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Original Article

Clinical evaluation of CT-guided radiofrequency target thermocoagulation combined with ozone injection ablation for treatment of cervical disc herniation

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Abstract: *Background:* Cervical disc herniation (CDH) is one clinically common spinal disease. This study aimed to evaluate the clinical efficacy and safety of computed tomography (CT)-guided radiofrequency target thermocoagulation combined with ozone injection ablation (RTT-OIA) for treating CDH. *Methods:* 542 CDH patients treated with CT-guided RTT-OIA (group A) and 522 CDH patients treated with single CT-guided radiofrequency target thermocoagulation (RTT) (group B) were enrolled in this study. The general data, clinical therapeutic efficacy, visual analogue scale (VAS) score and complications between two groups were compared. *Results:* There was no significant difference of gender, age or disease duration between two groups ($P < 0.05$). The efficacy rates in group A at 24 h, 1 week, 1 month, 3 months and 6 months after treatment were 85.98%, 85.24%, 85.42%, 86.90% and 86.35%, respectively, which were significantly higher than 80.08%, 79.12%, 79.69%, 78.74% and 77.01% in group B, respectively ($P < 0.05$). The VAS scores in both two groups at 24 h, 1 week, 1 month, 3 months and 6 months after treatment were significantly lower those before group, respectively ($P < 0.05$). The VAS score in group A at 1 week, 1 month, 3 months and 6 months after treatment was significantly lower than that in group B, respectively ($P < 0.05$). There was no obvious complication in each group. *Conclusions:* CT-guided RTT-OIA is an effective and safe method for treatment of CDH.

Keywords: Radiofrequency target thermocoagulation, ozone injection ablation, cervical disc herniation, efficacy

Introduction

Cervical disc herniation (CDH) is one clinically common spinal disease and can cause a series of clinical symptoms in patients, such as neck and back pain, numbness and dizziness or headache, thus seriously affecting the work and life of patients [1]. Currently, there are various treatment methods toward CDH, including orthopedic open surgery, low-temperature plasma radiofrequency ablation, percutaneous laser disc decompression, collagenase method, etc. The orthopedic open surgery has the disadvantages of large trauma and high cost of treatment, which are not easy to be accepted by patients [2]. The minimally invasive treatment such as low-temperature plasma radiofrequency ablation may lead to the risk of intervertebral disc inflammation and pin tract infection [3]. The percutaneous laser disc decompression is an effective method, but it is mainly widely applied to the intervention of lumbar intervertebral disc due to the high laser energy and tendency to causing endplate inflammation [4]. For collagenase method, the effect comes slowly. In addition, if the collagenase strays into the subarachnoid space, it may cause paraplegia and even death risk [5]. The radiofrequency target thermocoagulation (RTT) is widely applied in diverse methods with minimally invasive spinal surgeries [6, 7], and it is the most useful means in the minimally invasive cervical disc intervention [8]. Ozone is a strong oxidant, and has obvious anti-inflammatory and analgesic effects [9]. In addition, ozone can dissolve the proteoglycan in the nucleus pulposus, causing the nucleus pulposus cell membrane rupture, cell dehydration and necrosis [10]. Previous studies [11, 12] have shown that, the treatment of ozone injection ablation (OIA) also exhibits exact effects for CDH. This study compared the clinical efficacy and safety between computed

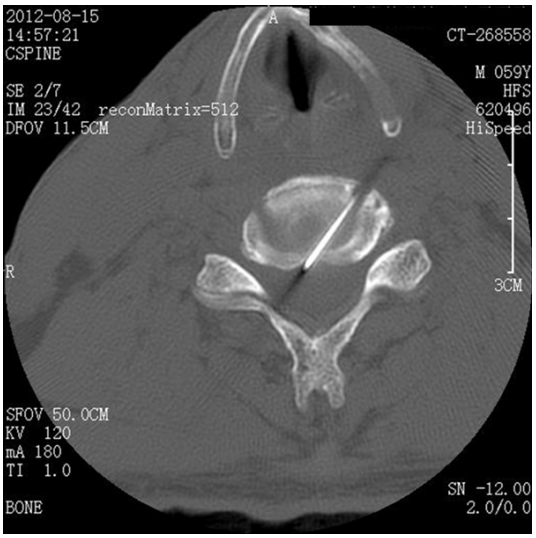

Figure 1. CT scanning of bone window: the puncture needle reached the herniated disc.

tomography (CT)-guided RTT and CT-guided RTT combined with OIA (RTT-OIA) for treatment of CDH. The objective was to provide a reference for further application of RTT-OIA to clinical treatment of CDH.

