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Original Article

Influence of humanistic care based on Carolina care model for ovarian cancer patients on postoperative recovery and quality of life

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Abstract: Objective: Our aim was to explore the influence of humanistic care based on Carolina care model on postoperative recovery and quality of life in patients with ovarian cancer (OC). Methods: In this prospective study, we selected 85 OC patients and randomly divided them into the Carolina group (n = 43) given humanistic care based on Carolina care model and the control group (n = 42) given routine nursing intervention. The postoperative recovery and Functional Assessment of Cancer Therapy-Ovary Cancer (FACT-O) scores were compared between the two groups. Results: After intervention, the time of first flatus and defecation after surgery, the time of first ambulation and the length of average postoperative hospital stay were much shorter, and the pain score, total complication rate, self-rating anxiety scale and self-rating depression scale scores as well as Cortisol, C-reactive protein and fasting blood glucose levels at 48 hours postoperatively were significantly lower in the Carolina group than in the control group. The nursing satisfaction in the Carolina group was markedly higher than that in the control group (97.67% vs. 78.57%, P<0.01). After 3 months of follow-up, the Carolina group showed higher dimension scores of FACT-O than the control group (all P<0.001). Conclusion: Humanistic nursing care based on Carolina care model can significantly ameliorate the recovery of OC patients, reduce the physical and psychologic stress response, and effectively enhance the nursing satisfaction and quality of life.

Keywords: Ovarian cancer, Carolina care model, humanistic care, physiological stress, quality of life

Introduction

Ovarian cancer (OC) is a common malignant tumor of the reproductive system in women of different ages [1]. Ovarian organs are small in size and located deep in the pelvis. The onset of OC is insidious, and the patients usually have no specific clinical symptoms in the early stage. Additionally, there is still a lack of sensitive indicators for its early diagnosis in clinical practice, which results in a very low rate of early diagnosis [2]. When patients develop symptoms such as abdominal swelling and distension and thereby visit the doctor, the disease has usually progressed to the middle and advanced stages, with significantly poor or fatal prognosis. The mortality rate of OC ranks first among gynecological malignancies, with even lower five-year survival rate [3]. At present, surgery is still the main treatment for OC, followed by radiotherapy, chemotherapy, and immunotherapy and other comprehensive treatments [4]. However, surgical trauma and prolonged continuous chemoradiotherapy can produce serious physical and mental damage to patients, leading to severe adverse reactions, strong body stress response, and poor prognosis for recovery [5]. Hence, active and effective nursing intervention during symptomatic treatment plays a certain role in improving the prognosis of patients [6].

In recent years, the nursing care for cancer patients has become a hotspot for clinical research. As the medical model and concept change, the nursing model has ameliorated from the traditional "functional system nursing" towards the direction of "responsibility

system holistic nursing". This is also due to the lower immunity and resistance of cancer patients and more vulnerable emotion in comparison with ordinary patients [7]. Carolina nursing care, originated from the nursing point of view in Swanson's theory of caring, is reported to be a new care model with responsibility system holistic care as its main working framework The nursing model consists of a series of core cross-disciplinary actions, aiming to place patients at the center of care and provide consistent, thoughtful and positive experience so as to improve the quality of care and patient satisfaction [8]. Moreover, this model applies the following nursing view to clinical practice: Humanistic nursing care given by nursing staff based on humanistic concepts essentially confers positive effects on patients, which are no less substantial than those of therapeutic behaviors such as administration and control of complications [9].

Humanistic care theory is also patient-centered, emphasizing that the care given to patients by nurses is the embodiment of interpersonal activity, humanity and emotion in the nursing process [10]. Considering the high risk of OC and physiologic particularity of women, OC patients are in more need of humanistic care services during cancer treatment [11]. The theory of the Carolina care model as a guide combined with humanistic care may be important for enhancing their mental status and the quality of life (QoL) of cancer patients. Currently, there are few practice-based studies on humanistic care under the Carolina care model at home and abroad. Therefore, we herein investigated the effect of humanistic care based on the Carolina care model on the prognosis and QoL of OC patients.

