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Original Research Article

Effect of combined application of apatinib and perioperative quality nursing based on Orem's self-care theory in patients undergoing cholangiocarcinoma resection

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Abstract

Purpose: *To investigate the effect of application of perioperative quality nursing based on Orem's self-care theory, in combination with apatinib in patients who underwent cholangiocarcinoma resection.*
Methods: *Ninety patients who underwent cholangiocarcinoma resection in The Fourth Hospital of Hebei Medical University from Feb. 2019 to Feb. 2020 were assigned to control group (CG) and study group (SG) based on their order of admission, with 45 patients in each group. Conventional nursing in combination with conventional treatment was applied to CG, while perioperative quality nursing based on Orem's self-care theory was used in combination with apatinib therapy in SG patients. Comparison was made between CG and SG regarding clinical efficacy, self-care ability and quality of life (QoL, based on QLQ-C30 score).*
Results: *Disease control rate (DCR) and Barthel index (BI) score were higher in SG than in CG ($p < 0.05$). After treatment, QoL score was higher in SG than in CG ($p < 0.001$).*
Conclusion: *Implementation of perioperative quality nursing along with apatinib therapy in patients undergoing cholangiocarcinoma resection improves their QoL and enhances their self-care ability. Thus, this treatment modality has high utility and treatment potential.*

Keywords: *Orem's self-care theory, Apatinib, Cholangiocarcinoma resection, Quality of life*

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INTRODUCTION

Cholangiocarcinoma is a malignant tumor which is frequently seen in hepatobiliary surgery in the extrahepatic bile duct [1]. In recent years, the incidence of hilar cholangiocarcinoma has become increasingly higher, and it accounts for approximately 11 - 24 % of all liver malignancies [2]. Cholangiocarcinoma is one of the malignant tumors that seriously threaten human health due to its characteristics such as early metastasis, insidious onset, high degree of malignancy, and poor prognosis [3]. Reports have indicated that it is difficult to perform radical operation on hilar cholangiocarcinoma because of its biological characteristics such as infiltrative growth and

special anatomical location [4, 5]. Furthermore, the prognosis of this tumor is poor. However, if good nursing measures are applied to the patients during treatment, their quality of life (QOL) may be markedly improved [4, 5]. The ultimate goal of nursing mode based on Orem's self-care theory is to maintain, restore, and promote the self-care ability of the patients [6]. Extant literature indicates that the treatment of cholangiocarcinoma is challenging because the disease has various etiologies and high heterogeneity [7]. Apatinib inhibits the growth of tumor vessels, resulting in tumor necrosis due to lack of nutrients and oxygen [8]. Currently, not much is known about the effect of combined treatment on patients undergoing cholangiocarcinoma resection. Therefore, this combined clinical intervention was investigated to provide more clinical evidence for its use in such patients.

METHODS

General patients' profiles

Ninety patients who underwent cholangiocarcinoma resection in *The Fourth Hospital of Hebei Medical University* were enrolled in the study. The patients were assigned to control group (CG, n = 45) and study group (SG, n = 45) based on the order of admission. This study was approved by the ethics committee of *The Fourth Hospital of Hebei Medical University* (approval no. 20181147), and followed the guidelines of the World Medical Association Declaration of Helsinki [9]. All subjects and/or close family members submitted signed attestation of consent.

Inclusion criteria

Subjects in the following categories were included in this study: patients who had pathologically confirmed cholangiocarcinoma, those with no distant metastasis in bone, lung and other regions during preoperative examination, and no peritoneal metastasis in intraoperative exploration; patients aged less than 75 years, patients with tolerance to pain from the surgical procedure, those who were adjudged potentially treatable with surgical resection *via* at least two imaging findings, subjects who could orally take medicines, and those with good cardiovascular and pulmonary functions.

Exclusion criteria

Patients with severe organ dysfunction, presence of other malignant tumors, severe mental illness and disturbance of consciousness, history of thoracotomy and laparotomy, surgical contraindications, and drug allergy, were excluded.

Control group (CG)

Conventional nursing

Conventional perioperative nursing was performed in CG. The patients were provided with a comfortable hospitalization environment and health education, and medical staff explained the precautions and objectives of surgery to the patients, assisted in anesthesia, and monitored patients' vital signs. After surgery, analgesia was administered to the patients. Rehabilitation training plans were developed, and psychological support was provided.