Materials and methods

Subjects

A total of 1064 CDH patients receiving treatment in Department of Neurosurgery, Jiashan First People's Hospital (Jiaxing, China) from July 2005 to May 2015 were enrolled in this study. There were 717 males and 347 females. Their ages were 36-76 years. The disease duration was 6-144 months. All patients failed in conservative treatments. The inclusion criteria were as follows: The preoperative cervical CT or MRI revealed CDH at C3-4, C4-5, C5-6, or C6-7 intervertebral disc, and the herniation types were of para-central herniation, posterolateral herniation, or intervertebral disc protrusion, with the clinical manifestations as one or both shoulder, neck, upper extremity pain and (or) numbness. The imaging findings were consistent with the clinical manifestations. The exclusion criteria were as follows: spinal cord-, sympathetic-, and vertebral artery-type cervical diseases, with intraspinal ischemia and malacia in the compressed segment, cervical spinal bone stenosis, severe cervical osteoarthritis, disc herniation and calcification, severe heart and lung diseases, coagulation abnormality, or contraindications of ozone. This study was conducted with approval from the Ethics Committee of Jiashan First People's Hospital of Zhejiang Province. Written informed consent was obtained from all participants.

Grouping and treatment

The CDH patients were randomly divided into group A (542 cases) and group B (522 cases), which received CT-guided RTT-OIA and single CT-guided RTT, respectively. In group A, according to the preoperative plain CT film of cervical vertebrae, the target discs were firstly identified, and the corresponding locations were also calculated so as to clear the puncture approach and depth. Each patient was placed in the backlying position after pushed into the operation room. The vital signs were routinely monitored, and the infusion approaches were established for intravenous administration of antibiotics and antiemetics. Under the CT guidance, one 20 G anterior radiofrequency needle (Elekta Instrument AB, STOCKHOLM, Sweden) was punctured via the anterior vascular sheath and tracheal sheath, and then inserted into the target disc. After confirming reaching the target location by CT (**Figure 1**), the needle was connected to one Leksell LNG30-1 nerve radiofrequency instrument (Elekta Instrument AB, STOCKHOLM, Sweden) for sensation testing with high-frequency current (50 Hz, 0.8-1.0 mA) and motion testing with low-frequency current (2 Hz, 0.8-2.0 mA). Once the tests confirmed that no pain and movement was induced from the dominant region, 60-sec radiofrequency thermocoagulation in the order of 60°C, 70°C, 80°C and 90°C was administrated so as to determine this patient's highest tolerable temperature, which was then used for the 4-course treatment (100 sec/course). After RTT, CT was re-performed to determine whether the puncture needle tip shifted. If the shift happened, the target position should be re-adjusted. Then, the needle core was pulled out, and certain amount of cerebrospinal fluid and blood were withdrawn. 1.5-2.0 ml of 40 μL/ml ozone (UMDNS-NO: 12899, Hermann ozone therapeutic apparatus, Germany) was injected into the internal disc (**Figure 2**). After the surgery, each patient was asked for 24 h absolute bedrest, and could perform ambulation 24 h later with the assistance of neck brace. Conventional neurotrophic treatment was performed for 3 days, and the dehydration therapy was also

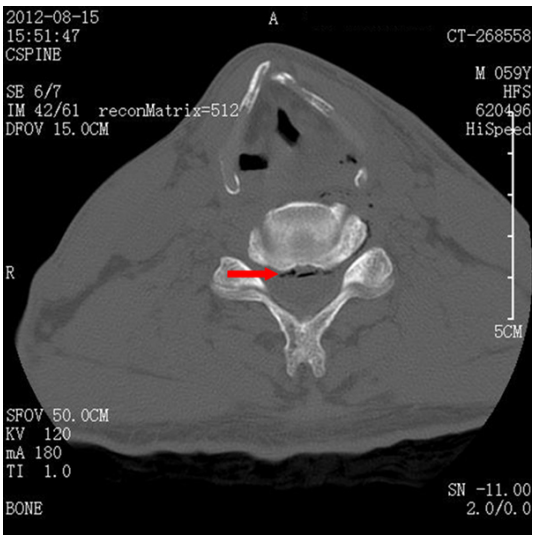

Figure 2. CT scanning of bone window: distribution of ozone injection (arrow).

performed for 3 days. In group B, only the CT-guided RTT was performed, with no ozone injection. The operation procedure and postoperative treatment in group B were the same with those in group A.