Materials and methods

General data

A prospective study was conducted on 85 OC patients who underwent comprehensive staging surgery in University-Town Hospital of Chongqing Medical University from March 2018 to August 2020. All the patients were randomly divided into the Carolina group (n = 43) given humanistic care based on Carolina care model and a control group (n = 42) given routine nursing intervention. This study was approved by the Medical Ethics Committee of University-Town Hospital of Chongqing Medical University.

Inclusion criteria: Patients who were diagnosed with OC according to the criteria issued by the World Health Organization, and the results were confirmed by pathological examination [12]; patients who had operative indications while no history of exploratory laparotomy; patients who were classified as clinical stage I~II, and diagnosed and treated under the guidance of "*Ovarian Cancer Diagnosis and Treatment Specifications*" (2018 version) [13]; patients receiving no hormone treatment or radiotherapy before enrollment; patients who were informed of this study and signed the informed written consent with their families' consent.

Exclusion criteria: Patients with lesions that have metastasized to the abdominal and pelvic peritoneum and other parts; patients with heart, lung, kidney and other major organ dysfunctions; patients with other organ tumors; patients with blood diseases; patients with disturbance of consciousness or mental illness.

Methods

The patients in both groups underwent elective laparoscopic cytoreductive surgery for ovarian tumor. After admission, an intravenous injection of 0.2 μg/kg sufentanil (Yichang Humanwell Pharmaceutical Co., Ltd., H20054171), 0.06 mg/kg midazolam (Jiangsu Nhwa Pharmaceutical Co., Ltd., H10980026), 0.2 mg/kg etomidate (Jiangsu Nhwa Pharmaceutical Co., Ltd., H20020511) and 0.15 mg/kg vecuronium (Hubei Meheco Keyi Pharma Co., Ltd., H20083109) was given to induce general anesthesia. Postoperatively, 0.1 mg/kg oxycodone (Mundipharma (China) Pharmaceutical Co., Ltd., J20130142) was injected, and ZZB-type patient-controlled intravenous analgesia pump (Nantong Epp Medical Devices Co., Ltd.) was connected to maintain analgesia for 48 hours.

Meanwhile, the patients in the control group were given routine in-hospital care in strict accordance with the "three inspections and seven verifications", including education on knowledge, dietary intervention, medication guidance and pain care, safety management, psychological counseling, infusion care and complication prevention and treatment. On the basis of this method, the patients in Carolina group were given humanistic care based on the Carolina care model as follows:

Multi-level ward rounds: Ward rounds were performed once an hour to timely and fully understand the changes and feelings of OC patients. At the same time, head nurses were required to participate in the morning and evening ward rounds, conduct inspection on the ward irregularly, monitor the progress of nursing work in the department, and find the deficiency of nursing care and potential safety hazards. What's more, managers of other relevant departments like logistics department may also participate in some ward rounds to obtain feedback from the patients and their families for better improvement.

Working language and mode: Connect-Introduce-Communicate-Ask-Respond and Exit (CICARE) communication style from medical institutions in the United States was used for nurse-patient communication [14]. For instance, nurses should actively introduce themselves, accurately and appropriately greet each patient, and inform patients of the purpose and reason of each ward round and their cooperative ways that need to be taken; ask patients about their doubts at the same time, make timely feedback and solutions, tell them to ring the bed bell if any help is needed, and leave politely and quietly.

Seamless transition: Seamless transition refers to that nurses should immediately deal with the request or inquiry from patients without pushing off the responsibility, even though he/she is not the duty nurse. For things that need to be taken by the duty nurse, it's necessary to immediately notify the nurse of the specific reason, so as to enhance the trust of patients, make them feel valued and thus increase the sense of treatment security.

Non-accusatory apology: In face of feedback or complaints from patients or their families, nurses should listen to their demands and apologize sincerely. The principle of apology is to solve the problem, which should be handled cooperatively and reasonably, without shirking the responsibility and blaming other relevant workers.

