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Influence of psychological intervention on patients undergoing spinal anesthesia: a randomized trial

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Abstract. – OBJECTIVE: The aim of this study is to evaluate the effects of positive intervention on the anxiety and the physiological and psychological aspects among preoperative and post-surgical patients with spinal anesthesia.

PATIENTS AND METHODS: A randomized trial was conducted with an intervention group (n=58) and a control group (n=59). In the intervention group, the patients were well-informed of the details during spinal anesthesia. Multiple methods were performed to control anxiety before surgery, and nurses were not allowed to discuss the condition during surgery. Anesthesiologists were invited to visit patients to avoid excessive anxiety.

RESULTS: The intervention group showed lower scores of State-Trait Anxiety Inventory (STAI) ($p<0.05$) than the control group 24 hours post-operation. Physiological indices such as systolic blood pressure, low frequency (LF) power, high frequency (HF) power and ration of LF/HF showed better surgery recovery ($p<0.05$) than the control group. The length of post-anesthesia care unit stay was also significantly shortened in the intervention group ($p=0.001$) compared with the control group. Positive intervention may alleviate the anxiety in surgical patients receiving spinal anesthesia and improve the physiological and psychological outcomes clinically.

CONCLUSIONS: Our results provide evidence indicating that proper intervention can be promoted clinically to improve the satisfaction and quality of life of patients undergoing spinal anesthesia.

Key Words:
Positive intervention, Anxiety, Physiological indices, Psychological recovery, Spinal anesthesia.

Introduction

With the development of the medical complexity, surgery has strengthened the entire health system[1,2]. To ensure a successful and smooth operation procedure and to achieve a high-value, patient-centered surgical care, anesthesia is indispensable[3,4]. Generally, intravenous and/or inhalation anesthetics are used for anesthesia in operation, and spinal anesthesia is the most commonly utilized method[5]. Despite the advantages of anesthesia in ensuring the normal execution for most operation and increasing the quality of patient during and after operation, anxiety in patients and their families is part of the operation not only because of spinal anesthesia but also because of the unknown fear[6,7]. The raised anxiety may impact the recovery of patients from surgery in both psychological and physiological aspects[8,9], calling for research for proper intervention to improve the recovery from spinal anesthesia.

Anxiety is an autonomic human emotional response to situations of danger and/or stress factors[10,11]. A subarachnoid injection of anesthetic into the spinal fluid will induce the sensation loss from waist to toes for four to six hours in patients[12]. However, as the patients are fully conscious during the spinal anesthesia procedure[10], the anxiety and fear will be raised not only by operation itself but also by the anesthesia for the patients undergoing surgery[13].

Many studies[14-18] have been conducted to explore proper intervention to increase the satisfaction of patients and alleviate the anxiety and physiological responses in patients receiving anesthesia. However, there are still some patients complaining the abandonment sense caused by the negligence of their concerns, insufficient information about the surgery and inadequate empathy by nurses from the perspective of the patients[8,19,20]. Therefore, in order to improve patient satisfaction and outcomes of surgery, especially for patients with spinal anesthesia, more research should be performed to explore proper interventions.

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Studies have showed that intervention with music or other drug-free treatment can effectively reduce the anxiety and improve the recovery of patients from surgery[21-24]. However, its effect on patients undergoing spinal anesthesia has rarely been studied. Herein, the aim of this study is to evaluate the effects of positive intervention on the anxiety and the physiological and psychological aspects for preoperative and post-surgical patients with spinal anesthesia.

Patients and Methods

Research Design and Participants

Patients in this clinical trial were enrolled in Quanzhou First Hospital Affiliated to Fujian Medical University (Quanzhou, Fujian, China). This study was approved by the Ethical Committee of Quanzhou First Hospital Affiliated to Fujian Medical University. All procedures performed involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. All the participants were well informed for the purpose of this study and could withdraw at any stage with any reason. This trial was registered in Chinese Clinical Trial Registry (ChiCTR2100045385).

The patients in this observation study were recruited following these inclusion criteria: 1) patients were receiving spinal anesthesia for the first time; 2) patients were 30-65 years old without vision or hearing impairments; 3) patients were conscious before and after the surgery; 4) patients with informed consent form; 5) patients had not been diagnosed with any mental or heart disease. The subjects who declined the study during the investigation were excluded or were rescheduled for surgery.

