Original Article

Assessment of Impact of Infertility & its Treatment on Quality of Life of Infertile Couples using Fertility Quality of Life Questionnaire

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ABSTRACT

Background: With rising trends of infertility in India, it is no longer just a medical concern, but is rapidly becoming a public health issue due to its social and interpersonal ramifications. Limited data is available regarding quality of life of the infertile couples. **Aim:** The aim of this study was to understand the quality of life (QOL) of Indian infertile couples using the fertility QOL (FertiQoL) tool and to find the correlation between the values of the core and treatment FertiQoL and various sociodemographic and clinical factors. **Study Setting and Design:** This cross-sectional study was conducted at fertility clinic at an urban tertiary care center. **Materials and Methods:** Over a period of 12 months, 274 completed questionnaires obtained from 137 couples were selected for the analysis. Demographic and clinical characteristics of all the patients were recorded. Data analysis was performed using the Statistical Package for the Social Sciences software version 25:0. IBM Chicago, USA. **Results:** Women had worse QOL than their male partners. They scored lower than men on emotional and mind body subscales. Women showed positive and uniform trend in mean scores of all core FertiQoL subscales with age and education. Rural population had poorer QOL. Patients with primary infertility had poorer QOL except in the relational domain. Couples, in whom both partners had some pathology, had the worse QOL compared to female factor, male factor or unexplained infertility. **Conclusion:** Our study is a step in the direction to establish the baseline QOL objectively in Indian couples with infertility.

KEYWORDS: *Assessment, infertility, psychological stress, quality of life, questionnaire*

INTRODUCTION

*I*nfertility is the inability of a sexually active couple to achieve pregnancy within a year or more of regular unprotected intercourse.[1]

Although not a fatal medical condition, infertility does have negative ramifications on various psychological,[2] emotional,[3] social,[4] and financial[5] aspects of life of an individual suffering from it, as shown by ample studies conducted worldwide.

Numerous studies have found an adverse association between infertility-induced stress and subsequent fertility[6,7] and treatment outcome.[8,9]

Treatment of infertility in itself is a complex, time-consuming affair, involving multiple visits to the specialist, running a gamut of investigations and procedures. The best prognosis of achieving a

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pregnancy, even after using a costly technology like *in vitro* fertilization (IVF)- intracytoplasmic sperm injection (ICSI), is very much variable, depending upon patient specific and treatment-specific factors.[10]

Going through the process can be quite overwhelming. Patients tend to stop treatment prematurely as they find it too much to handle, as shown by Shinoda *et al.*, using the Cornel Medical Index to assess the stress levels in infertility patients.[11] In a prospective cohort study, Olivius *et al.* found that psychological stress was a major reason for poor treatment compliance.[12]

Thus, infertility, its treatment, and treatment outcome are all intricately interlinked.

Eventually, some couples may need to deal with failure of medical treatment and biological childlessness. How they approach and adapt to it over a period of time determines their long term satisfaction and quality of life (QOL).[13]

The clinicians and health-care professionals need to be aware of these very real challenges faced by the patients and be able to assess the effect of infertility and its treatment on the quality of their life, in order to provide appropriate care.

QOL is a multifaceted concept pertaining to an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards, and concerns.[14] The fertility QOL (FertiQoL) is a sensitive and reliable instrument to evaluate the FertiQoL parameters in individuals with infertility. It was developed by a multidisciplinary team[15] and was internationally validated by expert teams from the European Society of Human Reproduction and Embryology and the American Society of Reproductive Medicine in collaboration with Merck Sereno.

It consists of a *Core* QOL set of questions which covers four specific domains.

The emotional domain reveals the impact of negative emotions arising due to infertility, for example, (sadness, depression jealousy, and resentment) on QOL. The mind-body domain conveys the impact on physical health (e.g., fatigue and pain), cognition (e.g., concentration) and behavior (e.g., disrupted daily activities, delayed life plans), while the relational domain expresses effect on partnership (sexuality, communication, and commitment issues). The social domain evaluates that how infertility interferes with social interactions of the individual (social inclusion, expectations, stigma, and support).

There is an optional additional treatment module which is formulated to know thoughts and feelings toward treatment quality and tolerability, in those undergoing treatment for infertility.

The goal of this study was to understand the QoL of Indian infertile couples, serving as a tool for patient counseling and reference for future research.

The study also intended to find the correlation between the values of the core FertiQoL and treatment FertiQoL with various sociodemographic and clinical factors in Indian couples with infertility.