Humanistic care: The humanistic care time should be provided. Duty nurses needed to communicate with the patients in each shift. The conversation contents including disease inquiry, patient feeling feedback generally lasted for no less than 5 minutes. During the conversation, the nurses should maintain an equal position with patients, such as sitting at the bedside, timely giving limb massage, supporting the patient's hand during infusion and performing other therapeutic contacts. The humanistic care record form was made and placed at the foot end of the patient's bed, which incorporated the conversation time, place, theme, and psychological and out-of-hospital humanistic care for patients with surgery, pain, and adverse reactions to chemotherapy. The nurses signed the record after the care was completed, and then the head nurses summarized it uniformly daily.

Bowel preparation was given before surgery, body temperature was maintained during surgery, and limb movement nursing was performed after surgery. At 2 hours postoperatively, passive limb movement was conducted with nasal inspiration and slow exhalation that lasted for 7 seconds each time to restore ventilation ability as soon as possible. At 2 days postoperatively, the patients could get out of bed with the assistance of duty nurses. If there was no discomfort after surgery, the patients were transitioned to normal diet after ventilation, with daily water intake monitored. Moreover, continuous pain caused strong physical and mental stress response in the patients, resulting in decreased QoL. Therefore, hot compress, manual massage, and other means were adopted to relieve pain, in addition to drug analgesia. During chemotherapy, the patients faced many adverse reactions such as alopecia, and nursing staff should comprehensively understand and support patients to wear appropriate wigs, so as to give sufficient psychological comfort. For limb edema during chemotherapy, nurses could help the patients elevate the affected limbs and control the intake of sodium salts. When the edema persisted, drug would be given for detumescence. As for vomiting, constipation, and other adverse reactions of digestive system, attention should be paid to the patients' diet, and enema (Anhui Guozheng Pharmaceutical Co., Ltd., H34020449) may be considered for constipation treatment. At the same time, nurses should tell the patients to relax and rest well to relieve fatigue and tension; then pacify and listen to the patients with obvious anxiety by active communication, and embolden them to

communicate with each other more for mutual encouragement. After discharge, the patient files were established for more convenient return visits, and QQ and WeChat groups were recommended for better communication. In this way, a platform for information sharing and emotional catharsis was built to encourage the patients to organize social activities, consult disease conditions, make exchange with other patients and share their own rehabilitation experience, which can help them alleviate stress, loneliness and helplessness.

Outcome measures

Main outcomes: Indicators of clinical recovery: The time of first exhaust and defecation after surgery, the time of first ambulation, the average postoperative hospital stay and the pain intensity at 2 days postoperatively were compared between the two groups. The pain intensity was quantified using the Numeric Rating Scale (NRS) [15]. The patients were asked to evaluate their pain sensation on a numeric scale (from 0 = no pain to 10 = intolerable pain).

Indicators of physiological stress: Cortisol (Cor), C-reactive protein (CRP) and fasting blood glucose (Glu) levels were determined and compared between the two groups. At 2 h preoperatively and 48 h postoperatively, the peripheral venous blood sample (5 mL) was collected from each patient. Moreover, Cor and CRP levels were measured by electrochemiluminescence immunoassay, while Glu levels were by glucose oxidase method.

Postoperative complications: Infection, bleeding, poor gastrointestinal, liver and kidney function, unhealed incision and other complications were compared between the two groups. Total complication incidence = (cases of complications)/total number of cases * 100%.

QoL scores after 3 months of follow-up: The Functional Assessment of Cancer Therapy-Ovary Cancer (FACT-O) was assessed at enrollment and after 3 months of follow-up [16]. The scale consisted of 4 domains (27 items) and OC specific module (10 items in 6 dimensions), with the Cronbach's α coefficient of 0.80. In the 4 domains, there were 6 items of emotional status, and 7 items of physical status, 7 items of functional status, and 7 items of social/family status. The Likert 5-level scoring method was used for scoring, with a positive score of 1~5 points. The actual score of reverse-worded items was obtained by subtracting the raw score from 6 points (higher scores of the reverse-worded items suggesting better QoL).

