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Original Research Article

RELATIONSHIP BETWEEN QUALITY OF LIFE AND INFERTILITY AS ASSESSED BY THE FERTIQOL QUESTIONNAIRE: A SINGLE CENTER CROSS SECTIONAL STUDY

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Abstract
Background: To assess the impact of infertility and its treatment on QoL in patients with fertility problems at a tertiary north Indian teaching hospital by applying the FertiQoL questionnaire. **Materials and Methods:** This was a cross-sectional study of patients presenting to the gynecology outpatient department with primary or secondary infertility, of a tertiary center for obstetrics, gynecology. Questionnaires were administered to a total of 204 women. The Treatment Module was administered to 184 women who had received treatment for infertility for 6 or more months, were included for analysis of Treatment FertiQoL scores. **Results:** When the mean scaled scores were analyzed (Table 3), the emotional subscale scored the lowest 52.06(SD 20.12). The least impact of fertility problems seemed to be on the relational domain 68.83(SD 13.2). The mental and physical symptoms because of fertility treatment (treatment tolerability) were associated with a better QoL 72.62(SD 14.79) than accessibility and quality of treatment (treatment environment) 67.92(SD 11.84). Women less than 30 years of age had better scores in the whole domain than older women. Duration of infertility less than 6 years resulted in better mind-body, relational, social and core scores. Educational status, rural or urban residence and religion did not affect the scores significantly. The mean Total FertiQoL score in the study population was 63.4 (SD 13.4). On univariate linear regression, there was no significant effect of age, marital life or body mass index on the Core FertiQoL items. Duration of infertility was significantly and negatively correlated with Core FertiQoL scores in all domains. Advanced maternal age negatively impacted emotional, mind body and relational sub-scores, but the difference is not significant. **Conclusion:** The levels of stress and quality of life in infertile women seem to require psychological intervention. This study provides a baseline measurement of the quality of life in infertile women in India, which will be helpful for developing psychological interventions for women with infertility.

INTRODUCTION

Infertility, a reproductive disease that results in the inability to conceive after 12 months of unprotected sex.[1,2] Despite the immense number of individuals that are affected globally, the vast social, physical, and mental health implications of infertility have been largely unaddressed in the last 15 years.[3] Infertility can be female-specific, male-specific, or a combination of various factors and etiologies.[4] Female-specific factors can include endometriosis, diminished ovarian reserve, and polycystic ovarian syndrome,[4] while male-specific infertility can evolve from poor sperm quality, quantity, or medical comorbidities.[5] In India, where the fertility rate is extremely high individuals and couples with infertility face significant stress due to social and financial issues. Individuals with infertility report symptoms of anxiety and depression at rates between 25 and 60%, similar to those with chronic health conditions.[6] In addition to the psychological distress of infertility, financial burdens of infertility treatments and patient comorbidities can further limit reproductive options, further compounding

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infertility-related stress and creating additional barriers to parenthood. Therefore, the present study aimed to apply the FertiQoL questionnaire to assess the impact of infertility and its treatment on QoL in patients with fertility problems at a tertiary north Indian teaching hospital.

MATERIALS AND METHODS

This was a cross-sectional study of patients presenting to the gynecology outpatient department with primary or secondary infertility, of a tertiary center for obstetrics and gynecology. The fertility treatment services provided at the institute include ovulation induction (OI) and intrauterine insemination (IUI); couples requiring in vitro fertilization (IVF) are referred to other centers. According to WHO infertility was defined as inability to conceive after 12 months or more of unprotected intercourse; women with primary infertility were those who had never conceived, and secondary infertility had a prior pregnancy irrespective of the outcome. Polycystic ovary syndrome (PCOS) was diagnosed by the Rotterdam criteria,[7] endometriosis either by ultrasound detection of endometriotic cysts or laparoscopic evidence of endometriotic lesions, tubal factor by hysterosalpingographic or hysterolaparoscopic detection of unilateral or bilateral tubal blocks and male factor by deviations from the WHO 2010 semen analysis reference standards.[8] The 'FertiQol International' questionnaire (English/Hindi) available from http://sites.cardiff.ac.uk/fertiqol/ was administered to patients after obtaining informed consent. The Core module of the FertiQoL evaluates the impact of infertility on emotional, mind-body, relational and social domains and an optional Treatment module assesses treatment environment and tolerability.

