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A RANDOMIZED CONTROLLED TRIAL FOR THE EFFECTS OF SEXUAL BEHAVIOUR GUIDANCE ON SEXUAL FUNCTION AMONG YOUNG AND MIDDLE-AGED MALE PATIENTS WITH RECTAL CANCER AFTER MILES OPERATION

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ABSTRACT

Purpose

This study was conducted to explore the effect of intervention in the form of sexual behaviour guidance on the quality of sexual life of young and middle-aged male patients with rectal cancer.

Methods

Twenty cases of young and middle-aged male patients with rectal cancer were randomly divided into experimental and control group in each group including 10 cases per group. The control group was given the traditional health education after the rectal cancer Miles operation. While the experimental group was given sexual behaviour guidance and "sex-focused training therapy" after the Miles operation and before sexual intercourse in order to overcome erectile dysfunction. The International Index of Erectile Function (IIEF-5) questionnaire was used to measure the sexual functionality of both groups upon admission, at the time of discharge and after 3, 6 and 9 months.

Results

In the experimental group, patients with normal sexual function at the 6th and 9th month after discharge were 7 cases and 9 cases respectively, which were significantly higher than the control group which included 5 cases and 6 cases (p-value < 0.05).

Conclusion

In conclusion, sexual health education not only could effectively improve the sexual function of young and middle-aged male patients with rectal cancer after a Miles operation, but also could improve the quality of the sexual life of the patients. It is considered to be worthy of promotion and application on clinical practice.

Key words: sexual behaviour guidance, rectal cancer, Miles operation, sexual function

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From the clinical viewpoint, outcomes assessment included mortality, morbidity, disease recurrence and long-term survival in rectal cancer patients. Although rectal cancer has an improved cure rate in response to oncological treatment, sexual dysfunction is a common complication of this malignant surgery.¹ Previous studies indicated the negative impact in sexual function of patients submitted to a surgical treatment for rectal cancer.^{2,3} The majority of colorectal cancer survivors often remain sexually active.⁴ A postoperative erectile dysfunction rate after colorectal neoplastic surgery of 83%.⁵ Risk factors already demonstrated are older age, the presence of stoma, the radiotherapy, technique applied, the tumour stage, and the surgeon's experience.^{5,6} Reduced sexual function is also related to a lower quality of life in cancer survivors.⁷

China has the largest population in the world and there are at least 100,000 colostomy operations performed every year. The incidence of postoperative sexual dysfunction is 32-100%. Due to various treatments and clinical skill could cause incidence differences also affect patients' physical and psychological status at pre-operation and post-operation,¹ there have been researches conducted in domestic and foreign on the new contents of health education for colostomy patients and the evolution of existing health education but most of research put emphasis on achieving higher quality of life for patients who involve an improvement of sexual life's quality, less on sexual health education. To enhance the work quality of specialist nursing, self-care ability of patients who accepted operation and their quality of sexual life. This study aims to evaluate the effects of sexual behaviour guidance on sexual function among young and middle-aged male patients with rectal cancer after the Miles operation

MATERIAL AND METHODS

Patients Selection

We selected 20 cases of young to middle-aged male patients with colorectal cancer from January 2013 to December 2013. All the study patients had received permanent colon stoma surgery (aged from 23 to 45 years old) and the postoperative pathological stages were Dukes A or B. The research excluded patients with preoperative existing urinary and reproductive system diseases and sexual dysfunction, lack of a spouse or fixed sexual partners, lymph node metastasis or distant metastasis, surgical pelvic autonomic nerve injury or other reproductive neural significant injury and drug or alcohol dependence. Patients were randomly divided into 2 groups with 10 cases in the experimental group, aged 26 to 42 (31.20 ± 2.26) years old and 10 cases in the control group, aged from 25 to 45 (32.18 ± 3.12) years old. There were no significant differences between the 2 groups (P >0.05).

Therapeutic Method

In this study, both groups accepted the Miles operation, and the resection scope included sigmoid colon and its mesentery, rectum, anus, musculi levator ani and cortical rectum fossa tissue and anal surrounding skin, blood vessels in the inferior mesenteric artery root or left colic artery point source below the ligature cut. The corresponding arterial lymph nodes were cleaned. A colostomy of a chronic disease in the abdomen was taken.

Nursing Methods

For the control group, preoperative nursing care is outlined below.

