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ORIGINAL ARTICLE

CONSTRUCTION AND VALIDATION OF EMOTIONAL AND SOCIAL DISTRESS SCALE FOR MEN AND WOMEN DIAGNOSED WITH INFERTILITY: FURTHER EVIDENCE OF ITS CONSTRUCT VALIDITY AND PSYCHOMETRIC PROPERTIES

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ABSTRACT

OBJECTIVE: To develop a valid and reliable tool to measure infertility-specific emotional and social distress (ESD) among men and women.

METHODS: This mixed-method study was conducted in infertility treatment centers of Lahore Pakistan. In Phase-I, in-depth interviews of diagnosed infertile patients, spouses, and infertility experts were conducted to explore and identify the phenomenon of ESD due to infertility. Item pool was generated through thematic analysis. Content validity of each item was vetted by eight experts. A pilot study was conducted and 74 items were finalized. In Phase-II, the developed scale was administered on a larger sample (N=504) to establish factorial validity. Four factors emerged through exploratory factor analysis (1. Distress & identity, 2. well-being, 3. feelings of insecurity; 4. sexual & marital issues) with 35 items explaining 44.35% of the variance, evidencing significant construct validity of the scale.

RESULTS: Confirmatory factor analysis (CFA) indicated that the model is well-fitted having acceptable model fit indices $x^2/df=1.84$, CFI=0.92, GFI=0.90, RMSEA=0.04, and TLI=0.91. The reliability estimates of alpha coefficients ($\alpha=0.92$) and item-total correlation (ranging from 0.37 to 0.64, $p<0.001$) supported the high internal consistency of 34 items of ESD-Scale. Convergent and discriminate validity of the instrument was established with a Fertility Problems Inventory and Satisfaction with Life Scale, it was found moderately high ($r=0.35$, $p<0.01$), ($r=-0.45$, $p<0.01$). The statistical measures depicted significant construct validity and acceptable psychometric properties of the ESD-scale.

CONCLUSION: The constructed ESD-scale consisted of 34 Items with four subscales and showed evidence of validity, reliability, and psychometric properties.

KEYWORDS: Infertility (MeSH); Infertility, Female (MeSH); Infertility, Male (MeSH); Infertile patients (Non-MeSH); Emotional and social distress (Non-MeSH); Construct Validity (Non-MeSH).

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INTRODUCTION

Psychosocial studies convincingly reported a high prevalence of emotional and social distress among infertile men and women which has an impact on their overall well-being.[1,2] Feelings of hostility, guilt, self-blaming and emotional distress such as depressive symptoms, anxiety, and stress are common among infertile individuals.[3] On the other hand, it is universally accepted that gynecological illness associated with psychosocial problems; including psychological distress, identity and wellbeing crises, social stigma, threats from family and role failure, partner, marital and sexual dissatisfaction may lead to infertility.[3] Further, it is associated with poor treatment outcomes. Although psychosocial problems have been investigated for the said purpose but most of the time generic instruments were used. However, generic measures lack specificity. Because disease-specific instruments not only comprise similar domains but also include items tailored to the disease in it. Thus, the participants better reflect on the consequences of the disease and are more open to changing the disease. The literature also illustrates that experiencing infertility is a culturally specific phenomenon.[4,5] Therefore, the need to develop an indigenous infertility-specific Emotional and Social Distress Scale (ESDS) for psychosocial problems is pivotal.

The assessment of the psychosocial problems of infertile people has gained the attention of researchers over the last decades. It has been accepted globally, to measure the impact of the disease, one needs to measure the disease-specific instrument.[6] It has been acknowledged in the western world as well as initiatives that have been taken in Pakistan for psychologists to play a critical role in the field of assessment and intervention in infertile men and women, especially for those who face difficulty in coping with infertility. Reproductive psychologists under the

umbrella of Health Psychology can play this role. In Pakistan, there are only a few institutions referred to infertile patients, which have obvious and severe psychiatric disorders. Moderate or mild level problems are never referred to psychologists.[4,5,7]

A psychosocial assessment is necessary for detecting emotional and social problems associated with infertility and providing the appropriate intervention. This requires an infertility-specific instrument.[8] Although psychosocial problems have previously been investigated, however, for measurement of psychosocial issues most of the time generic instruments were used. However, generic measures lack specificity and fail to measure the psychosocial problems arising from experiencing infertility and its treatment.[9] This is because disease-specific instruments not only comprise similar domains, targeting experiences of infertility and comprise items tailored to the disease. Thus, the participants can better reflect the consequences of disease and are more open to change due to the disease.[9]

Various generic measures (i.e., General Health Questionnaire,[10] Beck Depression Inventory,[11] and Hospital Anxiety and Depression Scale,[12] to measure stress depression and anxiety were used. Infertility-specific measures include Fertility Problem Inventory;[13] Fertility Adjustment Scale;[14] The Infertility Distress Scale,[15] FertiQol Scale[16,17], Fertility Problem Stress Scale[18], Infertility Questionnaire,[19] Infertility Cognition Questionnaire;[20] and Infertility Feeling Questionnaire,[6] have been used to assess different forms and dimensions of psychological problems relating to infertile men and women.

