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Original Article

Effects of comprehensive care on mood and quality of life in infertile patients

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Abstract: Objective: To evaluate the effects of a comprehensive care management program on bad mood and quality of life (QoL) in infertile patients. Methods: Three hundred and sixty infertile patients were recruited in this study. The psychological status of the patients was evaluated by the Symptom Check-List-90 (SCL-90) scale. The recruited patients were randomized into the control group or the study group. The patients in the control group were assigned to receive usual care, whereas those in the study group underwent a comprehensive care management program in addition to usual care. The overall satisfaction with care, the incidence of pregnancy, and the time to pregnancy were compared between the two groups. Additionally, the Hamilton Rating Scale for Depression (HRSD), the Zung Self-Rating Anxiety Scale (SAS), the medical coping modes questionnaire (MCMQ) and the Generic Quality of Life Inventory-74 (GQOLI-74) were utilized to evaluate the psychological status of the patients. Changes in sexual hormones and ovulation of patients in the two groups were monitored, and the effects of comprehensive care were assessed based on changes in endocrine hormone levels of the patients. Results: Comparison of the SCL-90 scores of all patients with national normal values revealed that the major psychological problems of infertile patients were somatization, depression, anxiety, hostility and interpersonal sensitivity. After comprehensive care, satisfaction with care, incidence of pregnancy and time to pregnancy were strikingly improved in the study group as compared with those in the control group (all $P<0.05$). Before intervention, the scores on the HRSD, SAS, FPI, MCMQ and GQOLI-74 differed insignificantly between the two groups (all $P>0.05$). Conversely, after intervention, the HRSD, SAS and FPI scores in the study group were substantially lower than those of the control group (all $P<0.05$). As for the MCMQ scores, the score of confrontation (a coping mode) was remarkably higher in the study group than in the control group ($P<0.05$), whereas the scores of submission and avoidance were markedly lower in the study group (both $P<0.05$). The QoL of the study group was significantly better than that of the control group ($P<0.05$). The follicle stimulating hormone (FSH), luteinizing hormone (LH), progesterone (P), and prolactin (PRL) levels in the study group were strikingly higher than those in the control group (all $P<0.05$), but the disparities in the estradiol (E2) and testosterone (T) levels were mild (both $P>0.05$). A remarkably higher rate of ovulation was noted in the study group ($P<0.05$). Conclusion: The addition of a comprehensive care management program to usual care for infertility results in greater improvements in the bad mood, the QoL, and physiological status of patients, which is worthy of clinically wide use.

Keywords: Infertility, comprehensive psychological intervention, bad mood, quality of life

Introduction

Infertility refers to the inability of women to achieve clinical pregnancy one year after having normal sexual intercourse without taking any contraception measure on the condition that their spouses have normal reproductive function. It can be subdivided into primary and secondary infertility [1, 2]. According to available statistic data, approximately 80 million women are suffering from infertility worldwide [3]. Infertility, following tumors and cardiovascular and cerebrovascular diseases, has become the third most severe disease affecting human's health and quality of life (QoL) in the twenty-first Century [4]. After a long-term clinical diagnosis and treatment, we find that infertility is a syndrome of many disorders instead of a single disorder [5]. During long-term treatment, refractory psychological problems result-

ed in endocrine disorders and a reduced probability of pregnancy, which forms a vicious circle [6, 7].

In the past, the treatment of infertility only focused on the physiological aspects of the patients, ignoring their huge psychological pressure. As a result, they developed mental disorders (anxiety and depression), which had a detrimental impact on their daily lives [8-11]. Comprehensive care refers to that in addition to usual care, the clinicians make an in-depth analysis on the mental status of infertile women and take tailored care measures to improve the prognosis of patients [12].

Previous studies have confirmed higher pregnancy rates, shorter times to pregnancy, and improved QoL and mental status are observed in infertile patients after they have received psychological care [13]. However, due to single outcome measures taken, most researchers failed to make a comprehensive assessment on the efficacy after intervention. Accordingly, the purpose of this study was to evaluate the efficacy of a comprehensive care management program with more specific outcome measures. A total of 360 infertile patients admitted to Shenzhen People's Hospital, Ji'nan University were recruited as participants and randomly assigned to the control group or the study group. The patients in the control group received usual care, whereas those in the study group were treated with comprehensive care in addition to usual care, with an aim to investigate the clinical efficacy for the care program in infertile patients.