- 1. Health Education: When study patients were admitted to hospital, the nurses of hospital would provide the professional assessment, health education, and establish the patient's personal profile in order to be the basis of the later treatment and comparative analysis.
- 2. Mental Health Nursing: Nurses actively communicated with the patients to ensure awareness of the patients' mental status and provide symptomatic counseling to build confidence for patients with previously successful rehabilitation cases to enable active self-attitude adjustment.
- 3. Bowel Preparation: Three days before the operation some semi-liquid substances are given to patients. One day before the operation 25% magnesium sulphate was given orally (Product code approved by SFDA H13022977, Hebei Wuluo Pharmaceutical Co., Ltd.), and the patient was instructed to drink a lot of water after 10 minutes. Then, gentamicin (Product code approved by SFDA H44023894, Maoming Liqi Pharmaceutical Co. Ltd.) and metronidazole

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(Product code approved by SFDA H2006086, Sichuan Xinsidun Pharmaceutical Co. Ltd.) were administered orally once every 4 hours to inhibit intestinal bacteria. observing The patients' stool frequency, texture, and colour was observed with liquid stool being ideal.

In addition, the postoperative nursing care for the control group included are outlined below.

- 1. Basic Nursing: It is necessary to monitor the patients' life indicators regularly, and carry out nursing instructions for the patients, especially daily activities such as food ingestion, cessation of smoking and drinking, prognosis, and having a positive mental attitude.
- 2. Nursing for Gastric Canal: After surgery, the nurse must continue to assist the patients with gastrointestinal decompression to prevent distortion, deformation, shedding, and other situations that might pose a threat to the patients' health. Also, the patient's gastric acid colour and any quality or quantity change need to be observed.
- 3. Incision Nursing: The stoma is attached to the excrement bag with an abdominal bandage after surgery.
- 4. Nursing of the Perineal Incision Drainage Tube. The outer dressing must be clean and dry. If there are signs of bleeding, nurses should inform the physician immediately.
- 5. Urinary Catheter Nursing: The urine volume and its properties should be observed to prevent urinary tract infection.
- 6. Stoma Nursing: Stoma care is the crux to prevent complications after surgery. The stoma can be washed one day after the surgery; plastic film should be used to separate the fistula from the abdominal incision in advance to prevent wound infection. It is also crucial to delivering related knowledge to patients, such as the correct replacement of the bags, regular diet, regular review.

The experimental group was given sexual health education. The preparation for resuming sexual behaviour are outlined below.

1. Environmental Setting: When there is an atmosphere for sexual activities such as occasionally arranging for a night out it often brings a strong feeling and unexpected effects.

- 2. Emotion: The patient should be advised to shift the attention away from the intestinal stoma via touching, appreciation, and enjoying the fun of sex. The patient should also share perspectives and opinions with their partner and to talk about the concerns and worries and to be more considerate with each other.
- 3. Body: For the colon stoma irrigation the closed type stoma bag can be pasted on in advance. This can prevent fecal leakage without odor generation. If without irrigation, cleaning the sewage inside stoma bag in advance could prevent the leakage. Corset bound is available for covering stoma. This can prevent the ostomy bag from dropping. Also, selecting a coloured bag for the outside of the stoma bag is better for the visual perception.
- 4. Posture: Patients are encouraged to use different postures in the coital process to establish the most comfortable and appropriate way for them. The guiding principle is to not directly oppress the intestine stoma so the patient should be located on the top or lying on their side.

Sex-Focused Training Therapy

The sex-focused training therapy is applied as a sexual behaviour guide to help patients overcome erectile dysfunction (ED) using the steps below.

- 1. Touching non-sensitive areas is allowed but sexual intercourse is forbidden. Training time is 7–14 days.
- 2. Touching sensitive areas is allowed but sexual intercourse is forbidden. Training time is 7–14 days.
- 3. Erection control should be started with prolonged penis stimulation, continued until the erection status is reached. The moment right before the ejaculation happens, the penis' head should be immediately squeezed. Once there is no longer a feeling of ejaculation, the re-stimulation process should start over again in order to prolong the penile erection time. Patients are not allowed any kind of sexual intercourse. This training period should last from 7–14 days.

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- 4. Penis Stimulation through Vagina. This process should happen in the following order: The male should be under the female and the female should lead the coital movements until the male's feeling of ejaculation happens. At that moment the female should stop the movement. Together with the last-mentioned point, the penis should be drawn out of the vagina, followed by an immediate squeezing of the penis head, in order to ease the ejaculation feeling. The male patient must wait until the feeling of ejaculation completely disappears before repeating the stimulation process. This training period should last from 7–14 days.
- 5. Patients have normal sexual intercourse.

