Original Article

Prevention of lumbar reherniation by the intraoperative use of a radiofrequency bipolar device: A case–control study

ABSTRACT

Objective: The most common complication after lumbar discectomy is reherniation. Although many studies have investigated factors that may increase the reherniation risk, few are agreed upon all. It has been suggested that limited nucleus removal is associated with higher reherniation risk, while more aggressive nucleus removal can result in increased disc degeneration. Here, we assessed the efficacy of a coblation-assisted microdiscectomy in adult patients undergoing single-level disc surgery.

Methods: We prospectively compared the reherniation rate in 75 patients (Group 1) undergoing single-level lumbar disc surgery completed with the radiofrequency bipolar system Aquamantys® (Medtronic, Minneapolis, MN, USA) to that of a historical control group ($n = 75$) matched for variables related to herniation level and characteristics (Group 2). Patients were followed up to 4 years. Reherniations were assessed, pain and function were monitored throughout, and imaging was performed at annual follow-up.

Results: The overall symptomatic reherniation rate was 4%. In particular, one case (1.3%) was observed in Group 1 and five (6.7%) in Group 2 ($P < 0.05$). Magnetic resonance imaging identified a total of 4 (2.7%) asymptomatic reherniations at 12 months, 6 (4%) at 24 and 36 months, and 7 (4.7%) at 48 months. Overall, Group 1 contained one (1.3%) asymptomatic reherniation case, while six (8%) were observed in Group 2 ($P < 0.05$).

Conclusions: The low reherniation rate in patients treated by the coblation-assisted microdiscectomy suggests that this technique may reduce the reherniation risk. Clinical outcomes for pain and function at 4 years follow-up compared favorably with literature data. Randomized controlled trial could confirm these results.

Keywords: Discectomy, radiofrequency, recurrent herniation, reherniation

INTRODUCTION

Lumbar disc herniation (LDH) affects a large number of patients annually. It has been reported that intervertebral disc disorders represent the largest specific diagnosis among patients with spinal pathologies.[1,2] The recurrence of a LDH is a common cause of poor outcome following lumbar discectomy and can account for a variable rate of failed back surgery syndrome.[3] Demographic factors such as age[4-6] and body mass index (BMI)[7] have been correlated with reherniation risk. Furthermore, it has been suggested that limited nucleus removal is associated with higher reherniation risk,[8-11] while more aggressive nucleus removal can result in increased back pain and disc degeneration.[10,12]

Over the years, a variety of minimally invasive techniques have been investigated as treatment of low back pain related to disc disease.[13] Techniques can be broadly divided

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Access this article online	
Website: www.jcvjs.com	Quick Response Code
DOI: 10.4103/jcvjs.JCVJS_47_19	

How to cite this article: Grasso G, Torregrossa F, Landi A. Prevention of lumbar reherniation by the intraoperative use of a radiofrequency bipolar device: A case–control study. J Craniovert Jun Spine 2019;10:94-9.

into techniques that are designed to remove or ablate disc material, and thus decompress the disc, and those designed to alter the biomechanics of the disc annulus. All these procedures are performed percutaneously with variable results. More recently, coblation nucleoplasty, a minimally invasive therapeutic option for patients with intervertebral disc degeneration, has been introduced.[14] Based on coblation technology, using bipolar radiofrequency energy, it has been used in the treatment of spinal degenerative and neoplastic diseases since 2000.[14,15] Since then, a number of prospective and retrospective studies have shown a good clinical outcome for coblation nucleoplasty; although in the long-term follow-up, a significant decline in patient satisfaction has been reported.[14,16,17]

The coblation-assisted microdiscectomy is a technique that incorporates the use of a coblation system with the standard microdiscectomy. Such a technique has been shown, in a short follow-up, to be effective in intradiscal decompression and pain control.[18] However, to date, no data exist about the ability of this technique in reducing the recurrent risk of LDH. Therefore, the purpose of this investigation was to evaluate the efficacy of the coblation-assisted microdiscectomy using the Aquamantys® system (Medtronic Advanced Energy, Portsmouth, NH, USA) in reducing reherniation. Specifically, we assessed the rate of both symptomatic and asymptomatic reherniations in primary discectomy patients treated by the coblation-assisted microdiscectomy, investigated whether factors that have been commonly associated with lumbar disc recurrence were significantly correlated with reherniation.