Materials and methods

Patients

A total of 360 infertile women admitted to Shenzhen People's Hospital, Ji'nan University from March 2015 to March 2017 were enrolled in this study. They were randomly assigned to the control group (n=180) or the study group (n=180) in terms of a random number table. The demographic characteristics including age, marriage duration, the duration of infertility, infertility type, educational levels, residence, and the infertility treatment duration were generally well-matched among the women (all P>0.05), so they were comparable.

Inclusion criteria

All the patients and their families were fully informed of the contents of this study and provided written informed consent. The Ethics Committee of Shenzhen People's Hospital, Ji'nan University approved this study. Patients aged 20 to 48 years were eligible for enrollment if they were married women, with the physical condition that met the diagnostic criteria for infertility and the duration of infertility was more than 1 year; if their spouses were healthy without any reproduction-related disease; if they provided full and detailed medical records with regard to the current and previous history of infertility; if they had good communication and language abilities and were able to cooperate in the interview.

Exclusion criteria

Patients were excluded from this study if they had a psychiatric or mental disorder, severe systemic infection, advanced cancer, hematological disease, severe cardiac, hepatic or renal insufficiency, or were unable to follow the protocol due to personal causes.

Study intervention

The primary care providers patiently answered all the problems asked by the patients, and instructed them to complete the symptom checklist-90 (SCL-90) questionnaires for assessment of their psychological status.

Usual care covered disease monitoring, medications and guidance and care related to diet promotion and education.

In addition to usual care, the patients in the study group also participated in a comprehensive care management program including psychological counseling, cognitive reconstruction, and strengthening the social support system. Psychological counseling included a good understanding of the patients' conditions, an emphasis on privacy protection, correct assessment of their psychological problems and a close observation of the changes in their emotions. In addition, meaningful communications should be made with the patients to relieve their psychological pressure and solve their problems by inspiring words and ideological conversations. The patients were informed

Table 1. Baseline characteristics of patients

Variables	Control group (n=180)	Study group (n=180)	t/χ^2	P
Age (year)	29.74 ± 2.63	29.21 ± 2.77	2.148	0.032
Marriage duration (year)	4.25 ± 1.11	4.43 ± 1.30	-0.788	0.431
Education level			0.777	0.678
High school	25	27		
University	141	137		
Graduate	14	16		
Residence			0.100	0.751
Urban	97	94		
Rural	83	86		
Infertility type			0.101	0.751
Primary	79	82		
Secondary	101	98		
Infertility duration	3.74 ± 1.63	3.56 ± 1.97	1.080	0.281

of the importance of psychological counseling, and the harms of negative emotions (anxiety and depression) to their own health and pregnancy. Cognitive reconstruction included the following aspects: the eligible women were organized to receive centralized health care education. Several senior nurses from infertility-associated departments who had excellent social skills, good patience, and compassion, with the use of multimedia, graphic or video tools, were able to get the patients aware of infertility-related knowledge, the factors affecting fertility, the relevant treatment methods, and cautions should be taken during treatment. Meanwhile, they also reminded the patients that they should psychologically make full preparations as it was uncertain when the intervention would take effect. Strengthening the social support system covered the following points: the spouses and other family members of the patients were aware that there was a high incidence of infertility. The medical staff should minimize the patients' pressure, both verbally and non-verbally. Additionally, it is advisable to comfort the patients and ensure to create a good environment at home for them.

