The efficacy of coblation nucleoplasty for protrusion of lumbar intervertebral disc at a two-year follow-up

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Abstract

Purpose The purpose of this study was to evaluate longer-term efficacy over a two-year follow-up of coblation nucleoplasty treatment for protruded lumbar intervertebral disc.

Methods Forty-two cases of protruded lumbar intervertebral disc treated by coblation nucleoplasty followed-up for two years were analysed. Relief of low back pain, leg pain and numbness after the operation were assessed by visual analogue pain scale (VAS). Function of lower limb and daily living of patients were evaluated by the Oswestry Disability Index (ODI).

Results Operations were performed successfully in all cases. Three patients had recurrence within a week of the procedure. Evaluation of the 42 patients demonstrated significant improvement rate of VAS: defined as 66.2% in back pain, 68.1% in leg pain, and 85.7% in numbness at one-week after the operation; 53.2%, 58.4%, 81.0% at one-year; and 45.5%, 50.7%, 75.0% at two-year follow-up. One week after the operation, obvious amelioration occurred in all the patients, but the tendency decreased. Before operation, the mean value of ODI was $68.2 \pm 10.9\%$. The value at one week was $28.6 \pm 8.2\%$; one-year at $35.8 \pm 6.5\%$; and two-years at $39.4 \pm 5.8\%$.

Conclusion Coblation nucleoplasty may have satisfactory clinical outcomes for treatment of protruded lumbar intervertebral disc for as long as two-year follow-up, but longer-term benefit still needs verification.

Introduction

Protrusion of the lumbar intervertebral disc is common in orthopaedics, usually causing loss of quality of life. Conservative therapy, minimally invasive interventions, integration and non-fusion surgery achieve good results, but their limitations are obvious. Conservative therapy, including bed rest, wearing a corset, physical therapy, administration of analgesics and epidural injection of steroids, has results better than fusion surgery for nonradicular low back pain with common degenerative changes [1]. But for severe cases, conservative treatment is ineffective. Discogenic low back pain had been treated surgically for centuries, but surgery did not achieve significant benefit until Mixter and Barr [2]. Common disc operations include discectomy for radiculopathy from herniated lumbar disc, decompressive laminectomy for symptomatic spinal stenosis with or without degenerative spondylolisthesis, and fusion for nonradicular low back pain with degenerative changes. Although discectomy and/or spinal fusion are known to be effective in immediately relieving back pain, long-term results have been less favourable [3, 4]. For nonradicular low back pain or patients without serious neurological deficits, benefits and risks of surgery are less certain. Furthermore, variation in satisfactory results of lumbar disc surgery is remarkable, ranging between 56% and 92% [5]. The common disadvantage of disc surgery is sacrifice of part, or most, of the functions of spine, leading to possible acceleration of disc degeneration [6–8].

In recent years, there has been a gradual shift to less invasive treatments for protruded lumbar intervertebral disc. These include lumbar chymopapain chemonucleolysis (LCC) [9], automated percutaneous lumbar discectomy (APLD), percutaneous laser lumbar discectomy (PLLD) [10], intradiscal electrothermal annuloplasty (IDET), microendoscopic

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discectomy (MED) [11] and more recently, minimally invasive nuclear decompression—known as nucleoplasty.

Lumbar disc prolapse, protrusion or herniation accounts for less than 5% of all low back problems, but is the most common causes of nerve root pain. LCC, APLD, PLLD and MED have been shown to reduce the pressure on lumbar intervertebral disc. But each treatment has its limitations and success rates vary considerably. LCC started in 1964 [12] and has a long-term success rate between 66% and 88%. However, LCC has the potential risk of paralysis secondary to transverse myelitis and an anaphylaxis rate estimated at 0.3–0.5% [12]. APLD, which was first proposed in 1984, is regarded as a safe procedure for contained disc herniation. But for patients in the non fragment-contained group, the recurrence rate reaches 38% [13]. PLLD is a laser-based system introduced by a needle in the nucleus pulposus. Success rates range from 63% to 89%, with pain relief lasting over 12 years. But complications are not rare, including moderate to severe intra-operative pain, low back pain and spasm after surgery [14]. Major drawbacks with IDET have been its questionable efficacy, the time necessary to thread the wire, and intra-operative pain experienced by patients during the procedure when the annulus is heated [15]. For MED, with a magnified view via an operating microscope, the deep structures can be seen more clearly to reduce the risk of nerve root injury. But it remains unclear whether MED offers better clinical outcomes than conventional procedures [16].