Evaluation of clinical efficacies

The modified MacNab low back pain surgery evaluation criteria were used for the evaluation of therapeutic efficacy 24 h, 1 week, 1 month, 3 months, and 6 months after treatment [13]: i) excellent: the pain disappeared, the patient could participate in work and sports, and could resume normal work; ii) good: there was occasional low back pain or sciatica, which did not affect work; iii) middle: the symptom relief was not complete, and the patient needed medication; iv) poor: the symptoms were not improved, and the physical activities were limited. The excellent and good results were added up for calculating the efficacy rate, and the sum of middle and poor results was used for calculating the failure rate. In addition, the changes of pain intensity at different stages (before treatment, 24 h, 1 week, 1 month, 3 months, and 6 months after treatment) were evaluated using visual analogue scale (VAS). There were 3 replicates for each measurement.

Statistical analysis

All statistical analysis was carried out using SPSS17.0 software (SPSS Inc., Chicago, IL, USA). The enumeration data were presented as number and rate, and were compared using χ^2 test. The measurement data with 3 replicates were presented as mean ± SD, and were compared using paired t test. $P < 0.05$ was considered as statistically significant.

Results

General information of patients

In group A, there were 375 males and 167 females. Their ages were 37-76 years, with mean age of 52.4±11.5 years. The disease duration was 6-144 months, with mean of 84.4±20.1 months. 384 cases had the history of upper extremity numbness (unilateral, 327 cases; bilateral 57 cases), 158 cases were accompanied with unilateral or bilateral upper limb muscle strength grade 3-4, 32 cases exhibited positive Hoffmann signs, and 302 cases were accompanied with tendon reflexes; 164 cases had C3-4 CDH, 351 cases were in C4-5, 387 cases were in C5-6, and 326 cases were in C6-7. Meanwhile, 255 cases had CDH in 2 segments simultaneously, and 282 cases had CDH in 3 segments simultaneously; a total of 10793 intervertebral discs were interventionally treated. In group B, there were 342 males and 180 females. Their ages were 36-72 years, with mean age of 50.4±10.1 years. The disease duration was 7-132 months, with mean of 80.6±17.3 months. 356 cases had the history of upper extremity numbness (unilateral, 302 cases; bilateral 54 cases), 133 cases were accompanied with unilateral or bilateral upper limb muscle strength grade 3-4, 30 cases exhibited positive Hoffmann signs, and 287 cases were accompanied with tendon reflexes; 152 cases had C3-4 CDH, 340 cases were in C4-5, 343 cases were in C5-6, and 301 cases were in C6-7. Meanwhile, 232 cases had CDH in 2 segments simultaneously, and 271 cases had CDH in 3 segments simultaneously; a total of 10446 intervertebral discs were interventionally treated. There was no significant difference of gender, age, disease duration or other index between two groups ($P < 0.05$) (**Table 1**).

Overall therapeutic efficacy

All patients were followed up for 6 months. The therapeutic efficacies at different time points were shown in **Table 2**. The efficacy rates in group A at 24 h, 1 week, 1 month, 3 months

Table 1. General information of patients

Group	A	B	P
n	542	522	
Age (years)	52.4±11.5	50.4±10.1	> 0.05
Gender (male/female, n)	375/167	342/180	> 0.05
Disease duration (months)	84.4±20.1	80.6±17.3	> 0.05
History of upper extremity numbness (n)			> 0.05
Unilateral	327	302	
Bilateral	57	54	
Accompanied with unilateral or bilateral upper limb muscle strength grade 3-4 (n)	158	133	> 0.05
Positive Hoffmann signs (n)	32	30	> 0.05
Accompanied with tendon reflexes (n)	302	287	> 0.05
CDH position			> 0.05
C3-4	164	152	
C4-5	351	340	
C5-6	387	343	
C6-7	326	301	
Number of simultaneous segment in CDH			> 0.05
2	255	232	
3	282	271	
Total of interventionally treated intervertebral discs	10793	10446	

CDH, cervical disc herniation.