Apart from generic tools, more than dozens of infertility-specific instruments have been developed worldwide. Among them, the Fertility Problem Inventory[13] is the most frequently used infertility-specific tool. However, the FPI items were developed without the consultation of infertile individuals, or experts dealing with infertility and the validation sample comprised a homogeneous socioeconomic status Caucasian patient category using the ART method. Besides, FPI only assesses the level of strain not broader psychosocial problems.[6] More or less the same issues applied to other infertility-specific scales. Moreover, some infertility-specific tools were designed for subpopulations (e.g., female factor, malefactor, and endometriosis), therefore they cannot be used as a generic assessment for all individuals with fertility problems. However, ESDS was designed comprehensively using maximum resources and contacted the population who are directly related to the sufferer due to infertility. It is estimated that in Pakistan about 22 percent (4 percent primary and 18 percent secondary infertility) of individuals suffer due to infertility,[20] but unfortunately, there is no assessment measure and treatment protocol available for this population. Therefore, there is a need to develop an indigenous measure to assess infertility-specific Emotional and Social Distress Scales for psychosocial problems is imperative.

For this reason, the present study focused on the development of an indigenous measure for diagnosed infertile men and women to assess their emotional and social distress in the Pakistani cultural context. The study was divided into different phases. Phase-I aimed at the generation of the item pool and trying out the developed items. Phase II aimed at exploratory factor analysis and confirmatory factor analysis was carried out in Phase III to determine the psychometric properties of ESDS. Phase-IV aimed at convergent and discriminate validation of the developed scale.

Objectives

1. To develop a reliable and valid ESDS for infertile men and women
2. To assess the gender differences in ESDS
3. To establish the construct validity of the Scale
4. To find the convergent and discriminant validity of the developed scale

METHODS

Research Design: This study has followed both qualitative and quantitative research designs by following a mixed method approach. The qualitative research techniques of focus groups, in-depth interviews, content, and thematic analyses were adopted to make the study more indigenous and authentic. Moreover, quantitative research techniques including; mean, standard deviations, correlations, Cronbach's alpha reliabilities, Exploratory Factor Analysis (EFA), Confirmatory Factor Analysis (CFA), and analysis of variance were used to establish the reliability, validity, factor structure, and psychometric properties of the ESDS.

The duration of the study was Sixteen months (January 2020 to April 2021). The participants of the study were diagnosed patients with infertility. They were included phase-wise from infertility treatment centers in various public and private hospitals, medical centers, and health treatment facilities centers.

The research was comprised of four phases:

Phase-I

Participants. The purposive sampling strategy was adopted to select the sample of 30 participants (infertile men=4, infertile women=6, male spouse=5, female spouse=5, infertility experts=10) for interviews from the different hospitals (i.e., Sir Ganga Ram Hospital, Lady Willington Hospital, Hameed Latif Hospital, and Mid City Hospital, Lahore, Pakistan).

Instrumentation and procedure. The study was approved by Advanced Studies and Research Board (AS&RB) of GCU, Lahore, Pakistan, and permission were taken formally from the Heads of the relevant hospitals and departments. Participants were made well aware of the objectives of the research and informed consent were sought from the participants before the interviews. Anonymity and confidentiality of the information were assured to all the participants.

Initially, a pool of statements in the Urdu language was empirically generated from 30 participants by using semi-structured interviews. These interviews were transcribed and analyzed through

content and thematic analysis. Moreover, item generation purely relied on the themes collected from thematic analysis. During the process, overlapping and peculiar items were eliminated. Initially, a pool of 85 items was generated and these items included the problems shared by men and women with infertility, spouses, and infertility experts. As the intended scale was meant to be used for both infertile males and females, therefore, problems shared by men and women only were not entertained in item generation.

Later on, items were analyzed for language clarity and content validity. Afterward, the initial item pool was presented to eight expert judges (psychologists, infertility experts, and a language expert) for consensus, grammatical and contextual corrections. The judges (N=8) independently, evaluated each item on the 4-point scale of relevance and clarity. During this process, few items were omitted due to less than 50 percent consensus of experts, and few items were revised. Finally, 79 items out of 85 were retained. To arrange in a general to more specified content, the sequence of the items was reshuffled. The response format of the Emotional and Social Distress Scale for Infertile men and women was decided to be a 5-point Likert type rating scale (1= Strongly Disagree, 5=Strongly Agree) because five points Likert scale is considered to a more balance as it provides sufficient choice to the respondents to select the most suitable response.

Try out Phase (Piloting): The sample of the tryout phase comprised of N=40 infertile participants (i.e., males=20, females=20) from Lahore having an age range between 24 to 44 years. Further, the minimum duration of their marriage was 1 year and they were diagnosed as patients with primary infertility. The qualifications range was illiterate to MS/M.Phil. Participants with comorbid psychological or physiological disorders having adopted a child were excluded. This step ensured the psychometric cleansing of the items, eliminating the vague unrelated, overlapping, and redundant items, and selecting the appropriate scale items. Five items were removed because these items were unrelated to emotional and social distress. This exercise resulted in more understandable, comprehendible, and explicable 74 items that were further used to establish the factorial validity (EFA & CFA).

Factorial Validity and Reliability of the Scale. In phase II, the factorial validity of the psychosocial problem scale for infertile men and women was computed to determine the factor structure and retention of final items for the scale. Principal Component Analysis (PCA) was performed using a Varimax rotation on the 74 items scale as the factor analysis extraction technique. Cronbach's alpha, item-total correlation, and item sub-scale correlation were also calculated.