Index of Erectile Function Score

The international index of erectile function score was applied as the observation index (IIEF-5) to measure the sexual function of 2 groups upon admission, at the time of discharge, and 3 months, 6 months, and 9 months after discharge. Scoring criteria: Grade A (normal)>21, Grade B (mild: ED)12-21 Grade C (moderate ED) 8-11, Grade D (severe ED) 1-7, Grade A is normal, Grade B or C or D are classified as abnormal.

Statistical Analysis

The study used SPSS 17.0 statistical software and EXCEL were used for carrying out all statistical analyses. A descriptive analysis of baseline characteristics of the experimental and control groups was conducted. We compared the categorical and continuous variables by using the Fisher's exact test and Mann-White U test, respectively.

RESULTS

Table 1 shows that no statistical significance of age, Duke's stage, and therapy between experimental and control groups. Table 2 indicated that there were significant differences in normal cases of sexual function between the 2 groups at 6 months (70% vs. 50%) after discharge and 9 months after discharge (90% vs. 60%) (P<0.05).

	Experimental group (n=10)	Control group (N=10)	P-value		
Variables	n (%) or Mean ± SD	n (%) or Mean ± SD			
Age	31.20±2.26	NS			
	Duke	s Stage			
А	7 (70.0)	8 (80.0)	NS		
В	3 (30.0)	2 (20.0)			
Therapy Chemotherapy	1 (oral Xeloda)	1 (oral Xeloda)	NS		
Radiation therapy	0	0			

TABLE 1 Baseline Characteristics Between Experimental and Control Group (n=20)

TABLE 2 Analysis of Two	Groups of Sexual Function in Differe	nt Periods of Time
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Group	On admission			At the time of discharge			3 months after discharge			6 months after discharge				9 months after discharge						
Grade	A	B	C	D	Α	B	С	D	A	B	C	D	Α	B	C	D	A	B	C	D
Experimental group (n=10)	8	1	1	0	0	3	5	2	4	4	1	1	7①	1	1	1	9①	1	0	0
Control group (n=10)	7	2	1	0	0	2	6	2	3	3	3	1	5	2	1	2	6	1	1	2

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DISCUSSION

Clinical Implication

Rectal cancer is considered a common malignant tumour and ranked as top 5 in malignant tumours that occur in the digestive system in the straight colon of the human body. It has a higher incidence in the elderly population, especially males. The incidence of rectal cancer is rapidly increasing annually around the world. Colostomy is where the doctor opens the abdominal wall of patients for treating rectal cancer. In this procedure, part of the intestines are moved in vitro and turned over and sewen to the abdominal wall. This allows the colostomy was made for replacing the function of the anus in defecation. The use of anorectal resection and colostomy not only affects the patients' overall physical image and external appearance but has an enormously negative impact on the patients' physical, social, and emotional function and quality of life.⁸

These following factors influenced a decline in postoperative sexual function in patients with rectal cancer after a Miles.

- 1. Age Factor. During surgical treatment, the more elderly the patients, the higher the possibility of postoperative sexual dysfunction will be. Data demonstrate the incidence of sexual dysfunction in patients aged <40 years old was 37.5%, patients 40-59 years old was 60.4%, and patients aged ≥ 60 was 95.7%.^{9,10} Other studies have shown that in 20 cases of patients aged <50 years of age who've undergone a Miles procedure, the incidence of impotence was up to 15%.¹¹ Based on previous studies, age is one of the most important factors that result in sexual dysfunction. With aging, sexual function gradually declines over time, and postoperative trauma is a heavy burden for those elder patients' physical and psychological status. This can result in the patient suffering from sexual dysfunction or even complete loss of sexual function.
- 2. Sex Factor. Increased incidence of sexual dysfunction has been proven to be much more common in male patients with an intestinal stoma Sexual dysfunction can include erectile difficulties,

abnormal ejaculation, no sexual desire, and lack of sexual orgasm.