MATERIALS AND METHODS

This was a cross-sectional study conducted at the department of reproductive medicine and surgery at a tertiary care institute over a period of 12 months (February 1, 2019–January 31, 2020).

Ethics committee clearance was obtained from the Institutional Ethics Committee (Approval Number: BVDUMC/IEC/2 dated 25/01/2019).

Considering 20.38% incidence of infertility in Asia,[16] using 95% confidence interval, and estimated sample size was 249.

Couples attending the outpatient department of reproductive medicine, from February 1, 2019, to January 31, 2020, who were willing to participate, who had at least two consultations by the specialist and in whom at least a provisional diagnosis of the causative factor was reached, were included.

Patients who had already undergone IVF/ICSI cycle at the center or at any other facility were excluded.

FertiQoL questionnaire was made available in three languages – the vernacular/local language, national language, and English.

Couples were explained about the study and nature of the questionnaire. All queries about it were answered by the investigator. It was then administered to the consenting patients. They were specifically asked to fill it directly and independently, without any communication with their partner.

Partners were provided with a separate, comfortable sitting arrangement so that they could respond without any interference or influence. Any doubts or comprehension difficulties about the questions or the responses were cleared personally by the investigator.

One hundred and fifty-two couples fulfilled the criteria and were asked to fill the questionnaire. We did not come across anyone who could not read. Fifteen

couples had incomplete or incorrect responses (e.g., ticking two responses for the same question/leaving few items unanswered). Completed questionnaires of 137 couples (274 patients) were analyzed.

Data analysis was performed using the Statistical Package for Social Sciences Version 25.0 IBM Chicago, USA. Qualitative data variables expressed by using frequency and percentage (%). Quantitative data variables expressed by using mean ± standard deviation (SD). Analysis of variance test used for the comparison of percentile score of domains (emotional, mind body, relational, social, environmental, and tolerability) with education and age, etc., Unpaired *t*-test was used for the comparison of percentile score for domains (emotional, mind body, relational, social, environmental, and tolerability) with type of infertility, gender, and diagnosis. $P < 0.05$ considered statistically significant.

RESULTS

Sociodemographic and clinical profile of the study population is summarized in Table 1. The study included 137 couples, i.e., equal number of females and males.

There was a significant difference in the distribution of age and education of females and males, which is likely due to sociocultural structure of Indian society.

The core FertiQoL score was found to be lower in women, the difference was statistically significant ($P = 0.017$) [Table 2].

FertiQoL subscale analysis revealed lower scores across all domains in women. The difference reached statistical significance ($P < 0.05$) in emotional and mind-body subscales [Table 3].

Treatment environment and tolerability scores show that are both women and men are affected similarly [Table 3].

Overall, among various age groups, there was a significant difference between the groups in three domains, i.e., emotional, mind-body, and social subscales of the core Ferti-QOL and environmental subscale of treatment QOL [Table 4].

When men and women were analyzed separately, it was revealed that the younger age in women was associated with significantly lower values on mind body domain of core FertiQoL and environmental domain of treatment FertiQoL. In women, emotional and social subscales improved, while relational scores went down slightly with increasing age, although the difference was not statistically significant. Treatment tolerability did not change with age.

In case of men, the effect of age on core subscales or the treatment subscales did not reach statistical significance [Table 4].

Table 1: Sociodemographic and clinical characteristics

Parameter	Female (%)	Male (%)
Age		
<25	30.65	5.1
26-30	42.33	29.19
31-35	20.43	45.25
>35	6.56	20.43
P	<0.001	
Education		
Primary	13.86	13.86
Secondary	29.92	13.86
Graduation	51.07	45.25
Postgraduation	16.78	27
P	0.012	

Parameter	Couples (%)
Residence	
Rural	30.65
Urban	69.34
Type of infertility	
Primary	69.34
Secondary	30.65
Cause of infertility	
Unexplained	58.39
Female factor	56.93
Male factor	10.21
Female+male factors	3.64
Duration of infertility (years)	
1-2	56.93
2-5	40.87
>5	2.18
Number of OI +/− IUI cycles	
Nil	25.54
1-6	62.04
>6	12.4

OI=Ovulation induction, IUI=Intrauterine insemination

Table 2: Core fertility quality of life

	Gender	n	Mean±SD	P#
Core percentile	Female	137	71.18±13.08	0.017*
	Male	137	74.94±12.74	