Phase-II

Participants: Five hundred and four (N=504) infertile participants including men (*n*=148) and women (*n*=356), were selected from the different infertility treatment centers of public, and private hospitals, and infertility centers in Lahore with the age range of 20 to 45 years (M=31.84, SD=6.43). The education of the sample was matric to MS/MPhil and above. In this phase, only primary infertile men and women who have been married for at least one year were included.

Instrument: An initially finalized 74 items of emotional and social distress scale after experts' opinions and try out phase were used for the further data collection to conduct exploratory factor analysis (EFA) along with demographic data sheet including (i.e., gender, age, duration of the marriage, income, cause of infertility and education).

Procedure: A sample of the study was approached at different public and private hospitals. Seventy-four items scale and demographic questionnaire were administered individually to a total sample of 608 infertile men and women after making sure the ethical consideration. The purpose of the study was explained to the participants after assuring the confidentiality of the information and informed consent. The participants were asked to fill in the questionnaire honestly and independently. Clinical information regarding infertility history was obtained from the patients, medical reports, records, and consulting physicians. Most of the participants filled in the questionnaire appropriately, some left the questionnaire unfilled due to personal reasons. Some unfilled questionnaires were completed at the next appointment and the remaining were discarded due to incomplete information. A total of 504 questionnaires were found appropriate, after checking EFA assumptions, (sample size, screening of data, normality of the data, and checking outliers among the cases) for further analysis.[4,7]

RESULTS

Exploratory Factor Analysis

Kaiser-Meyer-Olkin measure (KMO) was 0.93 indicating the sample was adequate and the pattern of correlations is relatively compact so far, factor analysis yielded distinct and reliable factors. Moreover, Bartlett's test of sphericity $\chi 2$ (595) =8189.55 ($p < .001$) showed that the R-matrix was not an identity matrix, thus factor analysis was appropriate.[4]

After analyzing the assumptions for exploratory factor analysis, 74 items were subjected to exploratory factor analysis. Varimax rotation was used for exploratory factor analysis on the responses of 504 participants.

Initial analysis revealed a factor structure with varimax rotation. Principle component analysis produced 15 factors with Eigenvalue >1.0. The correlation matrix was closely observed, problematic and non-significantly correlated 39 items were deleted after the consensus of committee members. After deleting the items, exploratory factor analysis was carried out again on 35 items by using the SPSS-22 version, four factors with 35 items (Distress, Identity and Well-being, Feelings of Insecurity, and Sexual/Marital Issues) were retained.

Table 1 indicates that all the factor loadings loaded at .30 and above have been retained. It is worthy to mention here that about a few of the items are loaded at .30 and above on more than 1 factor, for instance, item numbers 25,

TABLE I: FACTOR LOADINGS, EIGEN VALUES, PERCENTAGE OF EXPLAINED, VARIANCE, AND CUMULATIVE VARIANCE OF 35 ITEMS OF EMOTIONAL AND SOCIAL DISTRESS SCALE (N=504)

Items	Factors				
	Factor-I	Factor-II	Factor-III	Factor-IV	r
Item 1.	.70	.08	.17	-.03	.46**
Item 2.	.67	.15	.12	-.05	.46**
Item 8.	.67	.14	.07	.07	.55**
Item 14.	.66	.10	.06	.01	.54**
Item 20.	.61	.03	.07	.02	.38**
Item 9.	.59	.07	.22	.28	.51**
Item 28.	.51	.28	.20	.18	.54**
Item 15.	.49	.39	.04	.18	.52**
Item 31.	.49	.23	.22	.39	.36**
Item 24.	.48	.37	.13	.13	.45**
Item 32.	.42	.22	.10	.39	.47**
Item 35.	.41	.28	.25	.30	.40**
Item 27.	.39	.35	.08	.19	.58**
Item 25.	.38	.30	.35	-.14	.49**
Item 3.	.08	.66	.19	-.02	.41**
Item 6.	.04	.63	.29	.25	.52**
Item 23.	.23	.62	.04	.11	.63**
Item 13.	.07	.62	.19	.25	.47**
Item 30.	.20	.56	.22	.11	.56**
Item 4.	.15	.54	.27	.06	.50**
Item 18.	.21	.46	.23	.31	.62**
Item 34.	.24	.46	.18	.34	.49**
Item 5.	.13	.10	.73	.16	.54**
Item 7.	.05	.25	.67	.19	.56**
Item 12.	.16	.25	.64	.11	.52**
Item 16.	.16	.16	.63	.13	.40**
Item 19.	.16	.26	.62	.25	.49**
Item 21.	.10	.22	.51	.16	.54**
Item 26.	.40	.02	.40	.35	.59**
Item 11.	.21	.16	.37	.20	.58**
Item 17.	.07	.11	.14	.68	.56**
Item 29.	.12	.06	.18	.67	.50**
Item 22.	.00	.15	.06	.62	.41**
Item 10.	-.07	.18	.20	.51	.55**
Item 33.	.20	.06	.19	.40	.61**
Eigen values	10.13	2.42	1.59	1.36	
% of explained variance	28.94	6.93	4.56	3.90	
Cumulative variance	13.93	25.15	35.78	54.35	

Note. Factor loadings > .30 is in bold. The solution was obtained by Orthogonal rotation with the varimax method., Factor-I=Distress, Factor-II=Identity and Well-being, Factor-III=Feelings of Insecurity, Factor-IV= Sexual/Marital Issues, r= Inter-item Correlation

64, 16, 73, 55, and 35 were loaded on more than 1 factor at once. A close-by investigation of the content directed to the decision of comprising the items to which they were conceptually more interrelated. Additionally, these items' loadings were reasonably high on the retained factor. Item total association revealed that all the items are meaningfully and significantly correlated with the total of the Emotional and Social Distress Scale. Moreover, all the correlations were within the adequate significant ($p<.01$) range of .36 to .63 respectively. Therefore, all the items were retained for further analysis.