MATERIALS AND METHODS

Patient selection

Seventy-five patients with single-level LDH were prospectively enrolled (Group 1) at the Neurosurgical Clinic of Palermo. The surgical database of both Institutions was queried to identify 75 patients operated on LDH as control (Group 2), corresponding to the same levels of operation with Group 1. Patients of Group 2 were selected if they had a yearly clinical and neuroradiological follow-up. All procedures performed in this study were in accordance with the ethical standards of the institutional research committee. All patients provided informed consent. Patients had a confirmed primary lumbar disc herniation with at least 6 weeks of failed conservative treatment prior to surgery. Other inclusion criteria included patient age between 18 and 75 years, Visual Analog Scale (VAS) for leg pain of at least 40 out of 100, and Oswestry Disability Index (ODI) of at least 40 out of 100. Exclusion criteria included two or more lumbar disc herniations and spondylolisthesis Grade II or higher, prior spine surgery.

Coblation device

The Aquamantys® system (Medtronic Advanced Energy, Portsmouth, NH, USA) is based on a new bipolar coagulation technique, the so-called transcollation technology, a proprietary combination of radiofrequency energy and saline.[19] The technique is associated with simultaneous delivery of bipolar radiofrequency energy and conductive fluid through its electrode tip. Briefly, the system works by combining a bipolar electrosurgical generator with a rotary peristaltic pump to provide simultaneous delivery of radiofrequency energy and saline solution when used with Aquamantys® handheld disposable devices. The saline cools the tissue, as it is treated and evenly conducts the energy into the tissue causing its shrinking.[20] The saline solution used as a conductive fluid cools the tissue surface and prevents the surface temperature from reaching high temperature, thus avoiding charring formation.

The Aquamantys® device, when associated with the epidural vein sealer (EVS) handpiece, has a shaft diameter of 4 mm, thus offering good visibility and less crowdedness in the surgical field. The power setting, adjustable from 20 to 200 Watts, was 20 Watts and the saline flow, modifiable from low, medium to high, was set in "medium" position. External irrigation was also maintained as usual.

Surgical technique

The surgical treatment was performed under general anesthesia and with the aid of the surgical microscope. An open microdiscectomy with limited nucleus removal as previously described was performed.[21] The amount of nucleus removed was assessed.[22] Thereafter, the Aquamantys® system was applied in order to coblate the remaining nucleus pulposus. In short, the device was introduced into the intervertebral space and the coblation was performed in circumferential way. The extent of the decompression was verified by direct inspection and using a palpation instrument. Patients were discharged 2 days after, and given postsurgery care instructions without any additional bracing or other activity restrictions.

Outcomes assessment

ODI and VAS for leg and back pain were collected preoperatively and at 1, 3, 6, 12, 24, 36, and 48 months postoperatively. Magnetic resonance imaging (MRI) was taken preoperatively and every year to assess potentially asymptomatic reherniation. According to the recommendations of the Combined Task Forces of the North American Spine Society, American Society of Spine Radiology, and American Society of Neuroradiology,[23] the results of the MRI were classified as none, protrusion, extrusion, or sequestration. Any protrusion, extrusion, or sequestration was considered as a herniation.

Statistical analysis

Data were reported as mean ± standard deviation and categorical data were reported as frequencies and percentages. The clinical results were analyzed using the analysis of variance Chi-square test, Fisher exact test, Kruskal–Wallis test, and McNemar test. Univariate logistic regressions were used to investigate correlations between patient characteristics and reherniation.

RESULTS

Patient population

Seventy-five patients were enrolled in Group 1 and compared with the same number of cases in Group 2. Patient characteristics along with preoperative mean ODI and VAS scores are summarized in Table 1. No significant differences were observed between the two groups ($P > 0.05$). The most common operated level was L4-L5 followed by L5–S1. The mean volume of nucleus pulposus removed was 1.7 mL without significant differences between the groups ($P > 0.05$). Significant reductions in VAS and ODI were observed at 1 month relative to baseline in both groups ($P < 0.05$). Those reductions were maintained at 48 months in both groups without significant differences between the groups [Figure 1] ($P > 0.05$).

