% of missing data, but this percentage is high. However, AMOS software allows for sophisticated and acceptable missing value estimation. Thirdly, the infertile couples that were assessed were mainly involved in their first ART and are not representative of all infertile couples. Additionally, only heterosexual couples were included in the study, as required by Italian law for couples undergoing ART, and the results cannot be generalized to other groups of infertile patients, e.g. homosexual couples or single women and men. Finally, from a statistical point of view, a study including both components of a couple faces the problem of the lack of independence of dyadic data, with standard errors at risk of underestimation. Although we conducted partial correlations and paired t-test for testing the discriminant validity of the FertiQoL across gender, more sophisticated statistical methods, which are more suitable for testing dyadic data (i.e. multilevel CFA), could be adopted. Further studies with couple data should overcome this limitation and controlling for the partner effect.

Clinical implications

The present results could have important clinical implications. The FertiQoL was originally developed to provide clinicians with detailed and valid information about those domains in a patient's experience that are impaired most (Aarts *et al.*, 2011; Boivin *et al.*, 2011a,b). A couple's relationship quality, as assessed by the FertiQoL-REL, did not seem to be impaired by the infertility condition, differently from other QoL domains, and this may represent a key point for providing support and counselling to patients undergoing ART.

Clinicians should base their counselling strategies on the positive qualities in a couple's relationship, to reinforce the overall QoL in patients undergoing ART and support them in tackling the psychological burden, in order for them to keep on continuing treatment or choose discontinuation. It could be argued that couples which do not have a similar relational quality level could not cope well with a childless life. Moreover, we could expect that men, who generally show a better QoL than women, might play a pivotal role in the couple to help female partners to better adjust to the stress and burden due to infertility treatment. Marital and relationship problems are often reported as reasons for treatment discontinuation at the initial stage (Gameiro et al., 2012), but results on the congruence between partners on their relationship quality are still inconsistent. The results of the current study represent a first step towards the identification of patients who are more likely to report poor or good relationship quality through FertiQoL threshold scores. Previous studies reported that men and women at risk for maladjustment reported lower FertiQoL-REL scores than patients not at risk (Lopes et al., 2014) and FertiQoL threshold scores on relationship quality could help clinicians to identify patients at risk more easily, along with well-validated measures such as the SCREENIVF (Verhaak et al., 2010). In the present study women and men did not differ on the FertiQoL-REL as well as on marital satisfaction, commitment and cohesion, but women reported worse overall QoL scores than partners. Future research should shed a light on potential predictors of the different QoL domains in infertile couples, and test whether the good relationship quality of both partners remains stable over the course, or at the end, of ART in order to better cope with a potentially childless life.

To sum up, the FertiQoL is a gold standard for measuring QoL in infertile patients, and studies on the validity of such a measure might be important to further disseminate its use in clinical settings.

Authors' roles

Z.D. played a pivotal role in the conception and design of this study, was involved in the interpretation of the data and made significant contributions to improvements in the manuscript. G.L.C. contributed to the interpretation of data and wrote the article. S.G. participated in study design and performed the statistical analysis of the data. L.S. was involved in the acquisition of the data and wrote the article. A.M. participated in recruiting subjects and participated in the critical revision of the manuscript. F.S. collected data and reviewed the manuscript. A.A. contributed to the study design and to revision of the manuscript, with overall responsibility for the production of the Paper. All authors have approved the final version of the manuscript.

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Conflict of interest

None declared.

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