- 3. Surgical Approach. This is also one of the most important factors that can affect sexual dys-function in patients.¹² The incidence of sexual dysfunction after a Miles procedure was 75%, and the incidence of sexual dysfunction after a Dixon procedure was 45%.¹³
- 4. Nerve Injury: The postoperative sexual dysfunction of patients with rectal cancer is caused by the injury of the pelvic autonomic nerve during surgery. This nerve is sensitive and easily damaged during the surgical process which might result in sexual dysfunction for the patients.¹⁴
- 5. Vascular Injuries: During the operation, there is a high possibility of injury to the artery located in the rectum that supplies blood to the prostate.
- 6. The Pelvic Lymph Node Dissection's Size: The greater the extent of lymph node dissection, the greater the chance of autonomic nerve injury which can lead to the increased probability of male sexual dysfunction.¹⁵
- 7. The Patients' Psychological Factors: After the operation, the patients' mental status is much more unstable which might lead to sexual dys-function, including inferiority complex, anxiety, fear, depression, pessimism, and despair.
- 8. Family and Social Support: Negative mood in postoperative patients is very likely. And can include negative emotions, overall dissatisfaction, and even pessimism. In consequence, family and social support, and the delivery of sexual health guidance are correspondingly important to the patients' sexual life to lessen or mitigate possible negative impacts.^{16,17}
- 9. Spousal Factor. The spouse plays an important role in the patients' sexual life after surgery. If there are conflicts, rejection, and inattention, patients can experience psychological pressure, which can directly result in sexual dysfunction. Research showed that after the colon stoma, 33.0–70.0% patients have different levels of sexual dysfunction. In severe cases, this could directly affect the family. In addition, patients might have a certain degree of insomnia, fatigue, loss of appetite, or

other physical conditions.^{18,19} After the operation the patient can be inconvenienced by the stoma and dissatisfied by their own appearance which can affect their life and work. Therefore, patients might become introverted, refuse social life, and ultimately lose social function. Some patients might even have anxiety, depression, low self-esteem, suicidal tendencies, or other negative emotions.

Human sexual function is a complex physiological process, through a series of physiological and non-physiological reflex to complete.²⁰ Psychological sexual dysfunction is not rare in patients with an intestinal stoma; regardless of its original disease, and patients have to be able to deal with a series of physical changes and psychological fluctuation after the fistulation. Generally, these patients often feel inferior due to their defecation methods, have difficulties in maintaining a clean stoma, are concerned by physical appearance's changes. The intestinal stoma is regarded as an obstruction to sexual life due to its stench, gut contents leakage, and abnormal sound. As a result, patients and their spouses can feel depressed which can seriously interfere with the quality of their sexual life. In addition, patients who accepted the intestinal stoma because of malignant tumours not only need to handle physical and psychological differences but also suffer from the worry that cancer's recurrence might threaten their lives. The patients' mental status is especially sensitive and fragile. Without the support from society, family and friends, and their spouse's understanding, care and encouragement, along with the medical staffs' guidance during postoperative rehabilitation, the patients can easily lose confidence which is a primary cause of psychological sexual dysfunction.

Currently, colon stoma patients' health education mainly focuses on quality of life and in China, there is less focus on the quality of sexual life.²¹ Therefore, it is essential to establish a standardized sexual health education model. This research would build a model of sexual health education for patients with a colon stoma, apply it to the clinic, and investigate and analyze its effect and develop a sexual health education model which would suit the patient with a colon stoma.

The main idea of "sex-focused training therapy" can be classified in 2 stages: (1) The first stage is the

normal process of "making out." Patients can touch their partners to make the penis naturally erect but without the pressure of sexual intercourse. The first stage uses touching to induce a natural reaction to relieve the patients' mental burden. (2) The second stage is sexual intercourse training at the later stage. This postpones the patients' erecting time for carrying on normal sexual intercourse with scientific guidance and exercise.

Methodological Considerations

Our study has the strength of a randomized controlled trial and confirms the effect of intervention in the form of sexual behaviour guidance on the quality of sexual life of young and middle-aged male patients with rectal cancer. On the other hand, our study had several limitations. Firstly, though we have mitigated confounding by randomization for known confounders, there might have been residual confounding. Secondly, the study subjects were from an Asian population. More studies are warranted to confirm the clinical effects in Caucasian patients. Thirdly, due to a shorter follow-up period, we did not have a large enough sample size to estimate the "true" effects of sexual behaviour guidance. Finally, the statistical power could be lower due to smaller sample sizes. Further long-term studies should be conducted to explore the effects of sexual behaviour guidance on sexual function among male patients with rectal cancer.

CONCLUSION

In conclusion, it is crucial that hospitals and nurses integrate treatments and sexual health education for patients, encourage their family, peers, and society to give more concern and care to make the situation less stressful for the patients. When patients are in a friendly environment, it can improve their sexual life's quality and even enhance their overall quality of life.

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