The Effect of Baduanjin on Shoulder Function in Maintenance Hemodialysis Patients

Affiliated Hospital of Nantong University

2021-11-30

The Effect of Baduanjin on Shoulder Function in Maintenance Hemodialysis Patients

1.Research Background

Chronic kidney disease bone mineral metabolism disorders exist in maintenance dialysis (MHD) patients, with a high incidence of bone and joint pain of 58.7%. At the same time, the motor ability of patients with chronic kidney disease decreases as the disease progresses, and MD patients gradually experience muscle atrophy, decreased upper limb motor ability, slow walking, and slow sitting and standing. Long term lack of exercise further exacerbates bone and joint lesions. Studies have shown that exercise can improve joint function, alleviate joint pain, increase muscle strength, and improve inflammation in MD patients. However, due to the lack of relevant evidence-based evidence, exercise rehabilitation has not yet been included in routine clinical care plans.

Clinical needs for rehabilitation exercise research data suitable for the national conditions of MHD patients, in order to recommend reasonable, feasible, and easily acceptable exercise methods for the Chinese people. Baduanjin is a health preservation technique in ancient China that combines breathing and physical exercise. It is a multi element intervention method that integrates physical, psychological, emotional, spiritual, and behavioral factors, with moderate exercise volume and belongs to the category of aerobic exercise. Although studies have suggested that Baduanjin has a good rehabilitation treatment effect in people with shoulder joint dysfunction, there is still a lack of application data in MHD patients. This study aims to follow evidence-based medicine methods to observe the improvement of shoulder joint function in maintenance dialysis patients using Baduanjin, providing theoretical basis and data support for the exercise rehabilitation and personalized treatment of MHD patients.

References

1. Zhang L, Fang W, Wang L, et al. Prevalence of chronic kidney disease in China: a cross-sectional survey. Lancet 2012; 380: 214-214.

2. Roshanravan B, Gamboa J and Wilund K. Exercise and CKD: Skeletal Muscle Dysfunction and PracticalApplication of Exercise to Prevent and Treat Physical Impairments in CKD. American Journal of Kidney Diseases2017: 837-852.

3. Zelle DM, Klaassen G, Adrichem EV, et al. Physical inactivity: a risk factor and target for intervention in renal care. Nature Reviews Nephrology 2017; 13: 152-168.

4. Zhang H, Qian YL, Li C, et al. Brain-Derived Neurotrophic Factor in the Mesolimbic Reward Circuitry Mediates Nociception in Chronic Neuropathic Pain. Biological Psychiatry 2017: S0006322317313537.

2.Research Content

2.1 Research Purpose

Main objective: To observe the effect of Baduanjin on the shoulder joint function of maintenance dialysis patients.

Secondary objective: To observe the effect of Baduanjin on the quality of life and emotions of MHD patients.

2.2 Study Description

The aim of this study is to observe the therapeutic effect of Baduanjin on improving shoulder joints in MHD patients. A total of 60 maintenance hemodialysis patients will be included and randomized into an intervention group of 30 cases and a control group of 30 cases. The intervention group underwent a 30 minute Baduanjin exercise under the guidance of a professional doctor before the dialysis day, including a 5-minute warm-up exercise, a 20 minute Baduanjin exercise, and a 5-minute relaxation exercise. The intervention group practice Baduanjin three days a week, while the control group maintain routine treatment and daily activities. Measure the indicators of each group at baseline, months 6, 12, and 18. The evaluation of shoulder joint function is based on the shoulder Constant score (which includes three dimensions: pain, daily living activities, and active range of motion); The quality of life score is based on the SF-12 score, and the emotional score is based on the Anxiety and Depression Scale.

2.3 Grouping Criteria

Inclusion Criteria:

- Age>18 years old, ≤ 75 years old
- Maintenance dialysis treatment for ≥ 3 months, three times a week
- The six minute walking experiment were used to screen patients for suitability for Baduanjin
- Right handedness, fistula in left hand

Exclusion Criteria:

- The vascular pathway is a tunnel catheter with a polyester sheath
- The vascular pathway is a right arteriovenous fistula
- Known infectious diseases

- Individuals with primary or secondary muscle diseases, mental abnormalities, lack of autonomous behavior ability, and lack of cooperation with clinical observation and treatment.

2.4 Outcome Measures

Primary Outcome Measure:

1) Shoulder joint function score

Using the adjusted version of the CMS scoring scale, the total score is 75 points, including pain (15 points), daily living ability (ADL, 20 points), and joint range of motion (ROM, 40 points).

2) Shoulder joint internal rotation function

The patient takes a standing position and measures the distance between the fingers and vertebrae of the hemodialysis patient's fistulae and non fistulae hands, that is, the patient moves their thumb with the backhand as much as possible along the midline of the back, and uses a tape measure to measure the closest distance from the tip of their thumb to the spinous process of the 7th cervical vertebra. Relevant data is organized and recorded.