Procedure

Before the surgery, the intervention group received a 15-min individual interview by a trained nurse in the operating room waiting area. During the interview, the surgical procedure was explained to patients in a relaxed, comfortable atmosphere with soft music playing. Moreover, the patients were also well instructed with abdominal breathing to control anxiety. The technique to control pain during operation and the successful cases of treatment were also described in detail to the patients. During the surgery, the nurses and anesthesiologists were not allowed to discuss the condition of the patients and anxiety was distracted with talking in the operation room. After the surgery, the anesthesiologists visited patients to listen to any feelings and answer their questions to avoid excessive anxiety.

For the control group, basic levels of the physiological cares and instruments on postoperative indices were routinely given to the patients. The primary outcomes included State-Trait Anxiety Inventory (STAI) score, 40-item quality of recovery questionnaire (QoR-40) score and physiological indices. The pre-operative research questionnaires, including basic patient information and the STAI were completed by both groups 24 hours prior to surgery. A QoR-40 questionnaire was measured for each participant 24 hours after the operation. The heart rate and blood pressure were also measured before and after the operation for both groups. The staff who collect these data was blind to group allocation.

Questionnaires

STAI

STAI was firstly established in 1983 and is commonly used for the measurement of anxiety[25]. A Chinese version of STAI was used in the present study translated from the version of Form Y for the clinical diagnostic before and after surgery. Briefly, a total of 20 items contained in the two sections of the questionnaire were used to assess the trait and state of anxiety. All items were scored on a self-rating scale from 1 to 4 points, and the scores were highly associated with the degree of anxiety. Scores of 20-39 suggested low level of anxiety, 40-59 indicated mid-level anxiety, 60-79 indicated high level of anxiety and 80 indicated a panic status[26,27].

40-item quality of recovery questionnaire (QoR40)

The QoR40 questionnaire was used to assess the recovery of patients form the surgery on five dimensions: psychological support (7 items), physical independence (5 items), physical comfort (12 items), emotional state (9 items) and pain (7 items). Each item was scored on from 1-5 points and the total score ranged from 40 to 200. The score of the questionnaire is positively related to the anxiety level[28].

Statistical Analysis

The data were analyzed by SPSS version 13.0 software (SPSS Inc., Chicago, IL, USA). Data

were presented with mean ± standard deviation (SD) or n (%). Paired *t*-test was used to statistically analyze the differences of STAI scores and physiological indices between two groups both pre- and post-operation. $p<0.05$ was considered statistically significant.

Results

Flow Chart of the Study

A total of 185 patients were assessed for eligibility first, the participants who declined to participate (n=29), not meeting inclusion criteria (n=37) or with allergy (n=2) were then excluded for this observational study. A total of 117 patients with written informed consent were finally selected and randomly assigned into either the intervention group (n=58) or the control group (n=59). In the intervention group, two patients who declined the study and one patient with cancelled operation were further excluded during the study, leaving 55 participants in the intervention group for data analysis (Figure 1). One patient in the control group needed a reoperation, leaving 58 participants in the control group for data analysis (Figure 1).

Demographic Data of the Participants

There were 58 males and 55 females enrolled in this study with a mean age of 48.5 ± 15.2 years in the control group and 50.9 ± 14.6 years in the intervention group. No statistical differences were observed in terms of age, gender, weight, height, body mass index (BMI), education level, smoke status, hypertension, diabetes mellitus, surgery type, scores of American Society of Anesthesiologists (ASA) or the duration of the surgery ($p>0.05$) between the two groups (Table I).

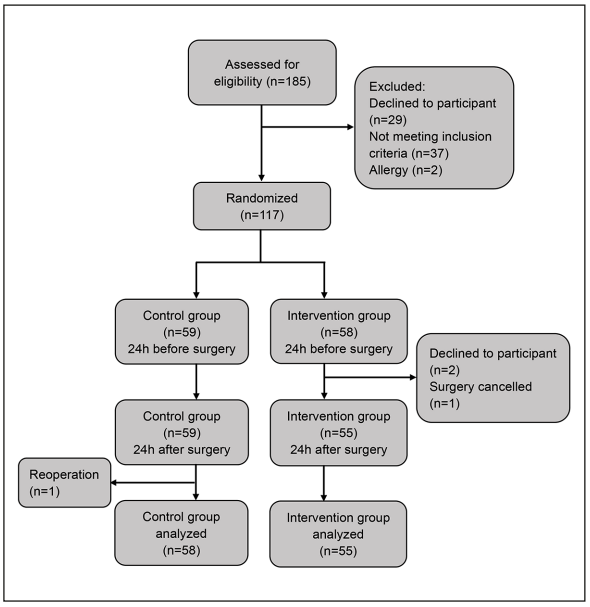

Figure 1. Flow chart of the study.