The table shows that a total of four factors were retrieved. Factor-I (Distress) has 14 items with 28.94 percent explained variance, factor-II (Identity and Wellbeing) has 8 items with 6.93 percent of explained variance, factor-III (Feelings of Insecurity) has 8 items with 4.56 percent of explained variance and finally, factor-IV (Sexual/Marital Issues) has 5 items with 3.90 percent of the explained variance respectively.

Factor-I (Distress): Item numbers (1, 2, 17, 23, 15, 39, 41, 25, 36, 64, 11, 73, 58, and 16) had higher independent loadings on factor-I. Though few items loaded .30 and above on other factors however loadings were less than the retrieved items. Further, a close examination and theoretical relevance of the content directed to the judgment of containing the items in factor-I. Items represent distress in infertile men and women. Items were related to sadness, pinching questions by others, future concerns, irritability, social pressure for having a child, tension, uncertainty, worry due to child desire, mental disturbance, somatic problems, disappointment, trying to solve the problem of infertility, colorless life due to childlessness and restlessness. The items showed (.70, .67, .67, .66, .61, .59, .51, .49, .49, .48, .42, .41, .39, and .38) loadings on factor-I and it explained 28.94 percent of the variance.

Factor-II (Identity and Well-being). Items (18, 54, 14, 53, 32, 13, 55, and 21) had higher independent loadings on factor II. Item 55 also had.31 loading on Factor-III but the reason to include the current item in factor-II was its higher loading and conceptual relevance. All the items were related to Identity and well-being. Variables like feeling incomplete and unworthy, diminished interest in life, feeling inferior when compared with others, reduced interactions with people, identity crises due to 'infertility', treatment makes me feel low and weak and getting punishment without sin. The items (.66, .63, .62, .62, .56, .54, .46 and .46 respectively) showed loadings on the factor-II and explained variance was 6.93 percent.

Factor-III (Feelings of Insecurity). Items (7, 56, 20, 8, 27, 49, 35, and 51) had higher loadings on factor III. Item 35 also had.3 and above loadings on factor-I

TABLE II: FACTOR LOADINGS AND ITEMS OF EMOTIONAL AND SOCIAL DISTRESS SCALE (N=504)

Factors No.	Factor Label/Sub-Scales	Items
I	Distress	1, 2, 17, 23, 15, 39, 41, 25, 36, 64, 11, 73, 58, 16
II	Identity and Wellbeing	18, 54, 14, 53, 32, 13, 55, 21
III	Feelings of Insecurity	7, 56, 20, 8, 27, 49, 35, 51
IV	Sexual/Marital Issues	29, 37, 50, 9, 61

and factor-IV but the item retrieved in Factor III was conceptually relevant. Items were related to Insecurity due to childlessness. That is why it is named Feelings of Insecurity. Items showed family complaints to her/his husband, feelings of insecurity, taunts and negative comments, giving explanations to others for infertility, keeping silent due to childlessness, fear of divorce, separation, opposing behavior of in-laws, and financial stress. The Items (.73, .67, .64, .63, .62, .51, .40 and .37) showed loadings on Factor III and explained variance was 4.56 percent.

Factor-IV (Sexual/Marital Issues). Items (29, 37, 50, 9, and 61) had independent loadings on factor IV. Items were related to the difficulty to follow the scheduled intercourse, diminished desire for sex, a negative impact on sexual life due to childlessness, negative effect on marital relations, and diminished love for the partner. The item (.68, .67, .62, .51, and .40) showed loadings on factor-IV and explained 3.90 percent of the variance.

Conclusion of Exploratory Factor Analysis. Retained 35 items of the ESDS for Infertile men and women based on a sample of 504 infertile participants by using the Varimax rotation method. Thus, the factorial validity of the scale was established on empirical, reasonable, logical, and statistical grounds. The final scale of 35 items with having four well-defined factors; I as Distress (14 items), II as Identity and Well-being (8 items), III as Feelings of Insecurity (8 items), and IV as Sexual and Marital Issues (5 items) was developed. All the items were positively phrased. The final factor structure was elucidated in the view of the degree of factor loadings and on the grounds of conceptual pertinence. These factors are conceptually and theoretically distinctive from each other. Interpretation of the 35 items loaded on the four factors revealed that the obtained structure is following domains of infertility-related Emotional and Social Distress.

Table III indicated that Cronbach alpha for the total scale was .92 which is considered an excellent range. Furthermore, Cronbach's alpha level for the subscales of the Emotional and Social Distress Scale ranged from .70 (Sexual/Marital Issues) to .87 (Distress) for men and women respectively. Results of correlation analysis revealed that Distress, Identity and well-being, Feelings of Insecurity, and Sexual/Marital Issues were significantly associated with each other.