Conventional drug therapy

Each patient in CG was orally given 40 mg of Tegafur, Gimeracil and Oteracil potassium capsules (manufacturer: Shandong New Time Pharmaceutical Co. Ltd.; NMPA approval no. H20080802; specification: 42 capsules, each = 20 mg) each time, twice a day (after breakfast and dinner) for 28 consecutive days. Then, the administration was stopped for 14 days. The above process was regarded as one treatment cycle. The patients were treated in two cycles.

Study group (SG)

Perioperative quality nursing based on Orem's self-care theory

Postoperative nursing diagnosis was applied to the patients to determine whether they had self-care demands. The demands, if any, were met by the nursing staff, and they comprised mainly symptoms such as postoperative pain, drain failure, hyperthermia and potential infections. Then, the patients were evaluated with regard to psychological state, awareness of Orem's self-care theory, condition, and self-care ability in daily living. The care ability of their family members and accompanying nursing persons were also evaluated.

On the first day after surgery, complete compensatory nursing was applied to nurse the patients, due to the lack of self-care ability. This care mainly involved closely observing their conditions, keeping the incisions dry, recording changes in body temperature, observing local inflammation, and providing basic living care such as taking of medicines, washing, and eating. From the second day after surgery to the

period before discharge, different partial compensatory nursing activities (such as allowing them to do things that they were able to do) were carried out according to patients' self-care abilities, since they already had clearer minds, milder pain, and more stable vital signs. These activities fully mobilized their subjective initiative.

Besides, the nursing staff provided assistance, teaching, and guidance for the patients as they carried out functional exercises, and gave timely answers to various questions related to postoperative rehabilitation. Patients were provided with psychological support through the supportive-educative system, as well as relevant health education at different stages, to enable them fully master the self-care skills. At the same time, the family members were required to encourage the patients in recovery and rehabilitation. Postoperative cautions in daily life were explained to the patients and their families to help the patients build confidence in fighting the disease, and improve their postoperative adaptive capacity and self-awareness. Moreover, during hospital stay, the nursing staff guided the patients to have proper daily diets, including more intake of high-quality protein and vitamins, and avoidance of spicy and cold foods.

Apatinib administration

Patients in SG received orally apatinib (0.850 g) with warm water after meal, once daily for 84 days.

Evaluation of parameters/indices

Clinical efficacy

The clinical short-term efficacy in both groups was evaluated according to the evaluation criteria in Response Evaluation Criteria in Solid Tumors (RECIST) [10]. It was divided into complete response (CR, i.e. disappearance of all lesions for over 30 days, and no new lesions); partial response (PR, i.e., a reduction in tumor volume > 50 % for over 30 days, with no new lesions); stable disease (SD, a reduction in tumor volume < 50 % but > 20 %), and progressive disease (PD, i.e. an increase in tumor volume > 25 %, with new lesions).

$$DCR\ (\%) = \{(CR + PR + SD)/T\}100 \quad \ldots\ldots\ldots (1)$$

where *DCR* = disease control rate; *CR* = number of complete responses; *PR* = number of partial responses; *SD* = stable disease; *T* = total number of cases.

Self-care ability

The patient's self-care ability after treatment was evaluated using the Barthel Index (BI) for Activities of Daily Living [11]. The scoring criteria in the scale were as follows: total scores ≤ 40 points indicated severe dependence, meaning that the patients required care from others all the time, while scores of 41 - 60 points indicated moderate dependence, meaning that the patients required care from others most of the time. Scores of 61 - 99 points indicated mild dependence, meaning that the patients occasionally required care from others, while a score of 100 points indicated total independence, meaning that the patients required no care.

Quality of life (QoL)

The QoL of patients after treatment was determined using EORTC QLQ-C30 [12]. There were 4 dimensions and 30 items in total. The maximum score was 126 points. The higher the score, the poorer the QoL.

Statistical analysis

This was done using the SPSS20.0 software, while graphics were generated with GraphPad Prism 7. The enumeration data and measurement data were tested using χ^2 test, *t*-test and normality test. Values of $p < 0.05$ indicated statistical significance.