Table 2. Therapeutic efficacies in two groups at different time points

Time	Group	Excellent (n)	Good (n)	Medium (n)	Poor (n)	Efficacy rate (%)
24 h	A	146	320	50	26	85.98*
	B	128	290	75	29	80.08
1 week	A	140	322	56	24	85.24*
	B	127	286	79	30	79.12
1 month	A	123	340	49	30	85.42*
	B	125	291	75	31	79.69
3 months	A	128	343	45	26	86.90*
	B	126	285	81	30	78.74
6 months	A	120	348	40	34	86.35*
	B	121	281	85	35	77.01

*$P < 0.05$ compared with group B.

and 6 months after treatment were 85.98%, 85.24%, 85.42%, 86.90% and 86.35%, respectively. The efficacy rates in group B at 24 h, 1 week, 1 month, 3 months and 6 months after treatment were 80.08%, 79.12%, 79.69%, 78.74% and 77.01%, respectively. The efficacy rate in group A was significantly higher than that in group B at each time point ($P < 0.05$).

VAS scores

Before treatment, the VAS score in group A was 7.17±1.23, and that at 24 h, 1 week, 1 month, 3 months and 6 months after treatment was 2.95±0.95, 2.87±0.73, 2.57±0.83, 3.72±1.15 and 3.90±0.73, respectively, which was significantly lower than that before treatment ($P < 0.05$). In group B, the VAS score before treatment was 7.25±2.03, and that at 24 h, 1 week, 1 month, 3 months and 6 months after treatment was 3.02±0.43, 3.34±0.56, 3.01±0.57, 4.29±0.77 and 4.92±0.78, respectively, which was also significantly lower than that before treatment ($P < 0.05$). In addition, at 1 week, 1 month, 3 months and 6 months after treatment, the VAS score in group A was significantly lower than that in group B, respectively ($P < 0.05$) (**Figure 3**).

Complications

In two groups, during treatment process, the patients had stable body temperature, respiration, pulse, blood pressure and blood oxygen

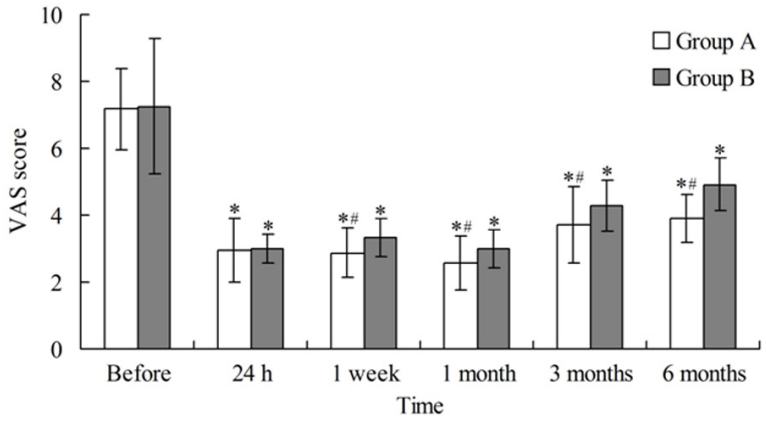

Figure 3. VAS scores before and after treatment (3 replicates; mean ± SD). *P < 0.05 compared with before treatment; #P < 0.05 compared with group B. VAS, visual analogue scale.

Table 3. Complications in two groups

Group	A	B	P
n	542	522	
Incision infection (n)	0	0	> 0.05
Intervertebral infection (n)	0	0	> 0.05
Intraspinal infection (n)	0	0	> 0.05
Hemorrhage (n)	0	0	> 0.05
Abscess (n)	0	0	> 0.05
Hematoma (n)	0	0	> 0.05

saturation. During treatment process, there was no obvious injury in spinal cord, nerve root, neck, or great vessels of thorax, without organ damage. In addition, no severe complication (incision infection, intervertebral or intraspinal infection, hemorrhage, abscess, hematoma, etc.) occurred in each group (**Table 3**).