Phase-III

Confirmatory Factor Analysis (CFA) was run to establish the construct validity by confirming the factor structure of the indigenously developed Emotional and Social Distress Scale. The data were subjected to statistical analysis by using the AMOS-20 version to confirm the model emerged in EFA, factor structure, and dimensionality of the Emotional and Social Distress Scale for infertile men and women. In the current study, standardized statistics criteria were used to describe the best model fit[1,21]

Participants and procedure. Participants of this phase of the study were selected through a purposive sampling strategy. The sample consisted of N=445 infertile participants (men=137) and (women=308), selected from the different public, private hospitals, and infertility centers of Lahore with the age range from 20 to 45 years (M = 31.12, SD = 6.44). The education of the sample was Matric to Masters and above. In this phase, only primary infertile men and women having at least 1 year of marriage were included. The purpose of the study was explained to the participants, after assuring confidentiality of the information and informed consent, participants were asked to fill in the questionnaire honestly and independently. A total of 445 questionnaires were found appropriate for further analysis.

Instruments. 35-items ESDS (developed in phase-I & II) were used to collect data. Cronbach's alpha estimate for the total scale is α=.92, for subscales, it ranges from α=.70 (Sexual/Marital Issues) to .86 (Distress).

The results of confirmatory factor analysis revealed that the factor structure model of the Emotional and Social Distress Scale for Infertile men and women is well fitted for the parameters of model fit indices.[1,21] Moreover, item number 31 was deleted while conducting CFA to achieve the model fit indices after analyzing the

TABLE III: RELIABILITY ANALYSIS AND CORRELATION OF TOTAL AND SUBSCALE OF EMOTIONAL AND SOCIAL DISTRESS SCALE (N=504)

Variables	Distress	Identity & well-being	Feelings of Insecurity	Sexual / Marital issues	ESDS Total	α	Range	
							Potential	Actual
Distress	-	.62**	.59**	.39**	.87**	.87	14-70	24-70
Identity & well-being		-	.63**	.44**	.83**	.81	8-40	8-40
Feelings of Insecurity			-	.52**	.84**	.82	8-40	8-40
Sexual/Marital issues				-	.63**	.70	5-25	8-25
ESDS Total						.92	35-175	63-172
M (SD)	54.45(10.35)	25.86(6.77)	26.61(7.28)	16.24(3.83)	123.16(23.33)			

Note: **Correlation is significant at the p=<0.01 level (2-tailed)

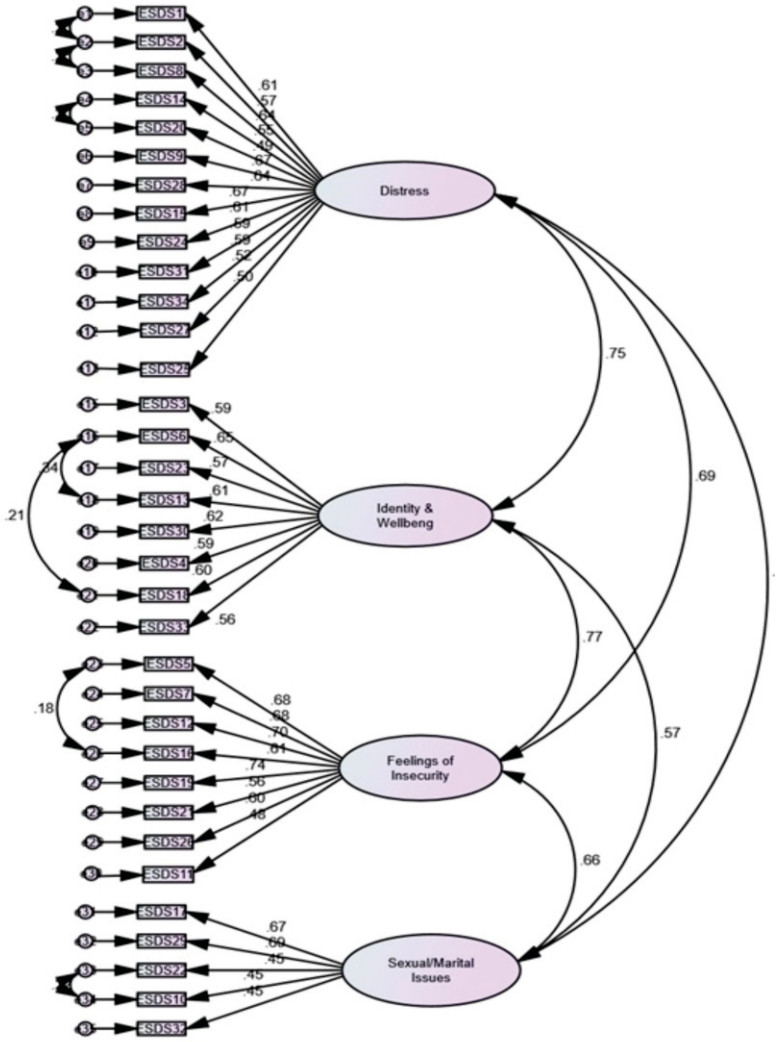

Figure 1. Indicating measurement model, Confirmatory Factor Analysis of Emotional and Social Distress Scale for infertile men and women.

residual variance.

Table V shows that all the item-total correlations are positively and significantly associated with the overall ESDS scores (r = .38 to r = .66) after CFA. All the factor loadings were within the recommended range (.45 to .74).