3) Muscle strength measurement

Grip strength can reflect the strength of the hand muscles, and a grip strength meter is used to measure the grip strength of the patient's hands separately. The patient takes a standing position, holds the handle with maximum force, and records the value when the number on the machine display screen no longer changes. Test three times, take the maximum value, and record the relevant results.

4) Area of biceps brachii muscle

Measure the thickness of the biceps brachii muscle in two groups of patients through skeletal muscle ultrasound examination.

Secondary Outcome Measures:

1) Changes in the Short Form-36 (SF-36) and European Quality of Life Five Dimension（EQ-5D-5L）

Changes from the Short Form-36 (SF-36) and European Quality of Life Five Dimension（EQ-5D-5L）scale at 0 months, 8 months, 12 months. The SF-12 score is used to evaluate an individual's health status and quality of life. The SF-12 score expressed as a number between 0 and 100, with higher numbers indicating better health. EQ-5D-5L evaluate quality of life from five aspects: action ability, self-care, daily activities, pain or discomfort, anxiety or depression. The score range generally ranges from less than 0 to 1, and the higher the score, the better the state; The VAS score range is 0-100, with

higher scores indicating better health status.

2) Changes in the Hospital Anxiety and Depression Scale （HADS）

Changes from HADS Index at at 0 months, 8 months, 12 months. HADS consists of 14 items, of which 7 items assess depression and 7 items assess anxiety. The scores for anxiety and depression range from 0 to 21, with higher scores indicating more severe symptoms.

2.5 **Statistical analysis, confidentiality plan**

In terms of statistical analysis, SPSS 23.0 statistical software is used to establish a database and perform statistical processing. Descriptive statistical analysis, qualitative indicators are described as percentages, and quantitative indicators are described as mean ± standard deviation. The data is subjected to normality testing and corresponding testing methods are adopted based on whether it follows a normal distribution. Qualitative data comparison adopts chi square test. Quantitative data conforms to normal distribution, t-test is used for comparison between two groups, and nonparametric test is used for abnormal distribution and $P<0.05$ is considered statistically significant.

2.6 **Preservation and Confidentiality of Information**

The researcher preserves all research data, including confirmation of all participants (able to effectively verify different record materials, such as hospital original records), all original informed consent forms with subject signatures, all case observation forms, detailed records of evaluation indicators, etc.

The results of this project may be published in medical journals, but we will keep the information of the subjects confidential in accordance with legal requirements. Unless required by relevant laws, the personal information of the subjects will not be disclosed. When necessary, research supervision and management departments, hospital ethics committees and their relevant personnel may access patient information in accordance with regulations.

3. Exit and Termination Criteria

1) Those who do not receive regular exercise guidance from doctors, which affects the accuracy and effectiveness of research;
2) Those who experience adverse events and are not suitable for further observation; The doctor determines that it is not suitable to continue observing the patient;

3) The subject experiences certain serious complications or complications, death or loss of follow-up, and is deemed unsuitable for further observation by the doctor;
4) During the research process, participants experienced endpoint events such as cardiovascular and cerebrovascular events and death.

4 **Ethical issues**

4.1 Ethical Approval

This clinical research protocol complies with the relevant provisions of the Helsinki Declaration regarding the protection of subject rights.This protocol, written informed consent form, and materials directly related to the subjects must be submitted to the ethics committee for written approval before the study can be officially conducted. If this protocol has been revised during the clinical research implementation process, it must be submitted to the ethics committee for approval before implementation, and these changes cannot be implemented without the approval of the ethics committee, unless they are made to eliminate obvious and direct risks to the subjects. When such situations occur, they will be reported to the ethics committee. If important new information related to the study is found, the informed consent form must be modified in writing and submitted to the ethics committee for approval before obtaining the consent of the subjects again. Each clinical research center agrees that before the start of this research project, the ethics committee of the team leader unit shall review the research plan. The ethics committees of each sub center may choose to file or review it themselves. If necessary (such as serious adverse events or protocol violations), the ethics committees of each center shall convene a meeting in a timely manner for review and report the review conclusions to the ethics committees of other centers.

4.2 Informed consent

The researcher must provide the subject or their legal representative with an easily understandable and approved informed consent form by the ethics committee, providing the subject or their legal representative with a complete and comprehensive explanation of the detailed information related to the clinical study, including the research purpose, research procedures, potential benefits and risks, subject rights and obligations, etc., and letting the patient know that they have the right to withdraw from the study at any time, After ensuring that patients fully understand and have sufficient time to consider and receive satisfactory responses to the questions raised, they agree and sign an informed consent form before starting clinical research. During the

participant period, all updated versions of the informed consent form and written information will be provided to the participants. The informed consent form should be kept as an important document in clinical research for future reference.

5.Principal investigator

Yuan Li Affiliated Hospital of Nantong University，yuanlint@163.com

Zhang Yuan Affiliated Hospital of Nantong University，49260183@qq.com

Shi Zhaoyu Affiliated Hospital of Nantong University，15251307956@163.com