Reherniation outcomes

The duration of follow-up was 48 months in all the patients. There were 6 (4%) reported symptomatic reherniations among the 150 followed patients. In particular, one reherniation case was observed in Group 1 (1.3%) and five (6.7%) in Group 2 ($P < 0.05$).

MRI identified a total of four (2.7%) asymptomatic reherniations at 12 months, 6 (4%) at 24 and 36 months, and 7 (4.7%) at 48 months. At the end of the observation, Group 1 contained one (1.3%) asymptomatic reherniation while 6 (8%) were observed in Group 2 ($P < 0.05$). In each case, reherniation were graded as extrusions. Figure 2 summarizes these findings.

Table 1: Demographic and clinical data

Characteristic	Group 1	Group 2
N	75	75
Sex		
Male	38	37
Female	37	38
Age (years)		
Mean±SD	47.2±9.1*	48.5±10.5*
Range	18–75	18–75
BMI	23.2±1.5*	23.5±2.5*
Nucleus removed (ml)	1.7±2.1*	1.7±1.8*
Operated level		
L4–L5	45	43
L5–S1	20	21
L3–L4	7	8
L2–L3	3	3
Preoperative VAS leg	77±12.1*	78.6±11.8*
Preoperative VAS back	67.5±12.5*	66.6±10.5*
Preoperative ODI	64.5±20.1*	66.6±21.8*

Data are presented as mean±SD. *P>0.05, no statistically significant differences between the two groups. SD - Standard deviation; BMI - Body mass index; VAS - Visual Analog Scale; ODI - Oswestry Disability Index

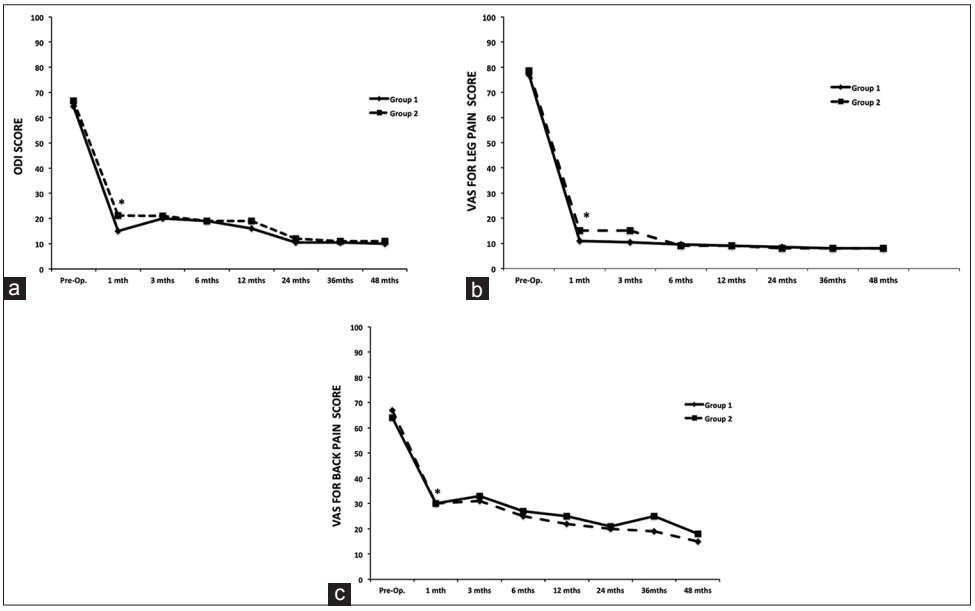

Figure 1: Graphs showing (a) Oswestry Disability Index, (b) Visual Analog Score for leg (c) and back pain for both Groups assessed preoperatively and over the entire follow-up. Significant reductions in Visual Analog Score and Oswestry Disability Index were observed at 1 month relative to baseline in both groups (*$P < 0.05$). Those reductions were maintained at 48 months in both groups without significant differences between the groups ($P > 0.05$)