*Significant #ANOVA. SD=Standard deviation

Table 3: Fertility quality of life subscale analysis

Subscales	Mean±SD		P^
	Female	Male	
Emotional	69.37±20.37	77.77±17.89	<0.001*
Mind body	70.10±19.07	76.03±20.29	0.013*
Relational	74.03±15.37	75.58±16.27	0.418
Social	71.47±20.03	74.54±17.47	0.177
Environmental	70.95±15.13	70.77±15.35	0.921
Tolerability	58.85±11.33	61.04±10.78	0.102

*Significant ^ unpaired *t* test. SD: Standard deviation

Table 4: Age

Age	n	Mean±SD					
		Emotional	Mind body	Relational	Social	Environmental	Tolerability
Female							
<25	42	64.2±20.3	63.4±20.4	75.2±13.9	68.0±21.7	65.2±18.1	58.5±11.6
26-30	58	69.5±22.7	70.6±19.9	74.0±17.0	69.6±21.4	73.8±12.3	59.7±12.2
30-35	28	75.1±15.4	76.2±13.2	73.7±13.0	77.4±12.9	72.3±15.5	58.3±9.9
>35	9	74.5±13.2	79.2±13.2	69.9±19.1	81.5±16.2	75.5±7.3	56.9±9.1
P^	137	0.134	0.016*	0.827	0.089	0.025*	0.876
Male							
<25	7	65.5±20.1	77.8±17.9	67.9±17.3	61.3±28.4	70.2±16.4	63.4±4.3
26-30	40	77.9±20.2	63.7±20.4	78.7±15.8	74.2±18.1	67.7±18.7	59.1±10.7
30-35	62	78.2±15.5	74.6±21.1	74.0±15.5	76.9±13.2	70.2±14.2	61.2±10.4
>35	28	79.6±18.7	77.9±18.3	76.5±18.2	73.2±20.8	76.5±10.9	62.9±12.6
P^	137	0.304	0.338	0.289	0.15	0.134	0.467
P^	274	<0.001*	<0.001*	0.830	0.016*	<0.019*	0.748

*Significant ^ unpaired *t* test. SD: Standard deviation

Table 5: Education

Education	n	Mean±SD					
		Emotional	Mind body	Relational	Social	Environmental	Tolerability
Female							
P	19	68.6±15.6	65.1±14.4	69.1±18.0	67.1±18.4	68.2±17.4	61.8±11.4
S	41	65.9±20.7	69.6±19.2	74.7±14.0	72.3±18.3	73.1±13.9	56.7±13.2
G	54	70.6±20.3	70.2±19.3	74.1±16.8	72.0±21.6	69.2±15.6	59.7±10.6
PG	23	73.4±23.5	74.8±21.5	76.8±11.6	72.5±21.3	73.6±14.1	58.2±9.1
P	137	0.511	0.44	0.427	0.791	0.34	0.365
Male							
P	19	78.51±13.77	70.83±18.69	69.08±17.91	78.07±15.14	67.54±21.81	59.54±9.63
S	19	75.66±20.19	72.15±23.20	77.41±20.85	69.52±25.12	68.20±14.18	58.88±11.09
G	62	77.49±17.13	76.95±20.51	76.95±14.86	74.46±16.08	73.52±14.67	63.81±11.15
PG	37	78.94±20.22	79.17±19.09	75.68±14.88	75.45±16.25	69.14±12.75	58.28±9.78
P	137	0.927	0.427	0.296	0.489	0.288	0.052
P total	274	0.163	0.081	0.12	0.856	0.618	0.037*

SD: Standard deviation

Women fared better across the domains of QOL parameters with improvement in education, although the difference across education groups was not statistically significant. Treatment tolerability was similar across different levels of education in women [Table 5].

Although all scores showed lower values for the rural population, the difference in relational subscale reached statistical significance [Table 6].

Patients with secondary infertility consistently fared better across all domains, except on relational subscale [Table 7].

Patients with male factor infertility had lower scores across all domains compared to unexplained infertility and female factor infertility [Table 8].

Patients in whom both the partners had some factors contributing to infertility, had overall lowest scores in the emotional, mind-body, and social domains, but fared best on relational subscale [Table 8].

With increasing duration of infertility, emotional, mind body, and social domains suffered albeit not reaching statistical significance [Table 9].

Patients scored worse on emotional, mind-body, and social domain when they started treatment, i.e., up to six cycles of ovulation induction with or without intrauterine insemination than those receiving no treatment. The scores improved after six cycles [Table 10].