Secondary outcomes: Psychological state: The self-rating anxiety scale (SAS) and self-rating depression scale (SDS) were evaluated at enrollment and after three-month follow-up, respectively [17, 18]. Each scale was 100 points in total, with 20 items (1~4 points each). The total score of each item * 1.25 was taken as the standard score through rounding. If the scores of SAS and SDS ≥50 and 53 points respectively, the patients can be diagnosed as anxiety or depression.

Nursing satisfaction: Questionnaires were filled out by the patients before discharge to assess the satisfaction with care by the self-made nursing satisfaction survey, which was categorized into three levels: very satisfied (the nursing work was highly recognized and affirmed), satisfied (the nursing work was recognized and affirmed) and dissatisfied (the nursing work was unrecognized) [19]. Satisfaction rate = (very satisfied cases + satisfied cases)/total number of cases * 100%.

Statistical analysis

Data analyses were performed with the SPSS 21.0 software. The measurement data with a normal distribution were expressed as mean ± standard deviation ($\bar{x}$ ± sd). Independent t-test was used for the comparison between the two groups, and paired samples t-test was applied for the comparison before and after intervention within the same group (both presented as t). Chi-square test (χ^2 test) was adopted as to the enumeration data expressed as the case/percentage (n/%). $P<0.05$ was considered statistically different.

Results

Comparison of general data

As is shown in **Table 1**, there was no statistical significance in the age, disease course, etc. between the two groups, suggesting the two groups were comparable ($P>0.05$).

Table 1. Comparison of general data ($\bar{x}$ ± sd)

Item		Control group (n = 42)	Carolina group (n = 43)	X^2/t	P
Age (year)		45.8±4.2	44.7±5.7	1.011	0.315
Disease course (y)		1.6±0.2	1.5±0.4	1.463	0.149
Tumor size (cm)		2.59±0.51	2.62±0.56	0.258	0.797
Operation time (min)		186.61±35.77	197.32±33.85	1.418	0.160
Intraoperative blood loss (mL)		252.45±57.36	267.21±60.54	1.153	0.252
Educational background (n)	Under senior high school	7	9	0.390	0.823
	Senior high school	17	15		
	At or above the junior college level	18	19		
Pathologic type (n)	Serous carcinoma	18	17	0.847	0.932
	Mucinous carcinoma	12	14		
	Poorly differentiated carcinoma	4	3		
	Clear cell carcinoma	3	2		
	Endometrioid adenocarcinoma	5	7		
Surgical-pathological staging (n)	I	26	30	0.584	0.445
	II	16	13		
Histologic differentiation (n)	Moderate or poor differentiation	17	20	0.315	0.575
	High differentiation	25	23		
Chemotherapy (n)	TP	11	11	0.639	0.888
	PVB	10	8		
	Cisplatin	17	18		
	CAP	4	6		

Note: Chemotherapy regimen: CAP = Cyclophosphamide + doxorubicin + Cisplatin, TP = Paclitaxel + Cisplatin, PVB = Cisplatin + Vincristine + Pingyangmycin.

Table 2. Comparison of indicators of clinical recovery ($\bar{x}$ ± sd)

Group	Time of first flatus (h)	Time of first defecation (h)	Time of first ambulation (h)	Average postoperative hospital stay (d)	Pain score (points)
Control group (n = 42)	45.16±8.27	60.21±15.72	50.13±5.36	10.84±3.17	6.14±1.52
Carolina group (n = 43)	35.34±5.82	48.91±11.34	38.23±5.21	8.36±2.13	3.78±0.93
t	6.318	3.793	10.380	4.224	8.610
P	0.000	0.000	0.000	0.000	0.000

Comparison of indicators of clinical recovery

The time of first flatus and defecation after surgery, the time of first ambulation, and the length of average postoperative hospital stay were much shorter (all P<0.001), and the pain score was markedly lower in the Carolina group than in the control group (P<0.001). See **Table 2**.

Comparison of indicators of physiological stress at 2 h preoperatively and 48 h postoperatively

At 2 h preoperatively, no significant difference was revealed regarding the indicators of physiological stress (all P>0.05). At 48 h postoperatively, the Cor, CRP and Glu levels were significantly lower in the Carolina group than in the control group (P<0.05). See **Table 3**.

