A Diagnostic Test of Abnormal Sound Waves in Modern Pulsology of Lumbar Disc Herniation

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Informed Consent Form

Dear Patient

We invite you to participate in the "Diagnostic Experimental study of abnormal Sound waves in Modern Pulse of Lumbar Disc Herniation" organized by the Department of Traditional Chinese Medicine of the first affiliated Hospital of Shandong first Medical University. This study will be carried out in the first affiliated Hospital of Shandong first Medical University and has been reviewed and approved by the Medical Ethics Committee of the first affiliated Hospital of Shandong first Medical University. Some of the contents covered in this article are subject to regulatory requirements, and to protect the rights and interests of patients participating in the study, this article has been reviewed and agreed upon by the Ethics Committee.

Why this study was conducted?

Research Background:

Modern traditional Chinese medicine has carried forward the traditional pulse, giving birth to the micro-pulse, such as Jin's pulse, Xu's pulse, Shou's pulse and so on. The development and maturity of micro-pulse science mark an important milestone in the rise of modern pulse science, in which the pulse characteristic with representative diagnostic value is "astringent pulse".

In his many years of clinical pulse diagnosis, Professor *** found that the formation mechanism of pulse information, especially astringent pulse, is similar to the principle of radar emission and reception: the heart is equivalent to the transmitting device of radar waves, and each contraction of the heart produces a cluster of powerful sound waves. This sound wave travels rapidly to the whole body along the arterial wall and the blood in it as a medium, including the viscera and various tissue structures of the whole body. More than 90% of the arterial blood flow in normal organs is a stable laminar flow, which does not produce turbulence, so there is no abnormal vibration. When a pathological change occurs in an organ or tissue, the arterial blood flow is squeezed and deformed, resulting in turbulence and abnormal vibration, which is fused with a larger cluster of sound waves conducted by the heart and then transmitted to the whole body. We can feel this sound wave that combines abnormal vibration waves by touching the different layers of the arteries close to the body surface, including the radial artery. At present, the acoustic pulse detection system has made an in-depth study on the characteristic astringent pulse of coronary heart disease, liver cirrhosis, gastritis and other diseases.

Some studies believe that prolapse of lumbar intervertebral disc is either sunken pulse or astringent pulse. In his long-term clinical practice, Professor *** often touched different parts and different depths of the radial artery. It was found that the "pulse of lumbar disc herniation" detected by acoustic pulse detection system was significantly different from that of relatively healthy non-lumbar disc herniation. Therefore, it is considered that the main physical characteristics of lumbar disc herniation may be the result of the effect of lumbar disc herniation on different laminar blood flow, resulting in local blood flow changes, resulting in a local blood circulation state different from that of non-lumbar disc herniation. The changes may be reflected in the pulse. However, the scope of macroscopic lesions and subjective empirical hand description reflected by traditional pulse diagnosis do have some limitations. To study the pulse of traditional Chinese medicine from the perspective of sound waves, using more objective detection to describe the acoustic characteristics of this pulse, there is no formed theoretical system and clinical practice

at home and abroad, so this study arises at the historic moment.

Purpose of the study：

We study the abnormal sound waves in the radial artery of patients with lumbar disc herniation. The pulse of the two groups were compared to evaluate the sensitivity and specificity of acoustic pulse in the diagnosis of lumbar disc herniation.

How the study will be conducted？

1. To understand the situation of the participants in the study and recruit patients continuously according to the standard of volleyball. two.

2. The information of the subjects was recorded and numbered in the observation record table.

3. The pulse sound waves of 45 patients with prolapse of the lumbar intervertebral disc and 45 relatively healthy people were collected by the acoustic pulse detection system.

4. During the process operation, the subjects and four assistant physicians cooperated with the collection and interpretation of pulse diagnosis information according to the specific requirements of the experimental design.

5. Pulse chart selection and analysis selected the collected participants' five corresponding levels and points of the waveform for research. SPSS software was used for statistical tests and analysis.

Expected benefits and risks of participating in this study：

You will not receive any remuneration for participating in this study. This study is a diagnostic experimental study, this test is non-invasive, non-invasive, does not increase your hospitalization costs, additional expenses, etc., will not increase your risk of any complications, and will not cause damage and compensation.

If there is any discomfort or related injury events, the research physician will deal with the symptoms according to the specific circumstances, and the subjects will receive appropriate treatment.

If you need further information about the trial data and the rights and interests of the subjects, or if test-related injuries occur during pulse collection, please contact your physician *** or ***.

If there is any information that may affect the subjects' continued participation in the trial, the subjects or their legal agents will be informed by the research physician promptly.

Subjects' obligations and inconveniences:

This study is a diagnostic test study and does not require additional collection of clinical data, and blood and histopathological specimens by the patient and the physician in charge, in addition to the normal medical procedures. Patients are only required to cooperate with normal medical procedures and pulse sound wave collection.

Is my personal information confidential?

Your medical records will be kept at the hospital and the investigator, study authorities, and ethics committee will be allowed access to your medical records. Any public reporting of the results of this study will not disclose your personal identity. Every effort will be made to protect the privacy of your personal medical information to the extent permitted by law.

Personal and medical information about you will be kept confidential and kept in a safe and secure place. At any time, you may request access to your personal information (such as your name and address) and may correct this information if necessary.

Subjects or their legal representatives will be notified promptly if the information is obtained that may affect the subject's continued participation in the trial.

By signing this informed consent form, you are consenting to the use of your personal and medical information for the purposes described above.

If you suffer any harm or have questions about your rights during the trial, please contact the study physician responsible for you.

Do I have to participate in the study？

Participation in this study is completely voluntary and you may decline to participate in the study or choose to withdraw from the study at any time during the study, without any reason.

If you have any questions, please contact your research doctor in time.

Subject Consent Statement:

I have read the above description of this study and am fully aware of the possible risks and benefits of participating in this study. I am voluntarily consenting to participate in the clinical study described herein.

I agree□do not agree□ to the use of my medical records and pathological examination specimens in studies other than this study.

Signed and stamped by the subject：_____ Date：_____

Name in block letters：_____

Signature of the subject's spouse (if contraception is required):_____

Subject's contact number：_____ Cellphone number: _____

Signature of legal guardian or legal representative (if any)：_____
Date：_____

Signature of legal guardian or legal representative's Name in block letters：_____

Signature of legal guardian or legal representative's contact number：_____
Cellphone number:_____

Investigator's signed statement: I confirm that the details of this study have been explained to the patient, in particular the possible risks and benefits of participating in this study.

Researcher's Signature：_____ Date：_____

Researcher's Name in block letters：_____

Researcher's contact number：_____

Emergency Contact： * Emergency Contact's contact number： *****