Outcome measures

The outcomes included the SCL-90 scores of patients before and after intervention, satisfaction with care, the time to pregnancy, incidence of pregnancy, assessments of psychological status, as well as the QoL of patients. The SCL-90 scale was employed to assess the psychological status of the patients before treatment (on a scale of 5 points, 1 point indicated no symptom, each additional point indicated a more severe level of the symptoms, with 5 points indicating the most severe disease). The final scores were compared with the national normal values in China (**Table 2**). Taking the situation of Shenzhen People's Hospital, Ji'nan University into consideration, the patients' satisfaction with the overall care was evaluated by questionnaires. The questionnaire consisted of 20 items totaling 100 points, with ≥85 points indicating satisfaction, the scores between 60 and 84 points indicating basic satisfaction, and <60 indicating dissatisfaction (**Table 3**). The formula for satisfaction rate is: Satisfaction rate = (satisfaction + basic satisfaction)/180*100%). All the patients completed the following questionnaires for assessment of their psychological status before and after intervention. The Hamilton Rating Scale for Depression (HRSD) is a multi-item questionnaire utilized to rate the severity of depression in patients by depression, feelings of guilt, suicide ideation, insomnia, light sleep, early sleep, work and interest, retardation, agitation, mental anxiety, somatic anxiety, gastrointestinal symptoms, systemic symptoms, sexual symptoms, hypochondriasis, weight loss, insight, diurnal mood variation, depersonalization, obsession, compulsion, hopelessness and inferiority; the Zung Self-Rating Anxiety Scale (SAS), the medical coping modes questionnaire (MCMQ) and the Fertility Problem Inventory (FPI) (**Tables 4** and **5**). The Generic Quality of Life Inventory-74 (GQOLI-74) questionnaire was used to assess the QoL of all the patients before and after intervention, including material life, somatic, social, and psychological functions (**Table 6**).

Other outcomes included the sexual hormone levels and the rate of ovulation on the vaginal ultrasound. The sexual hormone levels of patients were measured in the morning within 4-7 days after the end of menstruation. Some fasting blood was drawn from each patient (in a

Table 2. SCL-90 scores of patients and national normal values in China

Item	National normal value	Score of included patients	t	P
Somatization	1.37 ± 0.48	3.64 ± 1.48	-19.574	0.000
Depression	1.50 ± 0.59	3.49 ± 1.75	-14.457	0.000
Anxiety	1.39 ± 0.43	3.79 ± 1.66	-18.777	0.000
Hostility	1.48 ± 0.56	3.62 ± 1.52	-17.724	0.000
Interpersonal sensitivity	1.65 ± 0.51	3.28 ± 1.26	-13.640	0.000
Compulsion	1.62 ± 0.58	1.73 ± 0.59	-1.784	0.075
Terror	1.23 ± 0.41	1.31 ± 0.47	-1.721	0.086
Paranoid	1.43 ± 0.57	1.65 ± 0.54	-1.880	0.060
Psychotic symptom	1.29 ± 0.42	1.33 ± 0.47	-0.851	0.395
Total	1.44 ± 0.43	1.57 ± 0.61	-1.618	0.107

Note: SCL-90, Symptom Check-List-90.

Table 3. Care satisfaction and clinical efficacy

Variable	Satisfaction	BS	Dissatisfaction	SR	TP (year)	PR
CG (n=180)	121	40	19	89.44%	2.26 ± 0.47	93 (51.67%)
SG (n=180)	134	39	7	96.11%	1.15 ± 0.38	114 (63.33%)
t/χ^2			6.214		24.640	5.013
P			0.045		0.000	0.025

Note: BS, basic satisfaction; SR, satisfaction rate; TP, time to pregnancy; PR, pregnancy rate; CG, control group; SG, study group.

lying position) in the two groups for evaluating secretion of sexual hormones (follicle stimulating hormone (FSH), luteinizing hormone (LH), estradiol (E2), testosterone (T), progesterone (P) and prolactin (PRL)). Placed in a lithotomy position, each patient of the two groups was monitored for the profile of ovulation under the ultrasonic diagnostic device. Before monitoring, a probe covered by a condom was slowly advanced into the vagina to observe the profile of ovulation. The signs for ovulation were as follows: on the ultrasound, at least 1 dominant follicle matured and expelled, disappeared or diminished, morphologically irregular follicular walls, and the presence of high light echoes in follicles.