Comparison of postoperative complications

The Carolina group indicated a significantly lower complication rate of infection, bleeding, poor gastrointestinal, liver and kidney function, unhealed incision, etc. than the control group (9.30% vs. 26.19%, P<0.05). See **Table 4**.

Comparison of mental state before and after intervention

Before intervention, no significant difference was observed in terms of the patients' mental

Table 3. Comparison of indicators of physiologic stress at 2 h preoperatively and 48 h postoperatively ($\bar{x}$ ± sd, control group: n = 42, Carolina group: n = 43)

Item	Cor (mmol/L)	CRP (mg/L)	Glu (mmol/L)
2 h preoperatively			
Control group	5.13±0.44	23.67±5.74	465.27±122.86
Carolina group	5.20±0.36	24.13±5.68	471.34±117.42
t	0.804	0.371	0.233
P	0.424	0.711	0.816
48 h postoperative			
Control group	6.91±0.77①	107.05±13.74①	563.65±137.36①
Carolina group	5.97±0.86①	82.45±10.34①	494.53±124.17①
t	5.305	9.341	2.435
P	0.000	0.000	0.017

Note: Compared within the same group at 2 h preoperatively, ①P<0.05. Cor: Cortisol; CRP: C-reactive protein; Glu: fasting blood glucose.

Table 4. Comparison of postoperative complications (n/%)

Group	Control group (n = 42)	Carolina group (n = 43)	χ^2	P
Infection	3 (7.14)	2 (4.65)	0.238	0.626
Bleeding	2 (4.76)	0 (0.00)	2.097	0.148
Poor gastrointestinal function	3 (7.14)	1 (2.33)	1.110	0.294
Poor liver and kidney function	2 (4.76)	1 (2.33)	0.370	0.543
Unhealed incision	1 (2.38)	0 (0.00)	1.036	0.309
Total complication rate (%)	11 (26.19)	4 (9.30)	4.170	0.041

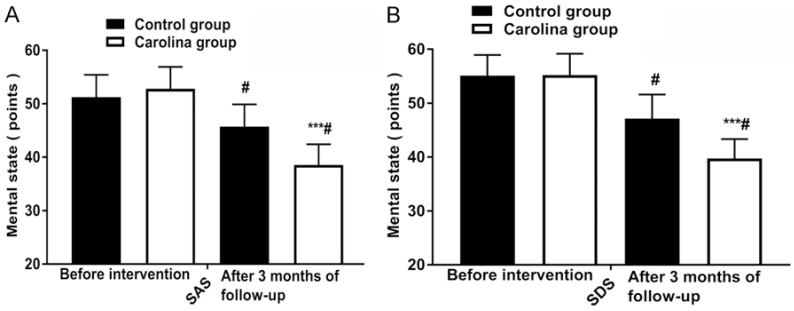

Figure 1. Comparison of mental state before and after intervention. A: SAS; B: SDS. Compared within the same group before intervention, #P<0.05; compared with the control group after intervention, ***P<0.001. SAS: self-rating anxiety scale; SDS: self-rating depression scale.

state (SAS and SDS scores) between the two groups (P>0.05). After intervention, the SAS and SDS scores were decreased in both groups as compared with those before intervention (P<0.05), while the scores were much lower in the Carolina group than in the control group (P<0.001). See **Figure 1**.

Comparison of nursing satisfaction

As **Table 5** shows, the Carolina group showed a markedly higher satisfaction rate than the control group (97.67% vs. 78.57%, P<0.01).

Comparison of QoL scores before intervention and after 3 months of follow-up

Before intervention, no significant difference was identified in the dimensions of FACT-O (all P>0.05). After 3 months of follow-up, all the dimension scores were increased in both groups as compared with those before intervention (P<0.05), while scores of emotional status, physical status, functional status, and social/family status as well as OC specific module scores were markedly higher in the Carolina group than in the control group (all P<0.001). See **Figure 2**.