RESULTS

Patients' baseline data

Table 1 shows no marked variations in patients' gender, age, BMI, TNM stage, maximum diameter of lesion, length of lesion, differentiation, and other baseline information between the 2 groups.

Clinical efficacy

Table 2 shows that DCR was significantly higher in SG than in CG ($p < 0.05$).

Barthel index (BI) scores

After treatment, BI score was significantly higher in SG (82.33±1.81) than in CG (62.71±1.50; $p < 0.001$).

Quality of life

Table 3 shows that after treatment, QLQ-C30 score, a measure of QoL, was lower in SG than in CG ($p < 0.001$).

Table 1: Between-group comparison of baseline data

Parameter	SG (n=45)	CG (n=45)	χ^2/t	*P*-value
Gender			0.051	0.822
Male	30 (66.67%)	31 (68.89%)		
Female	15 (33.33%)	14 (31.11%)		
Age (years)	59.36±9.27	57.20±9.51	1.091	0.278
BMI (kg/m^2)	20.05±0.62	19.93±0.65	0.896	0.373
TNM stages				
I	11 (24.44%)	10 (22.22%)	0.062	0.803
II	22 (48.89%)	23 (51.11%)	0.044	0.833
III	6 (13.33%)	7 (15.56%)	0.089	0.964
IV	6 (13.33%)	5 (11.11%)	0.104	0.748
Maximum diameter of lesion (cm)	4.06±0.59	4.00±0.51	0.516	0.607
Course of disease (months)	6.51±1.62	5.89±1.23	2.045	0.044
Differentiation				
Undifferentiation	20 (44.44%)	21 (46.67%)	0.045	0.832
Moderate	15 (33.33%)	14 (31.11%)	0.051	0.822
Well	10 (22.22%)	10 (22.22%)	0.000	1.000
Occupation				
Teacher	7 (15.56%)	6 (13.33%)	0.089	0.764
Civil servant	10 (22.22%)	11 (24.44%)	0.062	0.803
Worker	11 (24.44%)	12 (26.67%)	0.058	0.809
Farmer	12 (26.67%)	13 (28.89%)	0.055	0.814
Others	5 (11.11%)	3 (6.67%)	0.549	0.459
Level of education				
Primary school and junior high school	20 (44.44%)	21 (46.67%)	0.045	0.832
Senior high school and junior college	13 (28.89%)	14 (31.11%)	0.053	0.818
College and above	12 (26.67%)	10 (22.22%)	0.241	0.624
Religious faith			0.049	0.824
Yes	30 (66.67%)	29 (64.44%)		
No	15 (33.33%)	16 (35.56%)		
Family income			0.062	0.803
≥3,000 Yuan/(month/person)	34 (75.56%)	35 (77.78%)		
<3,000 Yuan/(month/person)	11 (24.44%)	10 (22.22%)		
Place of residence			0.055	0.814
Urban area	12 (26.67%)	13 (28.89%)		
Rural area	33 (73.33%)	32 (71.11%)		

Table 2: Comparison of clinical efficacy [n (%)]

Group	CR	PR	SD	PD	DCR
SG	0	29 (64.44%)	14 (31.11%)	2 (4.44%)	95.56% (43/45)
CG	0	20 (44.44%)	12 (26.67%)	13 (28.89%)	71.11% (32/45)
χ^2					9.680
P-value					< 0.05

Table 3: Comparison of QLQ-C30 scores (mean ± SD, n = 45)

Group	QLQ-C30 score
SG	35.33±3.24
CG	65.93±2.94
t	46.918
P-value	< 0.001

DISCUSSION

In recent years, a lot of progress has been made in chemotherapy modalities and surgical techniques. However, radical surgical resection, although potentially curative, has failed in improving clinical prognosis for patients with cholangiocarcinoma, as expected. Studies have indicated that the 5-year postoperative survival levels of patients with cholangiocarcinoma, ampullary carcinoma, and gallbladder carcinoma are merely 32.9, 52.7, and 41.5 %, respectively [13]. Given the high postoperative morbidity of cholangiocarcinoma patients, many postoperative treatment and care programs are being implemented in the clinics. However, currently, published studies have not achieved satisfactory results.

