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Lumbar discectomy with annulus fibrosus closure: a retrospective series of 53 consecutive patients

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Abstract

Introduction:

Lumbar disc herniation is most common degenerative alteration of the spine. Whenever surgical therapy proves to be necessary, recurrent disc herniation is most frequent concern. Here, primary aim was to determine the percentage of patients eligible for insertion of an annular closure device (ACD). Secondary aim to evaluate 12-month incidence of recurrent disc herniation at the operated level. Our hypothesis was that ACD might help in preventing recurrent disc herniation.

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Methods:

Patients in a single XXX neurosurgical center underwent limited discectomy alone (n=41, group 1) versus limited discectomy plus ACD (n=12, group 2). Mean postoperative follow-up period was 12 months.

Results:

Twelve out of 53 patients (22.6 %) were eligible for ACD implantation. Patients of group 2 were significantly taller (mean 176 cm, p= 0.007) as compared with group 1 (mean 170). The only statistically significant difference of intraoperative parameters between group 1 and 2 was amount of nucleus materiel removed (p= 0.01), being greater in group 2 (mean 0.9) as compared with group 1 (mean 0.3). In group 1 six patients (6/41, 14.6%) presented with symptomatic reherniation at same level of surgery, while in group 2 only one patient experienced recurrence (1/12, 8.3%). No adverse events were reported.

Discussion:

In the current study one out of five patients with lumbar disc herniation was considered suitable for ACD placement. In vast majority of these patients reherniation was precluded on the short-term basis. Patients with ACD were taller and had intraoperatively a higher volume of the nucleus pulposus materiel removed.

Introduction:

Les hernies discales lombaires constituent la pathologie dégénérative la plus commune au niveau de la colonne vertébrale. La chirurgie de révision des hernies discales en cas de récidive symptomatique peut poser des multiples problèmes. Lors du présent travail, notre objectif principal était de déterminer l'efficacité du traitement en mesurant le pourcentage des patients éligibles pour l'insertion d'un annular closure device (ACD). Notre objectif sécondaire était d'évaluer l'incidence à 12 mois des hernies discales récurrentes au même niveau opératoire. Notre hypothèse était que l'ACD pourrait être utile dans la prévention des récidives des hernies discales.

Méthode :

Nous avons analysé une série des patients opérées dans un seul centre Suisse, qui ont bénéficié soit d'une microdiscectomie (n=41, groupe 1), soit d'une microdiscectomie avec mise en place d'un ACD (n=12, 22.6%, groupe 2). La période moyenne de suivi a été de 12 mois.

Résultats :

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Les patients du deuxième groupe (microdiscectomie avec ACD) ont été plus grandes en taille (moyenne 176 cm, p= 0.007) comparées avec le premier groupe (moyenne 170 mm). Le seul paramètre statistiquement significatif de point de vue intraopératoire était la quantité de matériel discal retirée (p= 0.01), en étant plus grand dans le deuxième groupe (moyenne 0.9) comparées avec le premier group (moyenne 0.3). Dans le premier groupe, 6 patients (6/41,14.6%) ont eu une récidive symptomatique au même niveau, tandis que dans le deuxième groupe qu'un seul patient (1/12, 8.3%). Il n'y a pas eu d'effet secondaire.

Discussion :

Notre étude suggère que seulement un patient sur cinq avec une hernie discale lombaire était éligible pour l'implantation lors du même temps opératoire d'un ACD. Dans une vaste majorité des cas, ce dispositif a empêché une reherniation dans l'année qui a suivi la procédure chirurgicale. Les patients avec mise en place d'un ACD étaient plus grandes et ont bénéficié en intraopératoire de l'ablation d'une plus grande quantité du matériel discal.

Key words: hernia, lumbar, discal, reherniation, annular closure device, Barricaid ®

Secondary key words: hernie, lombaire, discale, reherniation, annular closure device, Barricaid ®

Funding: None.

Declaration of interest: None.

1. Introduction

The intervertebral disc is in terms of biomechanics the key structure to maintain the height of a yet deformable intervertebral space which absorbs potential shocks and supports flexibility (1). Lumbar disc herniation is the most common diagnosis of degenerative changes of the lumbar spine(2). Thus, it is considered as main cause of spine surgery in the adult population. However, the natural course is usually of quite rapid resolution of symptoms in four to six weeks after onset.