Statistical analysis

All the data were analyzed using the SPSS software, version 22.0. Measurement data are presented as mean ± standard deviation, and the t-tests were employed for between-group comparisons. Count data were described as rates, and Chi-square tests were utilized for between-group comparisons. P<0.05 indicated significant difference.

Results

Baseline characteristics of patients

Baseline characteristics were generally well-matched among the patients between the two groups (P>0.05), so they were statistically comparable (**Table 1**).

Comparison between SCL-90 scores of patients and national normal values in China

On the SCL-90 scale, the scores of somatization, depression, anxiety, hostility, and interpersonal sensitivity of patients were remarkably higher than the national norms (all P<0.05). Nevertheless, the scores of compulsion, terror, paranoid and psychotic symptoms of the patients were not different from the national normal values (all P>0.05, **Table 2**).

Care satisfaction and clinical efficacy

The rate (96.11%) of satisfaction with care of patients in the study group was markedly higher than that (89.44%) in the control group (P<0.05). The time to pregnancy (1.15±0.38 years) in the study group was substantially shorter than that (2.26±0.47 years) in the control group (P<0.05). The incidence of pregnancy was 63.33% in the study group, and 51.67% in the control group, suggesting a strikingly higher rate of pregnancy in the study group (P<0.05, **Table 3**).

HRSD, SAS and FPI scores before and after intervention

Before intervention, no significant differences were noted in the scores of HRSD, SAS and FPI between the two groups (all P>0.05). Nevertheless, after intervention, the scores of the

Table 4. HRSD, SAS and FPI scores before and after intervention

Variable	HRSD		SAS		FPI	
	BI	AI	BI	AI	BI	AI
CG (n=180)	26.58 ± 11.72	19.58 ± 9.72	48.53 ±7.12	38.25 ± 6.26	81.92 ± 3.41	68.31 ± 4.07
SG (n=180)	26.31 ± 12.11	13.57 ± 8.75	47.63±6.98	31.25 ± 5.93	82.61 ± 3.53	64.87 ± 3.25
t	0.215	6.165	1.211	10.891	-1.886	8.861
P	0.830	0.000	0.227	0.000	0.060	0.000

Note: BI, before intervention; AI, after intervention; CG, control group; SG, study group; HRSD, Hamilton Rating Scale for Depression; SAS, Zung Self-Rating Anxiety Scale; FPI, Fertility Problem Inventory.

Table 5. MCMQ scores before and after intervention

Variable	Confrontation		Submission		Avoidance	
	BI	AI	BI	AI	BI	AI
CG (n=180)	18.35 ± 3.04	19.97 ± 2.53	16.49 ± 2.73	14.67 ± 4.32	13.64 ± 2.16	11.98 ± 2.48
SG (n=180)	18.91 ± 2.65	24.39 ± 2.78	16.57 ± 2.61	12.73 ± 3.25	13.51 ± 3.34	8.46 ± 2.22
t	-1.863	-15.776	-0.284	4.815	0.438	-14.188
P	0.063	0.000	0.776	0.000	0.661	0.000

Note: BI, before intervention; AI, after intervention; CG, control group; SG, study group; MCMQ, medical coping modes questionnaire.

Table 6. GQOLI-74 before and after intervention

Variable	CG (n=180)	SG (n=180)	t	P
ML				
BI	15.64 ± 2.49	16.22 ± 3.11	-1.891	0.060
AI	16.53 ± 1.98	27.73 ± 2.16	-51.372	0.000
SF				
BI	17.25 ± 3.14	17.94 ± 3.51	-1.934	0.054
AI	18.91 ± 3.43	26.73 ± 3.55	-21.399	0.000
SOF				
BI	13.82 ± 2.76	14.01 ± 2.69	-0.635	0.531
AI	14.56 ± 2.28	27.24 ± 3.40	-41.524	0.000
PF				
BI	16.86 ± 2.63	17.13 ± 2.19	-1.257	0.210
AI	17.82 ± 3.04	29.41 ± 3.16	-35.254	0.000
Overall score				
BI	63.53 ± 5.49	64.12 ± 5.32	-1.088	0.277
AI	62.18 ± 5.64	113.73 ± 4.36	-97.011	0.000

Note: CG, control group; SG, study group; ML, material life; BI, before intervention; AI, after intervention; SF, somatic function; SOF, social function; PF, psychological function; GQOLI-74, Generic Quality of Life Inventory-74.

above variables in the study group were remarkably lower than those in the control group (all P<0.05, **Table 4**).

