

Pilot study of the efficacy of multiple impulse therapy for cervical spondylosis

Study product: Function Recording and Analysis System

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Pilot study of the efficacy of multiple impulse therapy for cervical spondylosis

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Abstract Objective: To investigate the efficacy of the PulStar Function Recording and Analysis System in the treatment of cervical spondylosis. Method: Sixty patients with cervical spondylosis were randomly divided into a treatment group and a control group, with 30 cases in each group. The control group received cervical traction while the treatment group received cervical traction and multiple impulse treatment. Evaluation methods included a VAS score and the Neck Disability Index. Results: The VAS scores and Neck Disability Index in both groups showed statistically significant decreases after 10 days of treatment ($P < 0.05$), and reductions in the treatment group were more significant compared with the control group ($P < 0.05$). Conclusion: Multiple impulse therapy using the PulStar Function Recording and Analysis System can significantly relieve pain and improve symptoms in patients with cervical spondylosis, and is worthy of more widespread application.

Key words multiple impulse therapy; cervical spondylosis; cervical traction

Pilot Study of the Effectiveness of Multiple Impulse Therapy for Cervical Spondylosis
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【Abstract】 Objective: To investigate the effectiveness of PulStar Function Recording and Analysis System in treatment of cervical spondylosis. Methods: Sixty patients with cervical spondylosis were randomly divided into treatment group and control group with 30 cases in each group. The control group received cervical traction while the treatment group received cervical traction and multiple impulse treatment. Evaluation methods included VAS score and the Neck Disability Index. Results: The VAS scores and the Neck Disability Index in both groups showed statistically significant different after treatment ($P < 0.05$), and reductions in the treatment group were more significant compared with the control group ($P < 0.05$). Conclusion: PulStar Function Recording and Analysis System can significantly relieve pain and improve symptoms of patients with cervical spondylosis by multiple impulse therapy and it is worthy of more application.
【Key words】 Multiple Impulse Therapy, Cervical Spondylosis, Cervical Traction

Cervical spondylosis is a condition with both high prevalence and high recurrence. In recent years, as working practices have changed and more time is spent using computers and mobile phones, the condition has begun to affect younger patients and attract more public attention. There are a variety of treatment options for cervical spondylosis, including neck braces, cervical traction, physiotherapy, massage, osteopathy, acupuncture, medication, injections, exercise therapy, and surgery. Despite this multitude of treatment methods, there are still patients who present no significant clinical improvement in their condition even after trying several different treatment options. This study presents a preliminary investigation into the efficacy of a relatively new treatment method in China for cases of cervical spondylosis: multiple impulse therapy.

1. Materials and methods

1.1 Background information

We randomly selected 60 patients being treated for cervical spondylosis in our department between January 2015 and May 2015, all with a clear diagnosis of cervical spondylosis. They were aged between 20 and 45 years, understood and agreed to participate in this study, and subsequently underwent 10 days of treatment. Exclusion criteria were relatively severe cases who were unsuited to receive multiple impulse therapy or cervical traction and/or required surgical intervention; patients with concomitant trauma, fracture, bleeding, infection, malignancy, osteoporosis, visceral pain, ankylosing spondylitis, rheumatoid arthritis, cervical deformity, or fitted with a pacemaker or defibrillator; patients with concomitant severe cardiovascular disease, nervous system disorder or mental illness; patients who had previously received drugs with an analgesic effect; patients who had previously undergone related cervical surgery; patients who had previously received related treatment in our department; patients who were currently enrolled in other clinical trials; and any other reasons our investigators believed rendered the patient unsuitable to take part in this study. The PulStar

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Function Recording and Analysis System is a medical device developed by Sense Technologies Inc., a world-leading

American sensor R&D company. It is predominantly used to treat musculoskeletal pain caused by damage or degeneration of the spine, joints or muscles, facet joint disorders, joint mobility issues, muscle spasm and sprain, and myofascitis. Its primary indications include cervical spondylosis, lumbar pain, frozen shoulder, soft tissue damage, lumbar disc herniation, osteoarthritis, joint disorder, limited joint mobility, cervicogenic headache and migraine. The PulStar system was first approved by the US FDA in 1994, and is now commonly used throughout America and Europe to treat spinal conditions and damage. The product first entered China in 2010, and was granted CFDA approval in February 2014. Studies conducted abroad have shown that the device is effective at alleviating pain ^[3,4].