Intervention Significantly Alleviates the Anxiety of the Patients

A STAI questionnaire was used to assess the anxiety level of the subjects before and after the surgery. The results demonstrated that anxiety was significantly eased for patients in the intervention group compared with the control group at 24 hours after the operation, whereas no statistical difference was observed before the surgery between the two groups (Figure 2). The results indicated that patients in both groups showed moderate or even high anxiety levels before receiving spinal anesthesia (Figure 2), suggesting positive intervention could be applied clinically to alleviate the anxiety of patients undergoing spinal anesthesia.

Intervention Greatly Improves the Physiological Indices for the Patients Undergoing Spinal Anesthesia

No significant difference was observed between the control and intervention groups for pre-operative physiological indices ($p>0.05$, Table II). In terms of blood pressure, the systolic blood pressure (SBPs) were 132.5 (12.6) mmHg and 135.2 (14.8) mmHg, the diastolic blood pressure (DBPs) were 73.3 (8.0) mmHg and 71.4 (7.3) mmHg, respectively in the two groups. The results also showed that the heart rates were 71.6 (8.8) bpm and 72.2 (10.2) bpm, with 550.4 (245.8) ms^2 and 552.2 (278.5) ms^2 for low frequency (LF) power, 342.9 (175.5) ms^2 and 340.1 (201.3) ms^2 for high frequency (HF) power, 1.76 (0.83) ms^2 and 1.73 (0.76) ms^2 for LF/HF, 893.3 (388.9) ms^2 and 892.3 (421.2) ms^2 for total power, respectively in the two groups (Table II).

When applying statistical analysis for physiological indices after intervention, the physiological indices, SBP, LF power, HF power and values of LF/HF showed significant improvement in the intervention group compared with the control group ($p<0.05$, Table II). The SBP was 122.6 (16.5) mmHg in the intervention group and 130.1 (14.3) mmHg in the control group ($p=0.011$, Table II) after intervention. After spinal anesthesia,

Table I. Demographic data of the participants.

	Control group (n = 58)	Intervention group (n = 55)	p
Age (years)	48.5 (15.2)	50.9 (14.6)	0.394
Gender			0.297
Male	27 (46.6)	31 (56.4)	
Female	31 (53.4)	24 (43.6)	
Weight (kg)	71.7 (11.3)	70.2 (10.6)	0.468
Height (cm)	160.1 (7.2)	162.8 (8.4)	0.070
BMI (kg/m^2)	27.0 (1.8)	26.4 (2.0)	0.097
Education level			0.853
High school or lower	41 (70.7)	38 (69.1)	
University degree or higher	17 (29.3)	17 (30.9)	
Current smoker	19 (32.8)	16 (29.1)	0.673
Hypertension	35 (60.3)	26 (47.3)	0.164
Diabetes mellitus	8 (13.8)	5 (9.1)	0.434
Surgery type			0.576
Urologic	16 (27.6)	20 (36.4)	
Rectal	9 (15.5)	5 (9.1)	
Trauma	8 (13.8)	6 (10.9)	
Gynecologic	11 (19.0)	6 (10.9)	
Orthopedic	8 (13.8)	11 (20.0)	
Others	6 (10.3)	7 (12.7)	
ASA score			0.276
I	13 (22.4)	16 (29.1)	
II	36 (62.1)	26 (47.3)	
III	9 (15.5)	13 (23.6)	
Duration of surgery (min)	88 (21.4)	93 (19.1)	0.192

BMI, body mass index; ASA, American Society of Anesthesiologists. Data are mean (SD) or n (%).

the LF powers were 446.1 (275.9) ms^2 and 551.6 (284.9) ms^2, the HF powers were 342.6 (183.7) ms^2 and 415.4 (190.8) ms^2, the LF/HF were 1.82 (0.91) and 1.34 (0.59) in the intervention and control groups, respectively. No statistical differences were observed in terms of DBP, heart rate or total power between these two groups after intervention (p>0.05, Table II). In summary, these data indicated that positive intervention before and during the surgery could improve the physiological indices to some extent for patients undergoing spinal anesthesia.