Sample size was estimated to be 200 women with completed questionnaires based on 95% confidence and a hypothesized 40% of women with infertility having low or poor QoL. Participant data was anonymized with the use of unique study IDs. Based on the participant's response, the raw scores were calculated, and the scaled scores were computed in accordance with instructions available at http://sites.cardiff.ac.uk/fertiqol/scoring/. The primary outcomes were the Total, Core and Treatment FertiQoL scores and the secondary outcome variables were the factors influencing the scores. The data were initially entered into a MS Excel spread sheet and exported into SPSS Version 20 (IBM Corp., Armonk, NY) for statistical analysis. The means and standard deviations of continuous variables and frequency distribution of categorical variables were calculated. The distribution of the scores and potential associations with other conditions were analyzed by comparison of means and a linear regression model reporting the b coefficients with 95% CI around the point

estimates. Multiple regression analysis was performed to assess the effect of independent risk factors on FertiQoL scores. A p values of ≤0.05 was considered significant.

RESULTS

Questionnaires were administered to a total of 204 women. The Treatment Module was administered to 184 women who had received treatment for infertility for 6 or more months, were included for analysis of Treatment FertiQoL scores. The age of these women ranged from 20 to 40 years (mean age 27.48 years) and majority had been married for 6 years (ranged from 1.5 to 18 years). One hundred twenty-eight women (68%) were educated (from primary school to graduate). Eighty-one percent women were from urban area.in our study group mean years of infertility was 3.98 years. Out of 204 women 36 (18%) were underweight and 38 (19%) were obese. Forty-nine women had other comorbidities. Total 132 women had ovulation induction with intrauterine insemination whereas 49 women had only IUI. Four were referred for IVF and 19 women underwent diagnostic hystero-laparoscopy. [Table 1]

PCOS was the most common cause of infertility in the study population. [Table 2] Tubal pathology, endometriosis and male factor attributed to 12, 9 and 17 women respectively.

When the mean scaled scores were analysed, [Table 3] the emotional subscale scored the lowest. The least impact of fertility problems seemed to be on the relational domain. The mental and physical symptoms because of fertility treatment (treatment tolerability) were associated with a better QoL than accessibility and quality of treatment (treatment environment).

The study population was evaluated for the Core FertiQoL subscales according to the demographic variables and type and duration of fertility treatment (Table 4). Women less than 30 years of age had better scores in the whole domain than older women. Duration of infertility less than 6 years resulted in better mind-body, relational, social and core scores. Educational status, rural or urban residence and religion did not affect the scores significantly.

On univariate linear regression, there was no significant effect of age, marital life or body mass index on the Core FertiQoL items. Duration of infertility was significantly and negatively correlated with Core FertiQoL scores in all domains. [Table 5]

The factors with p < .1 (see Table 4) were included in the multiple regression model: advanced maternal age negatively impacted emotional, mind body and relational sub-scores, but the difference is not significant. [Table 6]

Table 1: Demography of the study population (n=204)

VARIABLES	NUMBERS (%)
Age in years: Mean ± SD	27.48 ± 4.8
Years married: Mean ± SD	6.5 ± 4.16
Education	128 (64)
Urban residence	163 (81.5)
Years infertile: Mean ± SD	3.98 ± 3.36
Underweight-BMI ≤18.5 Kg/m^2	36 (18)
Obesity -BMI ≥30 kg/m^2	38 (19)
Other morbidities	49 (24.5)
Treatment: ovulation induction	132 (64.7)
Treatment: intrauterine insemination	49 (24.0)
Treatment: IVF	23 (11.2)

Table 2: Causes of Infertility in The Study Population (N=204)

CAUSES	NUMBERS (%)
Polycystic ovary syndrome	113 (55.4)
Endometriosis	9 (4.4)
Tubal factor	12(20.5)
Male factor	17 (8.3)
Unexplained	45 (22.0)
Other	8(3.9)

Table 3: FertiQoL scaled scores for the study population

Subscale	Number of items	Average scaled score (std deviation)
Emotional subscale	6	52.06 ± 20.12
Mind-body subscale	6	64.35 ± 18.32
Relational subscale	6	68.83 ± 13.2
Social subscale	6	57.68 ± 17.21
Treatment environment subscale	6	67.92 ± 11.84
Treatment tolerability subscale Core FertiQoL	4	72.62 ± 14.79
	24	60.73 ± 15.48
Treatment FertiQoL	10	69.8 ± 11.36
Total FertiQoL	34	63.4 ± 13.4