Results of the independent sample t-test indicated that women have significantly higher mean scores on distress, Identity & well-being, and Feelings of insecurity than men. However, in terms of sexual and marital issues men showed significantly higher scores than women. Furthermore, women showed statistically significantly higher scores on emotional and social distress compared to men.

Phase-IV

In the present phase of the study convergent and discriminate validity of the Emotional and Social Distress Scale was established by calculating correlation among other standardized scales measuring the same construct (convergent) and a test measuring contradictory behavior (discriminate).

Participants. For this part of the study, 100 participants (men= 39, women= 61), were approached to establish the construct validity (convergent and discriminant) evidence of ESDS, developed in phase-I. A purposive sampling technique was used to collect the data from Children Hospital Sheikhupura and Lady Willingdon Hospital Lahore, Pakistan. Only those participants were included in the study who had at least 1 year of infertility within the age range of 21 to 45years (M=33.35, SD=6.36). The education of the infertile patients ranged from illiterate to Master and having primary infertility.

Instruments. The following two measures were used to establish the construct validity of the newly developed ESDS. *Fertility Problem Inventory".*[9] This Urdu version scale, translated by Naz and Ikram in 2016,[7] was used to measure the convergent validity of the ESDS. The reported reliability of this scale is ranging from .77 to .87 and on the current sample was .75. The second scale was *"The satisfaction with Life scale"*[22] a self-report five items measure, the test-retest reliability of SWLS was .82 and the coefficient alpha was .87. This scale was used for the discriminant validity of the psychosocial problem scale. Urdu version of the SWLS was used to collect the data. Cronbach alpha in the current study was .70.

Procedure. Permission was taken from the heads of the hospitals. Data were collected from the Children's Hospital Sheikhupura and Lady Willington Hospital Lahore. One hundred married men and women with the diagnosis of primary infertility were approached in hospitals through infertility experts. Approximately 15-20 minutes were taken by the participants to complete the questionnaires. An emotional turmoil was seen during data collection. Debriefing was done after the data collection. There were no incentives offered to participate in this part of the study.

Results suggested that ESDS with 34 items has α=.88 Cronbach alpha on 100 samples. Same as FPI and SWLS have moderate to high reliabilities 0.75, to 0.70 respectively.

Table VIII shows the correlation between newly developed ESDS and FPI significantly ($p<0.01$) depicting the evidence of "convergent validity". Detailed analysis reveals that all four sub-scales of ESDS (distress, identity &

TABLE IV: MODEL FIT INDICES OF CONFIRMATORY FACTOR ANALYSIS FOR EMOTIONAL AND SOCIAL DISTRESS SCALE FOR INFERTILE MEN AND WOMEN (N=445)

Indexes	x^2	df	x^2/df	CFI	RMSEA	GFI	TLI	RMR
Final Model	1020.54	514	1.98	.92	.04	.91	.91	.07

Note: x2=chi square; df = degree of freedom; CFI=comparative fit index; RMSEA= root mean square error of approximation; GFI= goodness of fit index; TLI=Tucker-Lewis Index; RMR=root mean square residual.

TABLE V: SHOWING FINAL FACTORS, ITEMS, ITEM-TOTAL CORRELATION, EIGEN VALUES, AND PERCENTAGE OF VARIANCE ACCOUNT FOR BY FACTORS AND CUMULATIVE SCORES (N= 445)

Item Nos. (CFA)	Factor I	Factor II	Factor III	Factor IV	Item-Total Correlation (CFA)
1	.61				.53**
2	.57				.53**
8	.64				.56**
14	.55				.48**
20	.49				.44**
9	.67				.60**
28	.64				.61**
15	.67				.61**
24	.61				.58**
31	.59				.58**
34	.59				.62**
27	.52				.51**
25	.50				.51**
3		.59			.52**
6		.65			.63**
23		.57			.53**
13		.61			.59**
30		.62			.56**
4		.59			.55**
18		.60			.61**
33		.56			.56**
5			.68		.58**
7			.68		.61**
12			.70		.64**
16			.61		.60**
19			.74		.66**
21			.56		.54**
26			.60		.60**
11			.48		.50**
17				.67	.45**
29				.69	.49**
22				.45	.38**
10				.45	.40**
32				.45	.42**

Note. **p < .001. Note: item number 31 was deleted after EFA to achieve the required CFA indices after analyzing the residual variance.

well-being, feelings of insecurity, and sexual/marital issues) also significantly and positively correlated with the fertility problem inventory (FPI) that providing concrete evidence of "concurrent validity" of ESDS. These correlations suggest that all sub-scales of ESDS would assess the emotional and social distress specifically related to fertility problems. Evidence of "discriminant validity" has been shown by the correlations among the ESDS and Satisfaction with Life Scale. Results indicate a significant inverse association ($p<0.01$) with the Satisfaction with Life Scale thus providing evidence of "discriminant validity" of the ESDS.

DISCUSSION

It is universally accepted that disease-specific tools effectively assess the impact of disease as compared to generic measures.[6,22] Thus, the present study focused on the development of an infertility-specific measure for infertile men and women to assess their emotional and social distress in the Pakistani cultural context. Items of the Emotional and Social Distress Scale were empirically generated from infertile patients (both men and women), spouses, and infertility experts so that items truly represent infertility-related psychosocial problems. Researchers suggested that during the item generation phase, the qualitative information collected in the form of verbatim should be filtered and analyzed empirically to generate the items for scale.[5]

After maintaining the procedure for content validity, a tryout was carried out. The generated items underwent a tryout phase with a sample different from the exploratory phase. Researchers argued that piloting of the instrument has been desirable, to eliminate any ambiguity, language issues, errors, or omissions.[23] It further facilitates ensuring the understanding of the item structure.