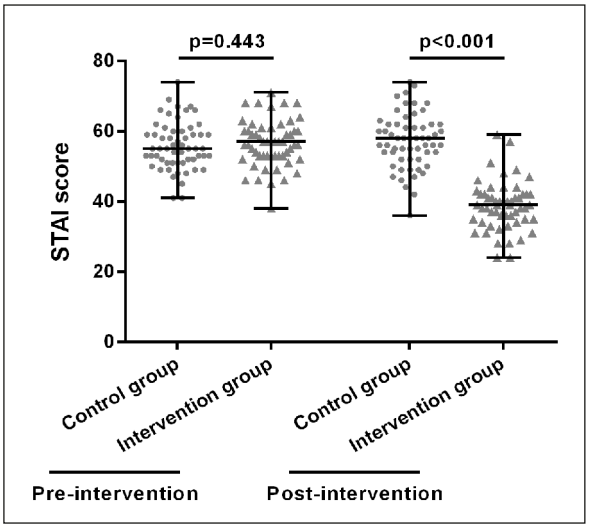

Figure 2. STAI scores in two groups pre- and post-intervention. Data are median and range. STAI, state-trait anxiety inventory.

Intervention Improves the Psychological Recovery and Decreases the Duration of the Post-Anesthesia Care Unit (PACU) for Patients Receiving Spinal Anesthesia

The QoR-40 questionnaire was used to measure the mental recovery of the operation after spinal anesthesia. Mildly increased postoperative QoR-40 score was observed between control and intervention groups (162.0 ± 17.8 *vs.* 169.1 ± 19.3, p<0.05). Interestingly, the score of the emotional state was significantly increased (p<0.001) in the intervention group (40.6 ± 3.3) compared with the control group (35.5 ± 5.2) and the score of psychological supports was also statistically increased between these two groups (32.4 ± 2.1 *vs.* 31.2 ± 2.5, p=0.007), while the other individual dimension scores showed comparable results between

Table II. Physiological characteristics in two groups pre- and post-intervention.

	Pre-intervention			Post-intervention		
	Control group (n = 58)	Intervention group (n = 55)	p	Control group (n = 58)	Intervention group (n = 55)	p
SBP (mmHg)	132.5 (12.6)	135.2 (14.8)	0.300	130.1 (14.3)	122.6 (16.5)	0.011
DBP (mmHg)	73.3 (8.0)	71.4 (7.3)	0.190	71.0 (6.8)	73.5 (8.4)	0.086
Heart rate variability						
Heart rate (bpm)	71.6 (8.8)	72.2 (10.2)	0.739	72.0 (11.2)	71.4 (12.5)	0.789
LF power (ms^2)	550.4 (245.8)	552.2 (278.5)	0.956	551.6 (284.9)	446.1 (275.9)	0.048
HF power (ms^2)	342.9 (175.5)	340.1 (201.3)	0.938	342.6 (183.7)	415.4 (190.8)	0.041
LF/HF	1.76 (0.83)	1.73 (0.76)	0.841	1.82 (0.91)	1.34 (0.59)	0.001
Total power (ms^2)	893.3 (388.9)	892.3 (421.2)	0.990	894.2 (425.1)	861.5 (443.5)	0.690

SBP, systolic blood pressure; DBP, diastolic blood pressure; LF, low frequency; HF, high frequency. Data are mean (SD) or n (%).

the two studied groups (Table III). Moreover, the length of the PACU stay was also significantly decreased in the intervention group compared with the control group (32.8 ± 22.3 *vs.* 46.1 ± 20.1, p=0.001, Table III). The incidence rates of postoperative nauseas and hypothermia urinary retention, as well as urinary retention, were similar between the two studied groups (p>0.05, Table III). Taken together, to some extent, these results suggested that positive intervention before and during the surgery could improve the psychological recovery and decrease the duration of the PACU for patients with spinal anesthesia.