Table 4: Potential moderators of core FertiQoL scores

Variable	Emotional (Mean ±SD)	Mind/Body (Mean ± SD)	Relational (Mean ± SD)	Social (Mean ± SD)	Core score (Mean ± SD)
Age					
≤30 (153)	53.62 ± 19.8	66.48 ± 17.13	70.15 ± 12.94	59.45 ± 17.29	62.43 ± 15.13
>30 (47)	46.99 ±20.52	57.45 ± 20.45	64.54 ± 13.29	51.9 ± 15.81	55.22 ± 15.51
ρ value	0.048	0.003	0.010	0.008	0.005
Education					
Yes (126)	52.02 ±19.82	64.45 ± 18.28	69.58 ± 12.85	59.09 ± 16.88	61.28 ± 15.16
No (74)	52.14 ±20.75	64.19 ± 18.5	67.57 ± 13.78	55.26 ± 17.62	59.79 ± 16.08
ρ value	0.967	0.923	0.300	0.129	0.512
Residence					
Urban (161)	51.19 ± 9.72	63.85 ± 18.6	69.07 ± 12.57	57.52 ± 16.62	60.41 ± 15.11
Rural (39)	55.66 ±21.58	66.45 ± 17.15	67.84 ± 15.71	58.33 ± 19.71	62.07 ± 17.07
ρ value	0.214	0.426	0.602	0.791	0.548
Religion					
Hindu (159)	52.1 ± 20.38	64.12 ± 18.87	69.18 ± 13.47	58.16 ± 17.62	60.89 ± 15.95
Muslim (41)	51.93 ±19.32	65.24 ± 16.15	67.48 ± 12.19	55.79 ± 15.59	60.11 ± 13.69
ρ value	0.963	0.728	0.463	0.434	0.774
BMI					
<30kg/m2(165)	52.41 ±19.88	64.58 ± 18.29	68.83 ± 13.23	57.86 ± 17.56	60.92 ± 15.5
≥30kg/m2(39)	50.46 ± 21.4	63.31 ± 18.66	68.87 ± 13.27	56.83 ± 15.72	59.87 ± 15.6
ρ value	0.600	0.707	0.987	0.746	0.712
Years infertility					
<6 yrs (152)	53.32 ± 19.3	66.15 ± 17.07	70.01 ± 12.79	59.43 ± 17.08	62.23 ± 14.85
≥6 yrs (48)	48.09 ± 22.28	58.68 ± 21	65.1 ± 13.93	52.12 ± 16.61	56 ± 16.64
ρ value	0.117	0.013	0.024	0.010	0.015
Years married					
<6yrs (99)	53.75 ± 19.68	66.41 ± 17.06	70.54 ± 13.77	59.64 ± 17.8	62.58 ± 15.44
≥6 yrs (101)	50.41 ± 20.5	62.33 ± 19.34	67.16 ± 12.46	55.75 ± 16.48	58.92 ± 15.38
ρ value	0.242	0.116	0.070	0.111	0.094
Parity					
Nulliparous (152)	52.44 ± 20.48	64.67 ± 18.31	69.41 ± 13.83	58.61 ± 17.22	61.28 ± 15.79
Parous (48)	50.87 ± 19.08	63.37 ± 18.49	67.01 ± 10.9	54.72 ± 17.03	59 ± 14.5
ρ value	0.638	0.670	0.275	0.173	0.375

Live child **Yes (45)** **No (155)** **ρ value**	51.85 ± 19.21 52.12 ± 20.44 0.937	64.07 ± 18.7 64.44 ± 18.26 0.908	67.04 ± 11.23 69.35 ± 13.71 0.301	55.5 ± 17.31 58.31 ± 17.19 0.337	59.62 ± 14.71 61.06 ± 15.73 0.586
Infertility **Primary (142)** **Secondary (58)** **ρ value**	53.26 ± 20.66 49.14 ± 18.56 0.190	65.23 ± 18.35 62.21 ± 18.22 0.292	69.75 ± 13.94 66.59 ± 11 0.126	59.36 ± 17.34 53.55 ± 16.31 0.030	61.9 ± 15.89 57.88 ± 14.16 0.096
Treatment taken **IUI (10)** **OI+IUI (132)** **Others (58)** **ρ value**	56.67 ± 18.24 52.56 ± 19.47 50.14 ± 21.94 0.570	68.33 ± 15.86 64.62 ± 17.88 63.08 ± 19.8 0.679	72.08 ± 11.79 69.79 ± 13.12 66.09 ± 13.39 0.150	61.67 ± 13.86 59.09 ± 17.03 53.76 ± 17.74 .109	64.69 ± 13.28 61.51 ± 15.08 58.27 ± 16.61 0.295
Treatment **duration** **<6M (112)** **>6M (88)** **ρ value**	54.65 ± 20.38 48.77 ± 19.4 0.040	67.37 ± 17.47 60.51 ± 18.74 0.008	70.31 ± 12.97 66.95 ± 13.32 0.074	59.75 ± 16.57 55.04 ± 17.75 0.055	63.02 ± 15.18 57.82 ± 15.46 0.018
Comorbidities **Yes (49)** **No (151)** **ρ value**	48.81 ± 17.26 53.12 ± 20.91 0.193	61.4 ± 18.57 65.32 ± 18.19 0.194	66.58 ± 11.3 69.56 ± 13.72 0.170	54.63 ± 14.96 58.66 ± 17.82 0.154	57.86 ± 13.63 61.67 ± 15.97 0.135

Table 5: univariate linear analysis with duration of infertility as independent variable and core FertiQuol scores as dependent variables