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Although the initial treatment is conservative, surgical therapy might be necessary in specific situations like insufficient pain control, major neurological motor deficit, or cauda equina syndrome(3). Recurrent lumbar disc herniation might be as high as 18% in patients who underwent initial discectomy(4). Moreover, the first postoperative year is crucial to attain long-term success, as recurrences appear most frequently during this period(5). Consequently, adjuncts have been developed which intend to keep the rest of the nucleus pulposus after initial discectomy in the disc space(6). In particular, several studies have suggested a role of the bone-anchored annular closure device (ACD), occluding the annular defect using polymer mesh(7) in patients at high risk for lumbar disc reherniation(7).

Here, we present our results of a unicentric XXX trial in a historical cohort group. The primary aim of the study was to identify the percentage of patients with lumbar disc herniation who are eligible for the insertion of ACD. We compared patients who had lumbar discectomy alone with others who underwent lumbar discectomy plus insertion of the ACD. We report data at 1-year interval, including further recurrences rates and eventual need for further surgery. Secondary aim was to evaluate the 12-month incidence of recurrent disc herniation at the operated level.

2. Methods

2.1. Patients

Data were prospectively collected without randomization and retrospectively analyzed.

Between October 2015 and January 2016, all 53 consecutive patients admitted for surgery of lumbar disc herniation were enrolled in YYY.

Eligibility criteria were: adult ≥18 years old patients able to provide written informed consent, lumbar herniated disc documented with MRI, single level microdiscectomy, follow-up of minimum 12 months. Exclusion criteria were inability to give written informed consent.

2.2. Surgery – indication for lumbar discectomy alone

Indications for lumbar discectomy alone are described in table 1. Patients underwent either limited discectomy alone (n=41, group 1) versus discectomy plus ACD (n=12, group 2).

2.3. Assessment

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Baseline data included patient's classical demographic data (table 2), including the body mass index (BMI), as well as patient's height, weight, level of surgery, prior surgery at index level, amount of nucleus pulposus material removed.

Preoperative magnetic resonance imaging (MRI) was used as gold standard for diagnosis of intervertebral disc herniation. No patient included in the present series presented MODIC changes at index level.

When surgery was indicated patients underwent limited discectomy as published by Spengler(8). The height and width of the annular injury were measured and the indications for discectomy alone were checked.

The removed disc material was placed in an opened and empty syringe. The piston was then reinserted allowing to determine the exact volume (in ml).

When the closure of the annular defect was decided the ACD used was Barricaid ® (Intrinsic Therapeutics, Woburn, MA, USA). The titanium part of this device is inserted in the adjacent vertebra and the attached polymer mesh is supposed to seal the defect of the posterior longitudinal ligament and the underlying annulus fibrosus (Fig. 1).

Postoperative outpatients visit was scheduled at 6 weeks, 3, 6, and 12 months after surgery. Whenever necessary and in case of clinical lumbar or radicular pain and recurrence in particular, a postoperative MRI of the lumbar spine was organized.

Primary outcome was the determination of the percentage of patients with lumbar disc herniation eligible for the insertion of ACD. Secondary outcome was the 12-month incidence of recurrent disc herniation at the operated level. We further also evaluated the eventual appearance of adverse events.

2.4. Statistical analysis

Statistical analysis was performed using STATA 14 (StataCorp, College 109 Station, Texas). Descriptive statistics were described as proportion/frequency for categorical data and mean, median, range for continuous variables.

Due to a limited sample size no multivariable analysis was performed.

A Mann-Whitney U-test was performed to compare the two groups.

3. Results

Basic demographic data

Basic demographic data can be found in table 2. The mean follow-up period was 12 months (median 12).

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The median age was 60 years (mean 55.5, range 27-84) in group 1 versus 51 (mean 51.6, range 24-79) in group 2 (p= 0.8).

The male to female ratio was 20:21 in group 1 and 8:4 in group 2.

The median BMI was 28.1 (mean 27.8, range 19-38.5) in group 1 versus 26 (mean 25.2, range 16.5-31.2) in group 2 (p=0.11).