Discussion

Spinal disc herniation appears in any spinal disc segment, and is more commonly seen in the cervical and lumbar spine [14, 15]. CDH is a clinical syndrome based on the cervical disc degeneration. It is caused by the spinal cord and nerve root compression due to slight external force or undefined inducement factors [16]. In clinic, CDH is the common cause of neck and shoulder pain [17]. Previous study [18] shows that, the degree of disc degeneration of CDH is generally lighter than that of bone degeneration in cervical spondylosis. Therefore, the early intervention of cervical disc degeneration can not only ease and treat the symptoms, but also prevent or delay a series of secondary lesions due to disc degeneration.

Magnetic resonance imaging (MRI) is the preferred method for the diagnosis of CDH. However, it is difficult to distinguish soft disc herniation from osteophytes at the anterior vertebral edge by MRI, which is much more obvious around the intervertebral foramen, so the diagnostic efficacy of MRI is reduced to a certain extent [19]. CT can provide clear cross-sectional images, exhibit high resolution in distinguishing the intraspinal soft disc herniation, osteophytes and yellow ligament, thus showing special values in diagnosing CDH [20]. Therefore, this study performed CT-guided puncture treatment, which could directly guide the puncture needle to the target site, so the puncture accuracy and safety were greatly increased. This benefits the precise treatment toward soft herniation.

There are many treatment methods toward disc herniation. The traditional conservative treatment cannot remove the herniated disc while only alleviates the symptoms, so the likelihood of recurrence still exists [21]. Although the surgery can remove the basic causes of disease, its shortcomings such as big trauma, complex complications, and non-ideal long-term effect have limited the clinical applications [22]. In recent years, the rapid development of interventional treatments toward CDH has obtained more and more attention and acceptance by patients and doctors. Among these interventional therapies, RTT directly applies radiofrequency current to act with the herniated cervical disc, so the local temperature can be increased, resulting in the degeneration, coagulation, and breaking of partial nucleus pulposus, which reduces the pressure inside the disc, and decompress the peri-disc nerve root tissue, arteries and spinal cord [23]. In addition, the thermocoagulation effects can help to reduce the inflammation and inactivate the pain factors, thus further reducing the symptoms [24]. It should be noticed that, RTT still has its limitations such as smaller range of thermocoagulation, etc. Therefore, RTT com-

bined with other technologies may improve the treatment efficacy for disc herniation.

In OIA technology, a small amount of high-concentration ozone is injected into the target site so as to rapidly oxidize the proteoglycans in the nucleus pulposus, and directly make the nucleic protofibril matrix and collagen fiber cells to dehydrate and retract, thereby reducing the compression on the surrounding nerves and blood vessels and exerting its therapeutic effects [10]. It is shown that ozone also has anti-inflammatory and analgesic effects, can eliminate the nuclei chemical and immune inflammation [25]. This study compared the clinical efficacy and safety between CT-guided RTT and CT-guided RTT-OIA for treatment of CDH. Results found that, the efficacy rates in CT-guided RTT-OIA group at different time after treatment were significantly higher than those in CT-guided RTT group ($P < 0.05$). The VAS score in CT-guided RTT-OIA group at 1 week, 1 month, 3 months and 6 months after treatment was significantly lower than that in CT-guided RTT group, respectively ($P < 0.05$). This suggests that, CT-guided RTT-OIA is an effective method for treatment of CDH. As different from this study, Chou *et al* [26] suggest that, RTT has limit therapeutic effect treatment of CDH. This may be due that, most interventional treatments of disc herniation are conducted under the guidance of "C"-shaped arm X-ray, so the positioning cannot be accurate [27, 28]. Therefore, we chose CT to guide RTT and RTT-OIA for the treatment of CDH, and achieved relatively satisfactory outcomes. In addition, it is reported that many soft tissue and bone structures present hard adhesion after the injection of ozone, leading to corresponding complications [29], but Buric *et al* [30] find by a retrospective study that, the ozone injection is safe and effective for about 75% cases of disc herniation, and can maintain the effectiveness for 10 years. In this study, there was no obvious complication in each group. This indicates that, the RTT-OIA is safe for treatment of CDH.

In conclusion, CT-guided TRT-OIA is as effective and safe method for treatment of CDH. As the present study is a retrospective analysis, so it lacks the random control, and the sample size is also limited, which therefore needs further large sample-size randomized controlled studies for the verification.

Disclosure of conflict of interest

None.

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