Discussion

Our study demonstrates that the positive intervention can alleviate anxiety and improve the physiological and psychological outcomes for patients undergoing spinal anesthesia. Interestingly, the positive intervention could even decrease the duration of PACU for patients with spinal anesthesia. This study indicates higher efficacy on patient recovery from surgery with empathic intervention before and during the operation and highlights the importance of attending to the concern, emotion, and fear of patients on spinal anesthesia. This study has shed light on the clinical needs of promoting positive intervention to patients receiving spin anesthesia.

Anxiety, a human response when facing fear and stress, and anxiety resulted from operation and anesthesia impairs post-operation recovery. One research study reported that, through a patient-centered approach on patients with general ambulatory surgery, the anxiety levels were reduced, and a better post-surgical recovery was obtained[29]. Other studies also revealed that music intervention could significantly alleviate the anxiety among patients undergoing spinal

Table III. Outcomes of patients receiving spinal anesthesia.

	Control group (n = 58)	Intervention group (n = 55)	p
Total QoR-40	162.0 (17.8)	169.1 (19.3)	0.045
Emotional state	35.5 (5.2)	40.6 (3.3)	< 0.001
Physical comfort	46.2 (6.8)	47.6 (7.5)	0.302
Psychological support	31.2 (2.5)	32.4 (2.1)	0.007
Physical independence	18.6 (3.4)	19.2 (4.0)	0.393
Pain	30.5 (3.7)	29.3 (3.3)	0.071
Length of PACU stay (min)	46.1 (20.1)	32.8 (22.3)	0.001
Postoperative nauseas	6 (10.3)	2 (3.6)	0.165
Hypothermia	9 (15.5)	5 (9.1)	0.300
Urinary retention	1 (1.7)	2 (3.6)	0.527

QoR, quality of recovery; PACU, postanesthesia care unit.

anesthesia[10,30]. Moreover, several similar studies demonstrated that listening to music could efficiently reduce the anxiety of patients, including those waiting to receive cardiac catheterization[31], treated with mechanical ventilation[32], with cardiac infarction and spinal surgery[30]. All these studies provide data consistent with our conclusion, that positive intervention can reduce anxiety of patients.

In addition to anxiety reduction, there are studies[18,30,33-35] reporting that interventions, such as listening to music, can prospectively improve the phycological outcomes of post-operation patients. A study[33] revealed that the HF was significantly increased while the LF and LF/HF ratio were statistically reduced after intervention for elderly patients undergoing spinal anesthesia. Similar results were elucidated in other studies which used music listening as the intervention method[18,30,34,35]. Moreover, quality improvement of PACU duration was also reported among patients on music intervention[10,35]. The same physiological improvements were observed in our present study, showing that positive intervention on patients with spinal anesthesia could effectively improve the heart rate variability and shorten the duration of PACU.

Nevertheless, there are some limitations in the present study. First, the sample size was relatively small, and more work should be performed to further validate the beneficial effect of positive intervention, including music listening. Moreover, the condition of our hospital was sufficient for us to further explore the mechanisms of the intervention in improving the post-operation outcomes and reducing the anxiety of patients. In addition, more systematic training courses are needed for nurses to expand their roles and function during the positive intervention.

Conclusions

Spinal anesthesia surgery is performed frequently in most operations, and helping patients handle their anxiety and improve the clinical outcomes at both psychological and physiological aspects is important. The result of this study provides evidence showing that proper intervention can reduce anxiety and improve the recovery of post-operation patients, which can be promoted clinically to improve the satisfaction and quality of life of patients.

Conflict of Interest

The Authors declare that they have no conflict of interests.

Informed Consent

All participants signed written informed consent.

Ethics Approval

This study was approved by the Ethical Committee of Quanzhou First Hospital Affiliated to Fujian Medical University. All procedures performed involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards. All the participants were well informed for the purpose of this study and could withdraw at any stage with any reason. This trial was registered in Chinese Clinical Trial Registry (ChiCTR2100045385).

Authors' Contribution

Naizhen Liu: Data curation, data analysis, drafting of the article, final approval of the version to be published. Zhenming Kang: Data curation, data analysis, drafting of the article, final approval of the version to be published. Guijin Lin: Data curation, data analysis, drafting of the article, final approval of the version to be published. Shuduan Chen: Data curation, data analysis, drafting of the article, final approval of the version to be published. Jianying Zhang: Data curation, data analysis, drafting of the article, final approval of the version to be published. Wenji Xie: Study supervision, coordination, funding support, design of this study, drafting of the article, final approval of the version to be published.

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