MCMQ scores before and after intervention

The patients in the two groups were compared with regard to the three coping modes (confrontation, submission and avoidance) listed in the MCMQ. Before intervention, there were only small disparities in the scores of the above three coping modes between the two groups (all P>0.05). After intervention, the score of confrontation was 24.39 ± 2.78 in the study group, and 19.97 ± 2.53 in the control group, and the scores of both groups were substantially higher than those before intervention (P< 0.05). Conversely, the scores of submission and avoidance were remarkably lower in the study group than in the control group (both P<0.05, **Table 5**).

GQOLI-74 before and after intervention

The GQOLI-74 of patients was assessed by their material life, somatic, social, and psychological functions. The differences in the GQOLI-74 scores between the two groups were small before intervention (all P>0.05). Nevertheless, after intervention, the GQOLI-74 score was strikingly higher in the study group than in the control group (all P<0.05; **Table 6**).

Sexual hormone before and after intervention

Before intervention, no remarkable differences were detected in the FSH, LH, E2, T, P and PRL levels of patients between the two groups (all

Table 7. Sexual hormone levels before and after intervention

Variable	CG (n=180)	SG (n=180)	t	P
FSH				
BI	9.24 ± 1.81	9.36 ± 2.23	-0.467	0.641
AI	11.13 ± 2.61	15.27 ± 2.43	-15.425	0.000
LH				
BI	15.36 ± 3.16	15.16 ± 2.93	0.623	0.534
AI	16.23 ± 2.84	19.46 ± 2.37	-11.607	0.000
E2				
BI	138.17 ± 58.36	134.48 ± 55.74	0.616	0.539
AI	50.71 ± 21.19	51.19 ± 20.46	-0.183	0.855
T				
BI	0.72 ± 0.14	0.74 ± 0.23	-0.997	0.320
AI	0.87 ± 0.19	0.84 ± 0.21	1.421	0.156
P				
BI	1.51 ± 0.84	1.62 ± 0.90	-1.090	0.277
AI	1.63 ± 1.17	2.16 ± 1.53	-3.483	0.000
PRL				
BI	17.04 ± 2.82	16.87 ± 2.97	0.655	0.513
AI	17.59 ± 2.56	22.34 ± 2.47	-18.103	0.000

Note: CG, control group; SG, study group; BI, before intervention; AI, after intervention; FSH, follicle stimulating hormone; LH, luteinizing hormone; E2, estradiol; T, testosterone; P, progesterone; PRL, prolactin.

P>0.05). After intervention, significantly higher FSH, LH, P, and PRL levels were observed in the study group than in the control group (all P<0.05), whereas the differences in the E2 and T levels were mild (both P>0.05; **Table 7**).

Changes in follicle and endometrium before and after intervention

The ovulation rate (67.78%) of the study group was substantially higher than that (56.11%) of the control group (P<0.05; **Table 8**).

Discussion

With the development of the society, the rising pressure in our life, growing unconfined sexual life, and the spread of venereal disease, the morbidity of infertility is increasing on a yearly basis worldwide. The relevant data show that in China 50%-60% of infertility is attributed to females, whereas 30%-40% of infertility is attributed to males. The remaining 10% is attributed to both wives and husbands [14]. Infertile patients suffer from various degrees of psychological problems in the face of social and family pressure. Holka-Pokorska et al. confirmed that infertile patients endure overt psychological pressure, and are more sensitive to acute stress [15]. Other clinical studies have revealed that some patients develop depression, and the severe ones develop self-mutilation, even submit suicide [16]. In our current study, the SCL-90 score tests were conducted in all the eligible patients; the results indicated that somatization, depression, anxiety, hostility, and interpersonal sensitivity were the major psychological problems faced by the infertile patients, which was consistent with the findings of previous studies [17, 18]. The long-term negative psychological status (depression or anxiety) in patients directly results in disorders in the endocrine system, increased adrenal hormone secretion, longer duration of androgen secretion, and the changes in cervical mucus, affecting the growth of oocytes; the severe patients even develop non-ovulation or amenorrhea, which further aggravates the difficulty of pregnancy in patients [19]. Therefore, addition of comprehensive care to active usual care in infertile patients improves their physiological condition and increases the probability of pregnancy.