Discussion

In China, there is an increase of 52,971 cases of newly diagnosed OC and a total of 30,886 deaths per year. Its high mortality rate seriously threatens the life of female patients [20]. Additionally, OC patients suffer from pain as well as various adverse reactions and heavy economic burden during treatment [21]. As a result, OC patients need more refined and humanized nursing care, and biomedical care centered on disease treatment and medical technology can obviously no longer meet the increasing needs of OC patients [22]. In contrast, the concept of the Carolina care model meets the care needs

Table 5. Comparison of nursing satisfaction (n/%)

Group	Very satisfied	Satisfied	Dissatisfied	Total satisfaction rate
Control group (n = 42)	11 (26.19)	22 (52.38)	9 (21.43)	33 (78.57)
Carolina group (n = 43)	25 (58.14)	17 (39.53)	1 (2.33)	42 (97.67)
χ^2				7.469
P				0.006

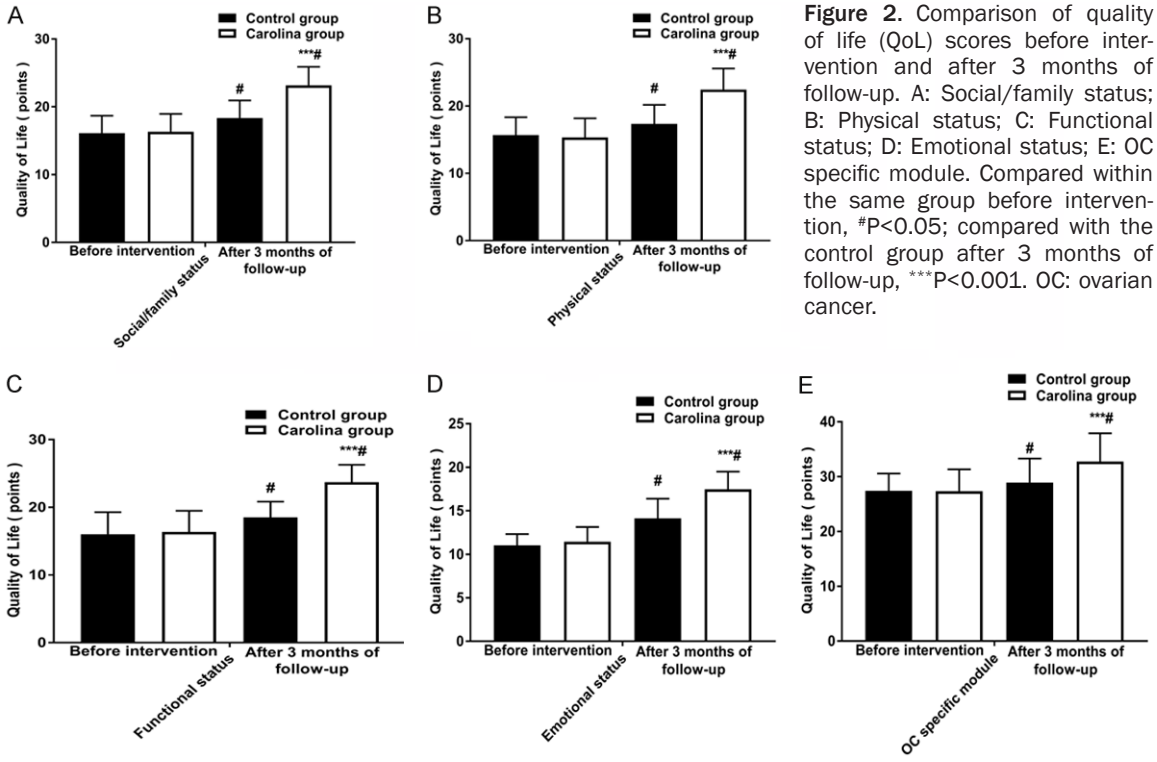

Figure 2. Comparison of quality of life (QoL) scores before intervention and after 3 months of follow-up. A: Social/family status; B: Physical status; C: Functional status; D: Emotional status; E: OC specific module. Compared within the same group before intervention, #P<0.05; compared with the control group after 3 months of follow-up, ***P<0.001. OC: ovarian cancer.

of OC patients well [23]. As a patient-centered care model, it focuses on putting theory into clinical practice, which is derived from five processes of Swanson's caring theory, namely, "knowing, doing for, being with, enabling, and maintaining belief" [24]. The interrelated care process can help nursing staff quickly identify which type of care is needed by patients in their daily work and when and where it's needed, and provide services accordingly, delivering important guidance for clinical work [25].