Duration of infertility (years)	Emotional subscale	Mind-body subscale	Relational subscale	Social subscale	Core FertiQoL
R square	0.024	0.043	0.027	0.03	0.038
F statistics	4.896	8.877	5.485	6.047	7.786
B coefficient	-0.93	-1.129	-0.645	-0.882	-0.896
t Test	-2.213	-2.979	-2.342	-2.459	-2.79
Significance	0.028	0.003	0.02	0.015	0.006
95% CI	-1.759, -0.101	-1.876, -0.382	-1.188, -0.102	-1.589, -0.175	-1.530, -0.263

Table 6: multiple regression analysis with subscale scores and Core FertiQol scores as dependent variables

Subscale score	Independent variable	Estimate	t value	p value
Emotional subscale R²= 0.018,F= 2.837, p = 0.061	Age in years	-4.404	-1.177	0.241
	Treatment duration	4.155	1.300	0.195
Mind-body subscale R²= 0.040,F= 3.792, p = 0.011	Age in years	-6.119	-1.603	0.111
	Years infertility	1.443	0.361	0.719
	Treatment duration	3.793	1.224	0.222
Relational subscale R²= 0.019,F= 1.948, p = 0.104	Age in years	-3.674	-1.296	0.197
	Years infertility	1.457	0.458	0.647
	Years married	1.006	0.443	0.658
	Treatment duration	0.968	0.427	0.670
Social subscale R²= 0.036,F= 2.860, p = 0.025	Age in years	-2.372	-0.614	0.54
	Years infertility	4.885	1.279	0.203
	Infertility	4.542	1.593	0.113
	Treatment duration	1.006	0.345	0.731
Core FertiQoL R²= 0.033,F= 2.672, p = 0.033	Age in years	-3.596	-1.033	0.303
	Years infertility	2.354	0.684	0.495
	Infertility	2.352	0.915	0.361
	Treatment duration	2.436	0.926	0.356

DISCUSSION

This study evaluated the QoL in women with fertility problems and the variables influencing QoL in these women. The mean Total FertiQoL score in the study population was 63.4 (SD 13.4) and this overall score was not influenced by socio-demographic or infertility specific factors.

On subscale analysis, women who are more than 30 years of age had a poor score in all domains when compared to younger women. Duration of infertility less than 6 years resulted in better quality of life in terms of mind-body, relational, social and core scores. Duration of infertility less than 6 years also resulted in better mind-body, relational, social and core scores. Roozitalab S et al concluded in their study that 41.3% of the infertile women were dealing of posttraumatic stress disorder. So regular designed psychological interventions are recommended for these infertile individuals.[9] It was determined in the study of Zeren F et al that in infertility treatment men had higher quality of life and dyadic adjustment than women. They compared the information about socio-demographic characteristics, the FertiQol Scale, and the Dyadic Adjustment Scale.[10] A study done by Hee-Jun Chi

et-al on Korean infertile women also concluded that the mind body and emotional scores had affected the quality of life compared to the other scales of psychological distress. It also concluded that the level of distress in these infertile women required psychological intervention.[11] Z. Donarelli et.al found in their study that Reliability of the FertiQoL-REL was higher for women than men although scores did not differ significantly in women and men.[12] Interestingly, Sexty et al. found that intra-cultural differences played a more important role than intercultural differences in determining the QoL.[13] Another study found that women with PCOS had lower total FertiQoL scores than those with unexplained infertility but scores in the present study were not affected by the cause of infertility.[14] Çambel B, et al concluded in their study that a high negative correlation was found between 'Infertile Women's Exposure to Violence Determination Scale (IWEVDS), score and QoL of women exposed to violence also that the treatment tolerance decreased in women who faced violence.[15] The negative psychological effects of infertility are generally ignored by treating facilities, and psychological support to women should be given regardless of the infertility factor (male or female), to improve their life quality.[16]

The results of this study provide a baseline QoL in infertile women at the study institute and can be used as a guide for future work. One of the limitations of this study is that the sample comprised predominantly urban women from a single tertiary center and hence the findings cannot be extrapolated to the general population. This study was restricted to women and the male partners were not involved. The other drawback is the non-availability of data pertaining to economic factors. Future research should be directed at determining cut-off values for poor QoL by comparing with other psychometric tools to identify women who may benefit from psychological counseling. Subscale scores can identify the specific domains where intervention might be most beneficial.

CONCLUSION

The results of this study provide a baseline QoL in infertile women at the study institute. Limitations of this study is that the sample comprised mostly urban women from a single tertiary center and the male partners were not involved. The other drawback is the non-availability of data related to economic factors. Future research should be directed at comparing the poor QoL with other psychometric tools to identify women who need psychological counseling. Subscale scores can be helpful for interventions related to specific domains to improve the quality of life of these infertile women.

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