In our current study, after intervention, the HRSD, SAS, and FPI scores of the patients in the study group significantly decreased as compared with those of the patients in the control group. The effective coping modes contributed to the positive attitudes of patients toward the treatment. This lessened the adverse effects of infertility on patients, and alleviated their depression, anxiety, and emotional stress, which was consistent with the results reported by Fassino et al. [20]. The patients in both groups were required to complete the MCMQ questionnaires before and after intervention. Before intervention, the patients expressed anger, sensitivity, fatigue, and other emotions, and they generally took negative attitudes (submission and avoidance) toward the adverse events. This was related to the fact that they had had no good response to the previous long-term treatment. After intervention, the patients in the study group dealt with the negative emotions by confrontation. We found that they over-

Table 8. Ovulation profile of patients

Variable	Case	Ovulation	Non-ovulation	Ovulation (%)
Control group	180	101	79	56.11
Study group	180	122	58	67.78
X^2				5.197
P				0.023

came their negative emotion, and became confident to overcome the disease. Physiologically and psychologically, the patients became more healthy and calm. Compared with the previous studies, out current study was involved in more comprehensive care assessments. Because we human beings are social animals, our emotional characteristics are diverse. We are not constrained to express any single emotion (anxiety or depression) when psychological problems arise. This study assessed the patients' psychological problems from multiple perspectives. Hence it provided more powerful evidence in support of the importance of care intervention.

The long-term huge psychological pressure on the infertile patients results in headache, insomnia, forgetfulness, hair loss, and other symptoms, which lowers the QoL in patients and further aggravates their psychological pressure, hence forming a vicious circle [21]. Our current study substantiated that after comprehensive care, in addition to alleviation of the bad mood in patients, their QoL was also significantly higher when compared with that of controls. Great improvements were found in the material life, somatic, social and psychological functions of patients. Thus, the patients were in a beneficial status, which is conducive to pregnancy and increases the probability of pregnancy. As a result, it is suggested that infertile patients should acquire relevant consultation in formal medical institutions, choose the appropriate ways to relieve their depression, and hold optimistic attitudes to the treatment.

In our current study, in addition to conventional artificial assisted reproductive treatment, infertile patients in the study group also received comprehensive care and others. Furthermore, we get across infertility-related knowledge to them to improve their cognition and guide them to get effective treatment. We found that the rate of satisfaction with care was up to 96.11% in the study group, and the time to pregnancy and the pregnancy rate were more greatly improved than those of the control group, which corresponds to the result of a previous study [22]. Additionally, after intervention, for sexual hormones and ovulation, the FSH, LH, E2, and PRL levels were substantially higher in the study group than in the control group, so was the ovulation rate. This is due to the effective comprehensive care provided which inspires patients to express their true inner thoughts. In a relaxing and harmonious environment, the emotional, physical, and mental health, and the QoL are improved in patients. All this increases their confidence in the treatment, improves their endocrine dysfunction, raises the pregnancy rates, and shortens the time to pregnancy [23].

In conclusion, during management of infertility, it is not easy to encourage the patients in a poor psychological state which is detrimental to the efficacy of the treatment. In this case, we should alleviate the patients' negative emotions and psychological pressure to improve their QoL and the rate of pregnancy. The comprehensive care management program for infertile patients is associated with shorter treatment duration and better rehabilitation. Therefore, it is advisable to implement it extensively among infertile patients.

Disclosure of conflict of interest

None.

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