The PulStar Function Recording and Analysis System was developed based around the theory of mechanical equilibrium and principle of minimum energy. These theories dictate that objects in normal conditions maintain mechanical equilibrium and that their internal energy is at its lowest point, i.e. mechanical equilibrium is equivalent to minimum energy. In the human body, the spinal system is a complex physiological system formed of interconnected vertebrae, muscles, ligaments and fluids, which also conforms with the theory of mechanical equilibrium or minimum energy. When there is a small energy drop at any single point within this complex system, it can potentially affect the entire structure and not just the area immediately surrounding this point. This means that any muscle spasms or stiffness near the spinal cord may impact the whole spine and disrupt its previous state of mechanical equilibrium, resulting in a new abnormal equilibrium. If we are able to reduce or eliminate the obstacles to the spine finding its optimum location and minimum energy (be these “obstacles” muscle spasms, inflammation, joint disorders, scar tissue, etc.), the spinal system will gradually revert back to its normal mechanical state and thus recover its original optimum location and minimum energy ^[5]. Multiple impulse therapy can eliminate the aforementioned negative factors, and restore the spinal system to its minimum internal energy state.

There is a long history of using mechanical waves induced by shock vibrations to treat spine disease. Since the invention of osteopathy, all manner of methods and tools have been used to induce mechanical shocks and vibrations for the treatment of spine disease. The first such tools included rods, wooden mallets and cams ^[3], but the technology used for mechanical impulse therapy has come a long way since then, and now includes devices such as the PulStar Function Recording and Analysis System. Its sensing probe was first invented by Dr Joseph Evans and allowed doctors to transmit mechanical impulses to specific muscles or bones. Studies showed that tissue pressure increased after the first impulse, increased again after the second, but then stabilised after the third. This discovery led to the development of the multiple impulse regulator in 1991, which provided patients with three consecutive impulses. Dr Walter Vernon Pierce then suggested increasing the number of impulses, so that continuous impulse therapy could be applied to patients ^[3].

The PulStar Function Recording and Analysis System is made up of three main components: the sensing probe, the probe monitoring system, and a computer. The device, inspired by the theories of biomechanics, chiropractic medicine and videography and based on the mechanical principles of force and counterforce, uses computer processing technology for sensor acquisition and equilibrium resonance. One of its main features is its ability to analyse muscle and joint stiffness at each level of the spine, and automatically generate an appropriate treatment regimen based on the test results, including which areas require treatment, as well as the treatment strength, speed, frequency, duration and other parameters. The machine’s sensing probes may then deliver multiple impulse therapy, after which spinal muscle stiffness in the treatment area can be retested for a before/after comparison and obtain data such as response rates ^[3,6]. When testing the patient’s spine, the operator holds the sensing probe in contact with any of the patient’s vertebrae and exerts a certain amount of pressure to transmit a single low-energy impulse to that vertebra. The energy sensor housed in the probe can then measure resistance to the impulse at this particular level of the spine and thereby calculate the degree of muscle and joint stiffness, which is related to spinal compliance. The greater the stiffness, the poorer the compliance, and vice versa. The monitoring system monitors the sensing probe and transmits the electric pulse to the probe, which then converts it to a mechanical impulse. The computer processes and analyses the data, and displays muscle and spinal stiffness in the form of a bar chart for each vertebra. The doctor can assess treatment efficacy based on the length of the coloured bars.

Compared with conventional treatments, the PulStar method has higher reproducibility (it takes years to gain proficiency in osteopathy and similar techniques, making them less reproducible), is pain-free for the patient, diagnosis and treatment are safer, treatment time is shorter (the advanced sensors can deliver 2,000 impulses in 5 minutes), there is no muscle resistance, treatment can be specifically targeted to the damaged area (with a measurement error of 3-7%, which includes physician error), and is more comfortable ^[3,5,6].

This pilot study demonstrates that using the PulStar Function Recording and Analysis System in multiple impulse therapy can relieve the pain felt by cervical spondylosis sufferers and improve functional efficacy, although a larger study sample and more diverse methodology will be required to further confirm this conclusion.