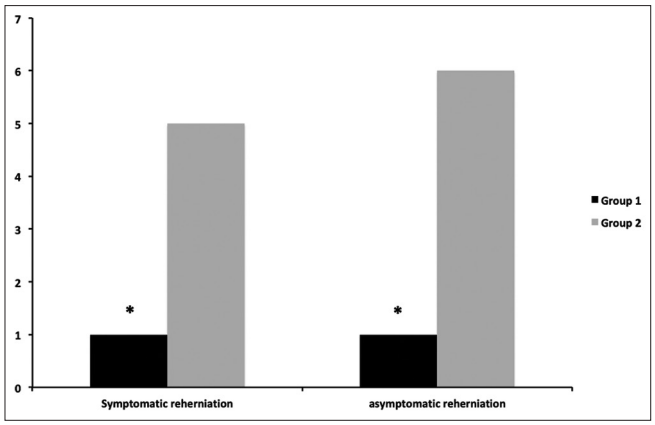

Figure 2: Bar graph showing symptomatic and asymptomatic reherniation cases for both Groups as observed at the end of the follow-up. One reherniation case was observed in Group 1 (1.3%) and 5 (6.7%) in Group 2 (*P < 0.05). Magnetic resonance imaging identified one (1.3%) asymptomatic reherniation in Group 1 and 6 (8%) in Group 2 (*P < 0.05)

Regression analysis

Symptomatic reherniation risk was not correlated with age (P = 0.828), BMI (P = 0.293), or volume of nucleus removed (P = 0.713). Inclusion of asymptomatic reherniations into the analysis did not show significant findings (P > 0.05).

DISCUSSION

Recurrent disc herniation is the primary cause of surgical failure and morbidity in patients treated with a lumbar discectomy. The purpose of this study was to evaluate the efficacy of the coblation-assisted microdiscectomy using the Aquamantys® system (Medtronic Advanced Energy, Portsmouth, NH, USA) in reducing the reherniation rate in a cohort of prospectively enrolled patients. In a follow-up spanning 48 months, we found that the overall symptomatic reherniation rate was 4%, and the asymptomatic reherniation rate was 4.7%. Specifically, one reherniation case (1.3%) was observed in Group 1, while five (6.7%) in Group 2 (P < 0.05). MRI identified a total of four (2.7%) asymptomatic reherniations at 12 months, 6 (4%) at 24 and 36 months, and 7 (4.7%) at 48 months. At the end of the observation, Group 1 contained one (1.3%) asymptomatic reherniation, while six (8%) were observed in Group 2 (P < 0.05).

Our results are in agreement with previous studies reporting a symptomatic reherniation rate ranging from 3% to 18%.[10,24,25] Furthermore, the asymptomatic reherniations rate compared favorably with pervious findings reporting an asymptomatic rate of 13%.[26]

The results of the Spine Patient Outcomes Research Trial identified younger age, lack of a sensory or motor deficit, and a higher baseline ODI score as risk factors for recurrent disc herniation.[27] Accordingly, the highest risk patients for reherniation are young patients with high disability and without a neurological deficit. A traumatic event preceding the onset of recurrent symptoms[28] was described in 32.1% of patients with recurrent lumbar disc herniation. In our regression analysis, symptomatic reherniation risk did not correlate with age (P = 0.828). Among risk factors investigated, it has been reported that disc height and range of motion positively correlate with risk of recurrence. In this regard, it has been pointed out that a sagittal range of motion at interested disc level of more than 10° resulted in a recurrence rate of 26.5% compared to a recurrence rate of 4.1%, with a range of motion of <10°.[29] The role of operative technique used in the initial discectomy, in reducing the risk of recurrence has been a matter of investigations. In this regard, a recent meta-analysis compared aggressive disc removal with large annulotomy and curettage of the disc space to a more conservative removal of the disc fragment (sequestrectomy).[30] Such a study showed that recurrence incidence was greater with the sequestrectomy compared to the aggressive technique.[30] Contrarywise, the results of a recent randomized clinical trial comparing discectomy and sequestrectomy in patients with lumbar disc herniation and radiculopathy showed no significant difference in reherniation rates between the two techniques.[9] Furthermore, sequestrectomy has been shown to be superior in physical and social functioning, use of analgesics, and overall outcome at 2 years.[9,11,31]

The coblation-assisted microdiscectomy is a technique that incorporates the use of a coblation system with the standard microdiscectomy. Such a technique has been shown, in a short follow-up, to be effective in intradiscal decompression and pain control.[18] We have shown that patients treated by this technique present less overall recurrence rate as compared to the solely microdiscectomy.