The Carolina care model has been widely used in the education, scientific research, and management of nursing. Based on that, the model has been applied to clinical humanistic nursing practice [26]. Wen et al. pointed out that the humanistic nursing model exerted a favorable effect on the mental health of critically ill patients and also enhanced the overall QoL after treatment [27]. Huang et al. reported that humanistic nursing measures in gynecological cancer patients could reduce their pain during treatment and improve sleep quality, confirming that humanistic care is effective in severe diseases, particularly in female tumors [28].

In this study, combined with the nursing characteristics of OC, we selectively learn from the essence of Carolina care model, apply it in the humanistic care service of OC clinical nursing, and transform the scientific high-quality nursing concept into specific methods in clinical practice [29].

First, multi-level ward rounds can help head nurses successfully find flaws and potential safety hazards that are easily ignored in daily work. Ameliorating gaps and nursing details can make the patients feel the professionalism and caring of nursing staff and improve their satisfaction with nursing care. Mean-

while, standardized language can help nurses establish emotional connection and coordinate an interpersonal relationship. Seamless transition and non-accusatory apology are high-quality nursing services that apply people-oriented concept to the everyday nursing practice. In this way, actual needs and feelings of patients are emphasized, the responsibility for flaws is never shirked, and patients' needs and problems are always the first duty.

Humanistic care time is provided, and the humanistic care always runs through the whole process (from preoperative bowel preparation and body temperature maintenance, early limb movement care and diet regulation, to ambulation guidance). These methods can effectively shorten the ventilation and defecation time of patients and promote their early rehabilitation and discharge. Also, psychological humanistic care for OC patients is essential. In our study, we explored humanistic care for patients with pain and aimed to minimize the pain intensity by combining drug intervention with non-analgesic drug intervention.

Furthermore, regular follow-up after discharge ensures continuity of humanistic care services. Our study demonstrated that the time of first flatus and defecation after surgery, the time of first ambulation, and the length of average postoperative hospital stay were much shorter, the pain score, postoperative complication rate, physiological stress (Cor, CRP and Glu levels) at 48 h after surgery were significantly lower, and the nursing satisfaction was markedly higher in the Carolina group than in the control group. The results suggest that humanistic care under the Carolina care model can promote the postoperative recovery of OC patients. This may be due to the fact that nursing work under the guidance of Carolina care model is templated and standardized so as to ensure that patients feel the humanistic care of the hospital from all aspects.

At the same time, close cooperation during surgery, early postoperative exercise, and analgesic technology can all effectively reduce the stress response and pain of patients, and promote postoperative rehabilitation. On the one hand, there is a lack of reports on the application of humanistic care under Carolina care model in OC patients, so our results cannot be compared with other studies. On the other hand, this is the innovation of this study. Our results showed that the psychological status (SAS and SDS) scores of patients were significantly lower, and the QoL after 3 months of follow-up was significantly better in the Carolina group than in the control group. Compared with routine care, humanistic care based on the Carolina care model can reduce the psychological stress response and exert a more positive impact on the QoL in the long run, which was consistent with the results reported by Wen et al. [27]. However, this study still has some shortcomings, such as its small sample size and long-term postoperative rehabilitation of cancer patients. Hence, further studies with larger sample sizes are desirable to explore whether humanistic care for OC patients has a significant impact on their survival.

In summary, humanistic care based on the Carolina care model can significantly promote the postoperative rehabilitation of OC patients, reduce their physical and psychological stress response, and effectively facilitate nursing satisfaction and QoL.

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Disclosure of conflict of interest

None.

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