A report has shown that the introduction of quality nursing in combination with treatment measures effectively improved patients' QoL [14]. Orem's self-care theory emphasizes that the task of nurses lies in the promotion of patients' subjective self-care ability which is beneficial in stimulating and mobilizing the patients'

subjectivity, so that the patients can switch from passiveness to activeness while receiving treatment [15]. In addition, application of the partially compensatory nursing system and supportive-educative system in Orem's self-care theory is of great importance for encouraging and supporting patients in completing self-care activities to maximum extents. Perioperative quality nursing under Orem's self-care theory makes patients realize that they have gradually acquired self-care ability, so that they can be more active, and can restore their self-care ability of daily living to a greater extent, thereby improving their QOL [16].

Tegafur, Gimeracil and Oteracil potassium capsules produce certain curative effect in the clinical treatment of cholangiocarcinoma. However, the effectiveness of this therapeutic strategy can hardly meet clinical needs. The widely used anti-angiogenic drug, apatinib, blocks subsequent signal transduction, and inhibits production of tyrosine kinase, thereby inhibiting tumor growth. It has been confirmed that apatinib produced a good disease control rate in phase I clinical experiments in various tumors such as breast cancer, nasopharyngeal carcinoma, non-small cell lung cancer and hepatocellular carcinoma, with overall disease control rate as high as 83.7 % [17].

In this study, clinical efficacy was higher in SG, indicating that, compared with conventional treatment, apatinib had a better curative effect on patients undergoing cholangiocarcinoma resection. The reason may be that perioperative quality nursing based on Orem's self-care theory improved patients' treatment compliance and self-care ability, and the addition of apatinib further enhanced curative effect.

Orem's self-care theory believes that a person is a whole with different degrees of psychological, physiological, and social self-care abilities. Self-care deficits occur when people are unable to meet their own needs. Individuals have specific self-care abilities and therapeutic self-care needs (i.e. self-care needs requiring nursing assistance). At any given time, if the level of such needs is beyond self-care ability, external nursing care becomes necessary. This involves mainly 3 nursing systems, namely, wholly compensatory nursing system, partly-compensatory nursing system, and assisted education system. The nursing staff make up for the self-care deficits through nursing activities.

Compared with conventional nursing, perioperative quality nursing based on Orem's self-care theory effectively improved self-care ability, reduced the effect of postoperative trauma, decreased the occurrence of complications, enhanced rehabilitation, and improved QoL for patients who underwent cholangiocarcinoma resection. The results of this research revealed better self-care ability in SG, which is in agreement with the findings of Oiwa *et al* [18]. In addition, SG showed better QoL than CG, thereby demonstrating that perioperative quality nursing based on Orem's self-care theory in combination with apatinib enhanced the QoL of patients undergoing cholangiocarcinoma resection.

Limitations of the study

Firstly, there was no diversity in source of the cases, since they came from one hospital. Secondly, the observation time in this clinical study was limited, and it had a small sample size which might lead to bias. Moreover, prolonged post-treatment monitoring was not carried out. These limitations will be addressed in subsequent studies so as to adequately investigate the effect of perioperative quality nursing based on Orem's self-care theory in combination with apatinib, on the short-term clinical effects, self-care ability and QoL of patients undergoing cholangiocarcinoma resection.

CONCLUSION

The findings of this study show that the combined use of apatinib and perioperative quality nursing based on Orem's Self-care theory for patients undergoing cholangiocarcinoma resection greatly improves clinical efficacy, QoL and self-care ability, thereby benefiting patients and improving prognosis. Furthermore, this intervention strategy is a breakthrough in relation to traditional intervention measures. Therefore, the combined approach provides a new strategy in clinical intervention programs for cholangiocarcinoma resection.

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Ethical approval

None provided.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest

No conflict of interest associated with this work.

Contribution of Authors

We declare that this work was done by the authors named in this article, and all liabilities pertaining to claims relating to the content of this article will be borne by the authors. Xinsheng Li and Limin Zhang conceived and designed the study, and drafted the manuscript. Xinsheng Li, Weina Zhong and Limin Zhang collected, analyzed and interpreted the experimental data. Xinsheng Li and Weina Zhong revised the manuscript for important intellectual contents. All authors read and approved the final draft of the manuscript.

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