Minimally invasive procedures are increasingly applied for the treatment of LDH such as intradiscal electrothermal therapy, laser spine surgery, and nucleoplasty.[17] Percutaneous nucleoplasty using coblation technique is a relatively new therapeutic option that was approved >10 years ago.[14] The therapeutic mechanism of percutaneous nucleoplasty is thought to be based on intradiscal decompression. Coblation technique involves the use of radiofrequency energy to excite the electrolytes in a conductive medium such as saline solution, creating a 1-nm thick region of precisely focused plasma at the tip of the wand. The energized particles in the plasma have sufficient energy to break molecular bonds, enabling excision or destruction of soft tissue such as the disc nucleus. Use of coblation technique provides removal of a portion of the nucleus tissue, resulting in decompression

of the herniated disc. Many factors can affect the efficacy of percutaneous nucleoplasty, the most important being the severity of the spinal degeneration. Accordingly, the nucleoplasty is not effective in patients with severely degenerated disc.[17] Integrity of the annulus fibrosus is also considered to be an important factor for achieving a beneficial outcome after nucleoplasty.[17] For these reasons, the best indication for nucleoplasty using coblation technique is a contained disc herniation. Although the short- and medium-term outcomes after this procedure appear to be satisfactory, long-term follow-up shows a significant decline in patient satisfaction over time.[17]

The coblation-assisted microdiscectomy, incorporating the coblation effect along with the microdiscectomy, seems to offer additional advantages over the simple microdiscectomy since the subsequent coblation of the disc remnant could reduce the occurrence of reherniation. Our finds are in favor with this hypothesis since patients of Group 1 presented with less both symptomatic and asymptomatic recurrences. The Aquamantys® system, which has been used successfully in orthopedic,[19] general and cardiac surgery, and neurosurgery,[20] is gaining interest as an innovative device. First introduced as coagulation bipolar sealers, to date, its use as pure coblation device has not been reported. The Aquamantys® system (Medtronic Advanced Energy, Portsmouth, NH, USA) is based on a new bipolar coagulation technique, the so-called transcollation technology, a proprietary combination of radiofrequency energy and saline.[19] The generator delivers transcollation technology, simultaneous radiofrequency power and saline delivery, to the disposable bipolar sealers. The 6.0 Bipolar Sealer is mainly used in orthopedic surgery where the system has been demonstrated useful in reducing blood loss during hip and knee replacement procedures and trauma surgery.[19] The EVS, with its out of body shaft length of 172.50 mm and shaft diameter of 4 mm, has been shown to be effective in minimally invasive surgery.[20] The technique is associated with simultaneous delivery of bipolar radiofrequency energy and conductive fluid through its electrode tip. The system works by combining a bipolar electrosurgical generator with a rotary peristaltic pump to provide simultaneous delivery of radiofrequency energy and saline solution when used with Aquamantys® handheld disposable devices. The saline cools the tissue as it is treated and evenly conducts the energy into the tissue causing its shrinking and blood vessels sealing.

This study has some limitations. First, it compares a prospectively enrolled group of patients with a cohort of retrospectively selected patients. Second, some important factors associated with recurrent disc herniation, such as smoking and occupation, were not included in the analyses. Prospective, randomized, controlled studies are needed to determine whether the coblation-assisted microdiscectomy offers true advantage in terms of recurrence rate with respect to the classical microdiscectomy.

CONCLUSIONS

Our findings indicate that the coblation-assisted microdiscectomy by the Aquamantys system is a simple, safe, and effective therapeutic option for LDH. Such a technique has shown to reduce reherniation risk in a period spanning 4 years. Further studies are required to confirm these results.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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