More recently, coblation nucleoplasty, a minimally invasive therapeutic option for patients with intervertebral disc degeneration has been introduced. Based on coblation technology using bipolar radiofrequency energy, it has been used in the treatment of spinal diseases since 2000. Since then, a number of prospective and retrospective studies have been reported revealing satisfactory clinical outcome for coblation nucleoplasty [15, 17]. However, all of them were short-term evaluations with less than one year follow-up. This study evaluated the efficacy of a longer follow-up over two years after coblation nucleoplasty treatment for protruded lumbar intervertebral disc.

Methodology

Forty-two patients were treated by coblation nucleoplasty in the university hospital in 2008. Data collection was retrospective. All the patients suffered from chronic back pain with or without leg pain and had been strictly treated with comprehensive non-operative therapy for six months before nucleoplasty. Inclusion criteria included discogenic low back pain confirmed by discography, preserved disc height at least 50%, discography confirming concordant pain at each suspected level and contained disc protrusion

on MRI (Fig. 1). Exclusion criteria included spinal stenosis on MRI, disc protrusion occupying more than a third of the canal, previously operated segments, and severe neurological deficits, spinal tumour or infectious diseases.

Age, sex and working status of all patients were recorded. The visual analog scale (VAS) was adopted to assess relief of low back pain, leg pain and numbness. The Oswestry Disability Index (ODI) was used to evaluate function of lower limb and patients' daily living.

Mean age of the patients was 39.8 years (range, 21–56) with a gender distribution of 13 females and 29 males. Five (11.9%) patients suffered from chronic back pain only, seven (16.7%) with radiating leg pain, and others (71.4%) with chronic back pain associated with radiating leg pain. In the straight leg raising test, 18 patients were positive, and all were negative in the strengthening test. Single level of disc compression was present in 32 patients (76.2%), while multilevel compression was present in ten patients (23.8%). Levels involved by disc protrusion were: L4–L5 in 32 patients, L5–S1 in 15 patients and L3–L4 in five patients.

Pre-operative prophylactic dose of antibiotic (1.5 g Cefazolin) was given intravenously. Surgery was carried out in prone position under sterile conditions. After infiltration of the skin and soft tissue with local anaesthetic, a 17-gauge needle was placed into the posterior centre of the disc under fluoroscopic guidance (Fig. 2). Discography was performed by injecting contrast medium into the nucleus pulposus to confirm the diagnosis of discogenic pain with positive provocative elicitation of concordant pain. Patients having a disrupted posterior longitudinal ligament were excluded.

Following insertion of the coblation bipolar device (ArthroCare, Sunnyvale, CA, USA), six channels were made at the two, four, six, eight, ten and twelve o'clock positions to ensure adequate decompression of the disc space. For patients with radicular symptoms, suffered nerve root injection of 2.0 ml of steroid solution (betamethasone) and 1.0 ml of 1.0% lidocaine was followed immediately after nucleoplasty. After removal of the instruments, the incisions were closed and the patients were allowed unlimited walking, standing and sitting post-operatively but they were advised not to perform lifting, bending or stooping. One week after the procedure, patients were permitted to return to light work.

Statistical analysis was performed using SPSS software. The Wilcoxon's signed rank test for nonparametric values was used to find the significance of differences between the pre-operative and post-operative VAS and ODI scores. All analysis was conducted at the $P \leq 0.05$ level of significance.