DISCUSSION

In our study, the core FertiQoL score was significantly lower in women compared to men [Table 2].

Table 6: Residence

Residence	n	Mean±SD					
		Emotional	Mind body	Relational	Social	Environmental	Tolerability
Rural	84	70.39±21.50	70.98±22.00	71.63±17.62	72.07±22.32	70.49±16.29	59.67±10.24
Urban	190	74.98±18.57	73.99±18.85	76.21±14.78	73.42±17.10	71.03±14.76	60.07±11.48
P#	274	0.092	0.278	0.039*	0.623	0.793	0.778

*Significant #ANOVA. SD: Standard deviation

Table 7: Type of infertility

Type of infertility	n	Mean±SD					
		Emotional	Mind body	Relational	Social	Environmental	Tolerability
Primary	190	72.57±20.13	72.66±19.96	76.60±15.74	72.31±19.44	70.44±15.44	60.28±11.49
Secondary	84	75.78±18.24	73.97±19.77	71.91±15.70	74.56±17.38	71.81±14.75	59.19±10.19
P#	274	0.194	0.614	0.043*	0.341	0.482	0.431

*Significant #ANOVA. SD: Standard deviation

Table 8: Cause of infertility

Cause of infertility	n	Mean±SD					
		Emotional	Mind body	Relational	Social	Environmental	Tolerability
Unexplained	80	75.68±18.51	73.44±21.97	72.97±16.06	94.32±17.52	70.68±14.53	62.89±10.86
Female factor	156	75.32±18.24	74.68±18.84	75.93±15.95	73.69±18.35	71.71±14.83	59.17±11.21
Male factor	28	62.8±25.56	68.15±18.22	73.21±14.98	69.2±23.58	69.2±17.25	57.14±10.31
Female+male factors	10	59.58±16.44	58.75±16.95	76.25±14.44	62.5±19.84	63.75±20.23	56.25±9.32
P^	274	<0.001*	0.046*	0.526	0.182	0.39	0.025*

*Significant ^ unpaired *t* test. SD: Standard deviation

Table 9: Duration of infertility

Duration of infertility (years)	n	Mean±SD					
		Emotional	Mind body	Relational	Social	Environmental	Tolerability
≤1	156	74.19±20.30	73.63±20.01	74.97±14.49	72.77±18.82	68.6±17.02	59.96±9.73
2-5	112	72.79±19.12	72.31±19.94	74.52±17.75	73.49±19.34	74.04±11.19	59.51±12.72
>5	6	72.22±6.80	72.92±17.63	75.69±11.31	70.14±7.18	69.44±22.77	67.71±10.01
P^	274	0.834	0.866	0.964	0.889	0.014*	0.212

SD: Standard deviation

Table 10: Number of ovulation induction +/− IUI cycles

Number of OI +/− IUI cycles	n	Mean±SD					
		Emotional	Mind body	Relational	Social	Environmental	Tolerability
Nil	70	79.05±17.07	78.33±18.29	75.65±14.41	75±17.89	72.86±13.75	61.25±11.73
1-6	170	70.96±20.08	69.75±20.74	73.48±16.69	70.05±19.40	69.26±16.49	59.04±11.07
>6	34	75.37±19.95	78.8±14.70	79.66±13.83	83.7±12.83	74.75±9.45	61.76±9.58
P^	274	0.012*	0.002*	0.100	<0.001*	0.070	0.223

*Significant ^ unpaired *t* test. SD: Standard deviation, OI=Ovulation induction, IUI=Intrauterine Insemination

Previous studies from India[17] and other countries[18,19] have shown similar results with significantly lower values of core FertiQoL scores in women.

Both Indian women and men had mean core FertiQoL scores similar to the German study by Sexty *et al*. (72.6/SD 12.8) in women (77.8/SD 10.8) in men,[20] and the Dutch study by Aarts *et al*. (70.8/SD 13.9).[21]

The scores were better than the values from a Taiwanese[22] study which had mean score of (60.63/SD 14.07) in men and (54.39/SD 13.52) in women.

Despite variable mean values in different studies across different countries, the difference in females and males was persistent, and in agreement to our study, that women with infertility had a worse QOL compared to their male counterparts.

On subscale analysis of core FertiQoL, women had significantly lower values on emotional and mind-body subscales [Table 3]. This finding was in agreement with many studies done worldwide[23,24] including the original developmental study of FertiQoL by Boivin *et al*.