The median weight was 78.5 (mean 77.6, range 56-94) in group 1 versus 78.5 (mean 77.5, range 56-94) in group 2 (p= 0.41).

Most common level of surgery was L4-L5 in both groups (group 1: 17/41, 41.5%; group 2: 7/12, 58.3%).

Preoperative statistically significant results between groups

The only statistically significant difference of preoperative parameters between group 1 and 2 was the patients' height (p= 0.007), being higher in group 2 (mean 176, range 162-187) as compared with group 1 (mean 170, range 150-184).

Applying the indications for discectomy alone 12 out of 53 patients (22.6%) were eligible for the insertion of the ACD. The indications for discectomy alone are described in detail in table 1.

Intraoperative statistically significant results between groups

The only intraoperative statistically significant difference between group 1 and 2 was the volume of nucleus materiel removed (p= 0.01), being greater in group 2 (mean 0.9, range 0.2-2.2) as compared with group 1 (mean 0.3, range 0.1-1.6).

Reherniation and further surgery

Six patients (6/41, 14.6%) presented with symptomatic reherniation at the index level in group 1, while only one experienced a recurrence of disc herniation (1/12, 8.3%) in group 2.

All patients with reherniation at the index level underwent additional surgery with further symptomatic alleviation of radicular and lumbar pain.

Adverse events

No adverse events were reported.

4. Discussion

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In the present single center study only about one out of five patients who were admitted for surgery of lumbar disc herniation (22.6%) was eligible for the treatment with the ACD. We compared two groups of patients who underwent either discectomy alone (group 1) or discectomy and insertion of a ACD (group 2). The preoperative parameters show that the patients of group 2 were taller than those of group 1. Intraoperative data reveal that they had a larger volume of the nucleus pulposus removed. Patients with the ACD implanted experienced a significantly lower rate of recurrences, with only one patient presenting with reherniation and need for a further microsurgery.

Lumbar discectomy is considered the most common spinal microsurgical procedure to treat back and/or leg pain caused by herniated disc(9). Subsequent loss of disc height and disc and facet joint degeneration are well-recognized consequences of lumbar discectomy(10). The average disc height loss might be up to 25%, as previously reported after lumbar microdiscectomy(10). Due to subsequent foraminal stenosis a proportion of such patients will eventually develop radicular symptoms that are less responsive to both medical and surgical therapy(11). Worsening lower back pain and increased disability may as well occur(12). A main concern is that recurrent lumbar disc herniation might be as high as 18% after initial discectomy(4). An important issue is that some of these aspects will eventually orient patients not only to revision surgery but possibly also to additional and more aggressive surgical approaches, including fusion or artificial disc replacement, with their inherent consequences(13). Thus, the need arose to evaluate the technical possibilities to close the defect in the posterior longitudinal ligament and the annulus fibrosus to prevent reherniation.

The Barricaid ® ACD, evaluated by the present trial, was developed to close the annular defect, thus preventing further leakage of disc material. Intended benefits are indirectly the preservation of the physiology of the disc and its height. The same applies to the height and surface of the intervertebral foramen. Additionally, facet joints have been suggested to have significantly lower rates and grades of degeneration after ACD implantation(14). Drawbacks are mainly related to breakage of such devices with further clinical and biomechanical implications(15).

The ACD has been also studied for medium term outcomes, including two years of follow up after lumbar discectomy. In particular, Parker et al.(16) suggested that implanting the ACD was associated with greater maintenance of disc height and improved leg and back pain, as well as low-back disability. Moreover, recurrent herniation did not occur in any of the patients after annular repair. Recently, Kienzler et al.(6) evaluated outcomes at 3 years after lumbar discectomy with and without insertion of ACD. The authors found that the addition of

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ACD in patients with large annular defects reduces the risk of reherniation and reoperation, with a similar safety profile over 3-years follow-up as compared with limited lumbar discectomy only.

In our experience, the indications for discectomy alone are mainly related to the physical dimensions of the ACD, the localization of the annular defect and the bone quality. Applying these criteria, only about one out of five patients with lumbar disc herniation was suitable for the treatment with the ACD.