Results

The operation was performed successfully in all cases. Three patients had recurrence within a week of the

Fig. 1 T2-weighted MRI showing a contained disc protrusion of L4–L5 in sagittal and horizontal plane

procedure. Before the operation, the mean value of VAS was 7.7 ± 0.2 in low back, 6.9 ± 0.1 in leg and 2.8 ± 0.2 in numbness. The one-week value was 2.8 ± 0.2 in low back, 2.2 ± 0.3 in leg and 0.4 ± 0.1 in numbness; the improvement rates were 66.2%, 68.1% and 85.7%, respectively. The one-year value was 3.8 ± 0.3 in low back, 3.0 ± 0.1 in leg and 0.6 ± 0.1 in numbness, with improvement rates of 53.2%, 58.4% and 81.0%, respectively. Two-year follow-up values of VAS were 4.2 ± 0.3 in low back, 3.4 ± 0.2 in leg and 0.9 ± 0.2 in numbness, and the improvement rates were 45.5%, 50.7% and 75.0%, respectively (Figs. 3 and 4).

A statistically significant difference in both low back pain and leg pain was seen between the pre-operative VAS scores and scores one week after surgery, and after one- and two-year follow-ups ($P < 0.05$). The results demonstrated an improvement in relief of symptoms after using nucleoplasty. For numbness, there was a statistically significant difference between the pre-operative VAS and scores recorded one week after operation ($P < 0.05$). Compared pre-operatively with one-year and two-year follow-ups,

there was no significant difference ($P = 0.180$, $P = 0.414$). Before the operation, the mean value of ODI was $68.2 \pm 10.9\%$. The value at one week was $28.6 \pm 8.2\%$, one year at $35.8 \pm 6.5\%$, and the two-year follow-up value was $39.4 \pm 5.8\%$ (Fig. 5). Statistically significant differences were found between pre-operation and one-week, one-year and two-year follow-up ($P < 0.05$).

Discussion

Our retrospective outcomes of coblation nucleoplasty indicated a satisfactory clinical outcome in terms of the treatment of protruded lumbar intervertebral disc evaluated up to a two-year follow-up. Evaluation of 42 patients demonstrated significant improvement rate of VAS: defined as 66.2% in back pain, 68.1% in leg pain and 85.7% in numbness at one-week after operation; 53.2%, 58.4%, and 81.0%, respectively, at one-year; and 45.5%, 50.7%, and 75.0%, respectively, at two-year follow-ups. One week after

Fig. 2 Fluoroscopic image under fluoroscopic guidance; the needle was introduced into the posterior centre of the L4–L5 disc

Fig. 3 Significant differences were found between pre-operation and one week, one year, and two years ($P<0.05$) post operation, except numbness in one-year and two-year follow-ups ($P=0.180$, $P=0.414$)

operation, dramatic amelioration was seen in all the patients, but the tendency decreased. Similar results were found in the one-year and two-year follow-ups.

Since being approved for treatment of intervertebral disc degeneration, nucleoplasty has been widely used. Sharps and Isaac reported an overall success rate of 79% at 12 months, with 67% success in patients with previous surgery and 82% success in those with no previous surgical intervention. They concluded that coblation nucleoplasty is a promising and efficacious minimally invasive procedure for treatment of symptoms associated with contained herniated discs [15]. In another study by Masala et al., 79% of patients achieved significant improvement in numeric pain scores [18]. Singh et al. reported that in 53% of 67 patients, pain scores were reduced by at least 50% at one year [19]. Reddy et al. [20] reported improvement among 54% of 67 patients after a year. Extending this monitoring, our study followed-up progress

Fig. 4 The improvement rate of VAS; all patients experienced improvement of at least 50%, except rate of back pain, at two-year follow-up (45.5%)

Fig. 5 Significant differences were found between pre-operation and one week, one year and two years ($P<0.05$) post operation. Note an increased tendency in the value of ODI from one-week to two-year follow-up, but no significant difference between each post-operation group ($P>0.05$)

for up to 28 months. Average improvement was 55.8% after one year, but final follow-up after two years had an average score of 48.1%, with no statistical difference.