Women face serious emotional turmoil and physical manifestations due to infertility. Emotions can range from confusion, anger, hopelessness, feeling of unworthiness and frustration, to denial, withdrawal, social isolation and depression, only added by anxiety of extensive treatment.

All other domain scores of core (social and relational) and treatment (environment and tolerability) FertiQoL were not significantly different in women and men. This indicates that poor support from spouse, friends, or family may not be the only reason for poor emotional and mind-body scores in Indian women, and other contributing factors need further exploration.

In our study, women showed positive trend in the mean scores of core FertiQoL subscales with age and education [Table 4 and 5]. The positive effect of age was statistically significant on the mind-body subscale of core FertiQoL and environment subscale of treatment FertiQoL. It indicates that with maturity, women were better equipped to tackle the infertility experience.

Many studies in the past have shown that younger age and low education levels are prognosticating factors for lower QOL.[25,26] Less education may mean lesser opportunities for work or jobs. Women are dependent on the spouse and family. In such a situation, motherhood as an identity becomes crucial to them, both at personal and social level.

Rural population fared poorly across all subscales of core FertiQoL compared to the urban population; significantly so on relational subscale [Table 6]. This finding should be viewed in the Indian context, where sociocultural norms are more stringent in the rural area.[27]

Patients with secondary infertility had better QOL compared to those with primary infertility, [Table 7] findings compatible with Karabulut *et al*.[28] and Turkish study by Dural *et al*.[29]

In our study, out of 42 couples with secondary infertility, only 13 had a live healthy child. Rest had conceived, but lost the pregnancy (missed abortion/spontaneous miscarriage/ectopic).

Even if conception did not result in birth of a live healthy baby, just getting pregnant had a positive impact on all the domains of the QOL, except relational aspect. This was akin to the findings in original developmental study by Boivin *et al*. in which couples with secondary infertility did worse on relational subscale.

Couples, in whom both partners had some pathology, had the worst core QOL scores,[30] understandably so, as this group of patients has the least probability of conceiving their own child naturally or with treatment. This group of patients scored best on relational subscale, although the difference was not statistically significant. They had worst treatment tolerability. This may be explained by the fact that in this group, both partners will require go through plethora of investigations and procedures and eventually need help of advanced assisted reproductive technologies [Table 8].

Couples with male factor infertility and those in whom both partners had some pathology tend to suffer emotionally and physically. In couples with female factor infertility, the overall QOL was much better. This shows that the female being the cause of infertility was a better accepted fact by both partners [Table 8].

Patients with unexplained infertility had better core QOL scores than the other groups in emotional and social aspects. Similar findings were obtained by Heredia *et al*.[31] but not by others.[32] [Table 8]

The data from our study showed that patients with longer duration of infertility performed slightly better on relational subscale. Treatment tolerability also improved with increasing duration of treatment. None of these differences, although were statistically significant. [Table 9]

Strengths

Infertility is a situational life crisis faced by couples. Although actual medical problem may be diagnosed in either of the partner, both of them, or none of them, the emotional stress, financial burden and social hardships are faced by both. Hence, it is essential that they are not only evaluated and treated as individuals but also as partners.

This study includes 137 couples. Hence, it offers a better chance at insight into how both the individuals in the relationship can affect their own and their partners' QOL.

Limitations

Patients' knowledge about their own medical diagnosis was not objectively tested.

This is a cross-sectional study conducted at a single urban tertiary center. Similar studies are required across different regions of the country with diverse geography, ethnicity, social, cultural values, and accessibility of health care.

Further research is required to test the correlation of FertiQoL scores with other standardized scales for psychometric analysis in patients of infertility.

Different treatment modalities may have different tolerability which may depend upon their duration,

painful nature or invasiveness. There is a scope of research in patients undergoing different forms of ART, i.e., IVF-ICSI cycles.

CONCLUSION

The sociodemographic background as well as clinical factors of patients should be taken into account at all the steps of management, as these are associated with how they handle the plight of infertility and its treatment.

The use of standardized disease-specific tool such as FertiQoL is helpful
• In objective assessment of baseline QoL parameters in infertile couples
• In directing interventions to the most affected subgroup of patients, thereby allowing rational use of resources.

Patients can be offered focused counseling or treatment protocols can be modified, keeping in mind the particularly affected QoL domains.

Hence, psychological assessment of the infertile couples using standardized disease-specific tool like FertiQoL should become an integral part of infertility management.

Conflicts of interest

There are no conflicts of interest.

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