The EFA was carried out to investigate the factor structure of the newly developed scale on the 504 samples. Principle component analysis yielded 35 items into four factors having a factor loading of .30 and above (see Table I). Although the items had a homogeneous construct, a close examination of the content of items defining four factors, showed that they were conceptually distinct from each other. The first factor, consisting of infertility distress included the symptoms of depression, anxiety, and stress related to infertility. This factor was composed of thirteen items and the dimension was labeled as "Distress" (see Table II). Contemporary research on infertility has suggested that infertile men and women suffered emotional and psychological distress.[20,24] This happened because of the

TABLE VI: GENDER DIFFERENCES IN TERMS OF EMOTIONAL AND SOCIAL DISTRESS SCALE FOR INFERTILE MEN AND WOMEN (N=445)

Variables	Men (n=137)		Women (n=308)				95%CI		
	M	SD	M	SD	t (443)	P	LL	UL	Cohen's d
Distress	45.62	7.97	53.94	9.44	9.23**	.00	10.09	6.54	.95
Identity & well-being	23.71	5.69	26.92	7.05	4.68**	.00	4.55	1.96	.58
Feelings of Insecurity	24.27	5.58	27.71	7.98	4.57**	.00	4.92	1.96	.49
Sexual/Marital issues	16.78	3.68	15.87	3.92	2.30*	.02	.13	1.68	.24
ESDC Total	110.39	16.74	124.45	23.97	6.22**	.00	18.50	9.61	.68

Note. ** Correlation is significant at the p< 0.01 level (2-tailed), ESDC= Emotional and Social Distress Scale.

TABLE VII: RELIABILITY ANALYSIS OF STUDY SCALES (N=100)

Scales	*k*	*α*
Emotional and Social Distress Scale	34	.88
Fertility Problem Inventory	46	.75
Satisfaction with Life Scale	5	.70

Note. k=Numbers of Items, α=Cronbach's alpha level

TABLE VIII: CORRELATIONS OF EMOTIONAL AND SOCIAL DISTRESS SCALE WITH FERTILITY PROBLEM INVENTORY, AND SATISFACTION WITH LIFE SCALE (N=100)

Variables	Fertility Problem Inventory	Satisfaction with Life Scale
Emotional and Social Distress Scale	.34**	-.43***
Distress	.22*	-.33**
Identity & well-being	.32**	-.34**
Feelings of Insecurity	.31**	-.32**
Sexual/marital issues	.24*	-.31**

Note. k=Numbers of Items, α=Cronbach's alpha level

increasing demand for a child and getting frustrated over childlessness.[25] However, it is important to note that pinching questions by others were linked to prominent symptoms and had the highest loadings in this factor. Generally, it is a cultural phenomenon as in Pakistan joint family system prevails. Thus, family, relatives, and friends, expect good news after the marriage.[7] They use different cues, prompts, curiosity questions, and personal comments to guess the happening in the womb. Several other scales measure infertility stress, but the issues explored in factor-I are unique and about the individuals particularly those living in Pakistan. Likewise, the highest number of items were included in factor-I. The reason might be that the emotional and social distress and the manifestation of emotional and social symptoms are more prominent in Pakistani infertile men and women. This finding coincides with the previous researches on Pakistani and other samples addressing the family and self-demand.[4,7,8]

Additionally, a few items (sadness and grief) of the current domain were treated as "emotional domain" on the scale of fertiqol.[9] Feelings of worthlessness in comparison to others, a dual talk by others, colorless life, no patriarchal lineage, and low feelings low were the prominent items for the distress subdomain of ESDS.

The second factor named "Identity and Wellbeing" contained eight items (see Table II). A close examination of the symptoms manifested incomplete and unworthiness, diminished interest in life, feeling inferior when compared to others, and identity crises. Significant others were reported to inculcate such irrational thoughts among infertile couples, which later becomes a gigantic issue. There was no other scale that specifically discussed this dimension but few researchers identify some of the symptoms presented in the current factor.[2,7,5] Factor-II specifically, assessed the self-indulgence, and self-blaming and highlighted the well-being of the sufferers.

The third factor was "Feelings of Insecurity" due to childlessness. In a joint family system, inheritance issues are common and, in such circumstances, childlessness leads to any form of insecurities, even loss of inheritance share. For women, the most prominent threat would be the second marriage of husband, divorce, and pinching questions of in-laws. For men, fear of separation was also reported. Men and women reported that they ignored pinching questions or used to tell a lie to their family and friends. This factor consisted of eight items explaining the perceived threats from significant others. Our results are partially consistent with other research that reported fear of separation, divorce, and insecurity due to childlessness.[6,26]

The fourth factor was "Sexual and Marital issues". The dimension included five items with significant loadings. Items were related to the difficulty to follow the scheduled intercourse, diminished desire for sex, a negative impact on sexual life due to childlessness, negative effect on marital relations, and diminished love for the partner. The current subscale assesses the degree the extent to which sexual and marital relationships had been impaired by infertility. The Fertiqol scale developed by Boivin et al. (2011) in the "dimension of interpersonal quality of life" has few items related to sexual and marital relations. Along the same line, western researchers also reported sexual dysfunction and marital discord among infertile men and women.[16,26] This dimension is very important concerning infertility and many other scales had discussed the issues in their scales.[9,13] The present study not only

offered infertility-specific information but also provided four domains after EFA, that were confirmed through CFA For this very purpose, confirmatory factor analysis (CFA) was carried out to assess the goodness of fit indices of the model that emerged through EFA. Our result revealed that the model extracted through EFA was further confirmed and demonstrated a good model fit index for CFA. Thus, the final ESDS emerged with 34 items and revealed strong construct validity.