Among minimally invasive therapies, nucleoplasty has advantages of faster recovery, earlier return to work, less operative time, less surgery-related trauma, less significant pain, and fewer complications. Compared with other minimally invasive treatments, nucleoplasty has distinct merits. It removes only a small volume of disc tissue, which has great significance in prevention of future progressive disc degeneration [21, 22]. Yet this small reduction in disk volume, involving removal of part of the nucleus, results in a large change in intradiscal pressure for relief of discogenic low back pain [23]. Traditional microdiscectomy creates an incision in the annulus fibrosus of the herniated disc and may weaken or reduce the stability of intervertebral disc leading to reherniation and subsequent reoperations. But nucleoplasty preserves the integrity of annulus, which has an important function in both the regulation of nutrient supply to the disc, and removal of waste from the cells of the nucleus pulposus. Lacking nutrients and oxygen, cells of disc generate large amounts of lactic acid and greatly increase the probability of annular tear and/or herniation [18]. In addition, the operation is performed under safer local anaesthesia. Another important factor affecting the outcome is the formation of adhesions and scar tissue. Adhesions between the posterior annulus and nerve root (failed back syndrome) are common following discectomies [24].

VAS is a single straight 100-mm line commonly used to evaluate pain. The extremes of the line denote the limits of pain experience—from ‘no pain’ to ‘worst possible pain’ [25]. Different from VAS, the ODI questionnaire evaluates changes in patients’ function and health status over a period

of time, and is the most widely used outcome measure for patients with low back pain. Taylor et al. [26] compared the responsiveness of several common outcome measures for patients with low back pain, and concluded that ODI was mostly responsive to changes in health status for patients with low back pain and sciatica. Combining VAS and ODI, this study increased the validity and reliability of identifying changes in patients' function, health status and pain relief.

The effect of decreasing intradiscal pressure by nucleoplasty is still controversial. Chen et al. demonstrated a noticeable reduction in disc pressure after using nucleoplasty in human cadavers, but there is still no irrefutable evidence in vivo [27]. A possible explanation of coblation effect may be the thermal effect of nucleoplasty. New theories have suggested that through chemo-inflammatory and neurotransmitter, neovascularisation and nerve ingrowth into the degenerated disc can cause chronic back pain [28]. Ferass et al. [21] postulated that the thermal effect on disc tissue during nucleoplasty would directly contact and ablate these painful intranuclear nerve endings. Interestingly, two patients with serious symptoms were initially excluded because disc protrusion occupied more than a third of the canal, and were advised MED. However, they rejected MED and when nucleoplasty was performed instead, symptom relief was dramatic in the first year after operation. Possible explanations might include both nerve root decompression and thermal effect on nerve endings.

The most common side effect reported was soreness at the needle insertion site and new leg pain/tingling or numbness. Though a concern, these were not functionally limiting and were in any event resolved within two weeks in all affected patients [29].

In this study, such side effects were sporadic and not prominent. The main reason, we believe, was the reaction of nerve root injection immediately after nucleoplasty, using betamethasone and lidocaine. This injection is now adopted as routine for our patients with radicular symptoms.

Limitations of our study included a limited sample size and lack of patient randomisation, as well as the absence of a control group undergoing conservative treatment. Although our follow-up lasted two years, it cannot evaluate nucleoplasty completely and objectively, compared with other techniques with longer follow-up. Nevertheless, we consider nucleoplasty as an effective, minimally traumatic and safe alternative treatment for decompression of intervertebral disc herniation, provided that strict inclusion criteria are followed.

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