Our present data do not show an association of the patients' body height and the dimension and localization of the annular defect. Hence, the question why the patients of group 2 were significantly taller than those of group 1 remains unclear. Kienzler et al.(17) found that the amount of nucleus pulposus resected was not significant between patients treated with discectomy alone and discectomy with insertion of ACD. In our study, however, the volume removed from the nucleus was significantly higher in the patients who had undergone discectomy and ACD. The discrepancy could be due to the fact that the individual surgeons interpret and practice the extent of the limited discectomy in a subjective and consequently different manner. The fact that junior surgeons learn from senior surgeons of their team may explain why several or even a vast number of surgeons of the same unit have the same understanding of limited discectomy which may differ considerably from other surgical units.

In recent years, endoscopic surgery is becoming more and more popular(18). The placement of ACD requires a more conventional approach that differs from the endoscopic one. In our opinion, the less invasive endoscopic approach that spares the posterior longitudinal ligament should not be abandoned to place an ACD.

Our study has several inherent limitations. Firstly, it is a historical cohort study, with all the related aspects of such a design. Secondly, the number of patients included in the group with ACD is relatively low.

Conclusions

The present trial suggests that about one out of five patients with lumbar disc herniation and high risk for recurrence is eligible for ACD insertion with a short-term benefit of the ACD, up to one year after surgery, reducing the risk of reherniation at the same level as first surgery. Patients with ACD were taller, while intraoperatively they had more material of the nucleus pulposus removed. No adverse events were encountered.

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Conflict of interest

No Conflicts of Interest:

All authors certify that they have no affiliations with or involvement in any organization or entity with any financial interest (such as honoraria; educational grants; participation in speakers' bureaus; membership, employment, consultancies, stock ownership, or other equity interest; and expert testimony or patent-licensing arrangements), or non-financial interest (such as personal or professional relationships, affiliations, knowledge or beliefs) in the subject matter or materials discussed in this manuscript.

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Figure 1

Model of the Barricaid ® annular closure device. The device is composed of a titanium bone anchor that is inserted into the vertebral body parallel to the endplate and an attached polymer mesh that occludes the annular defect

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Table 1: Indications for discectomy alone

	Discectomy alone (n=41)
Indications for discectomy alone:	
• Annular defect too small: intraoperatively measured < 4 mm in height or <5 mm in width	• 15/41 (36.6%)
• Original defect not found, and new defect not created	• 7/41 (17.1%)
• Posterior disc height preoperatively measured <5 mm	• 7/41 (17.1%)
• Annular defect too medial	• 5/41 (12.2%)
• Osteoporosis/bone density concern	• 2/41 (4.9%)
• Annular defect too large: intra-operatively measured >6 mm in height or >12 mm in width	• 2/41 (4.9%)
• BMI > 40	• 1/41 (2.4%)
• Active systematic or infection at the site of implantation	• 1/41 (2.4%)
• Patient refused Barricaid ® implant	• 1/41 (2.4%)

Table 1 : Indications for discectomy alone

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Table 2: Basic demographic data and statistically significant results
Table 2: Basic demographic data and statistically significant results

	Discectomy alone (n=41): median; mean (range)	Discectomy with Barricaid® (n=12) median; mean (range)	
Age	60; 55.5 (27-84)	51; 51.6 (24-79)	p= 0.8
Follow-up			
Male: Female	20:21	8:4	
BMI	28.; 27.8 (19-38.5)	26; 25.2 (16.5-31.2)	p= 0.11
Body height (cm)	172; 170.7 (150-184)	174; 176 (162-187)	**p= 0.007**
Weight	78.5; 77.6 (56-94)	78.5; 77.5 (56-94)	p= 0.41
Amount of nucleus material removed (ml)	0.2; 0.3 (0.1-1.6)	0.8; 0.9 (0.2-2.2)	**p= 0.01**
Prior surgery	4/41 (9.8%)	2/12 (16.7%)	
Level of surgery • L2-L3 • L3-L4 • L4-L5 • L5-S1	 • 1/41 (2.4%) • 7/41 (17.1%) • 17/41 (41.5%) • 16/41 (39%)	 • 1/12 (8.3%) • 1/12 (8.3%) • 7/12 (58.3%) • 3/12 (25%)	

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