After CFA, ESDS proved to be a standardized construct with evidence of adequate fit indices. An estimation of the total item correlation yielded that all 34 items with high factor loadings were positively and significantly correlated with the total score (ranging from .37 to .64). The 34 items Emotional and Distress Scale for infertile men and women were also found to exhibit high internal consistency. The ESDS yielded a high alpha internal consistency coefficient of .92. Moreover, the alpha reliabilities of the four factors were also found to be significant.

After developing and validating the Emotional and Social Distress Scale, the analysis of differences was computed. Among the differences gender was the prominent variable. Infertile women are confronted with more emotional and social distress as compared with infertile men (see Table VI). This might be due to cultural reasons as Pakistani men are not as victimized due to childlessness as women are. Another explanation might be that men in general, handle their problems in a positive light and used meaning-based coping resources as compared to women.[26] Additionally, they are busy with their jobs. It is also demonstrated that expectations from women to have their children are stronger as compared to men which is the why reason women face more severe consequences as compared to men. This difference is consistent with the previous studies which reported the significant difference between men's and women's perceptions of psychological and emotional problems.[27,28] Additionally, the results are in line with the studies in Pakistan that women have to bear more psychological and social problems.[4] Similarly, women suffered more due to infertility-specific distress, a subdomain of emotional and social distress, as compared to men. This finding indicated that women suffer more due to uncertainty, disappointment, somatic complaints, mental disturbance, worry, sadness, tension, social pressure, irritability, and pinching questions by others. Though men are not exempted from this challenge related to infertility yet in many societies, for women infertility is still a devastatingly negative psychological and social experience.[2,7,26,30]

The purpose of phase IV was to evaluate the convergent and discriminant validity of the newly developed Emotional and Social Distress Scale by using the Fertility Problem Inventory for convergent validity and the Satisfaction with Life Scale for discriminant validity.[13] The evidence for the convergent validity of the ESDS showed a significant positive correlation with the Fertility Problem Inventory developed by Newton et al. (1999) to measure fertility-related stress of infertile individuals. The results indicated the empirical evidence of the convergent validity of the total ESDS was moderately significantly positive.[26] Moreover, the Correlation of FPI with all the subscales of ESDS was also significant and positive that showing the convergent validity of ESDS. Similar results were found when the convergent validity of FPI with depression was established in the Korean sample.[30] All correlations among ESDS, and FPI were moderate and positive. These results are compatible with the previous research. Newton et al. (1999) investigated inter-correlation between the FPI scales and standardized measures of Depression and found a significantly positive correlation. In this study, the researcher used the FPI with ESDS for convergent validity and found a moderate correlation that supports the previous empirical investigations. Discriminant validity has been established by calculating the correlation between the Emotional and Social Distress Scale and Satisfaction with Life Scale.[25] The findings showed significant negative correlations with the newly developed ESDS scale. The results indicated that ESDS has excellent discriminant validity. Our results are consistent with previous research, as Kim and Shin, 2014 established the discriminant validity of the FPI Korean version through FPI and fertility-related quality of life and found significant negative correlations. Results are also consistent with prior research as the patients with infertility showed a significant reduction in quality of life and increased psychological problems.[30] Moreover, Gana and Jakubowska (2016) reported the association between infertility-related stress and emotional distress.[31]

Overall results were aligned with the hypotheses of this study and previous research in the same area that provide enormous support to establish the convergent and discriminant validity of the ESDS.

LIMITATIONS AND SUGGESTIONS

The sample comprised hospital-based primary infertility, thus, in the future secondary infertility and community-based sample could also be included.

IMPLICATIONS AND CONCLUSION

Due to the lack of a valid and reliable measure to assess emotional and social distress in infertile men and women in Pakistan, using the ESDS is suggested in infertility centers. Overall results indicated that women have more emotional and social distress, which indicated that Pakistani infertile women have a marked need for infertility counseling. The results of this study can be used as a baseline of information for psychological intervention.

Despite some limitations, based on the result of EFA, CFA, evidence of reliability, and convergent and discriminant validity, it could be concluded that 34-items ESDS is a valid and reliable instrument and could be used to assess the emotional and social distress in Pakistani infertile men and women with confidence. Further pre- and post-studies differences can be observed with ESDS. It would be helpful for health practitioners and researchers.

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AUTHOR'S CONTRIBUTION

Following authors have made substantial contributions to the manuscript as under:

BN: Conception & study design, drafting the manuscript, approval of the final version to be published.

SSB: Study design, analysis and interpretation of data, critical review, approval of the final version to be published.

MKF: Acquisition of data, drafting the manuscript, approval of the final version to be published.

MZK: Analysis and interpretation of data, critical review, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

CONFLICT OF INTEREST

Authors declared no conflict of interest

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