Journal of Clinical Neuroscience 34 (2016) 288–293

Contents lists available at ScienceDirect

Journal of Clinical Neuroscience

journal homepage: www.elsevier.com/locate/jocn

Opinion paper

Occurrence of discal and non-discal changes after sequestrectomy alone versus sequestrectomy and implantation of an anulus closure device

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ARTICLE INFO

Article history:
Received 24 June 2016
Accepted 26 September 2016

Keywords:
Lumbar discectomy
Sequestrectomy
Disc herniation
Anular closure device

ABSTRACT

Sequestrectomy alone represents a procedure for the treatment of lumbar disc herniation. For selected cases, an anulus closure device (ACD) can be implanted which may result in lower reoperation rates. However, comparative magnetic resonance imaging (MRI) changes and their clinical relevance of both procedures are unclear and have not been reported so far.

Clinical and MRI data of patients after limited discectomy with ACD implantation (group ACD; $N = 45$) and patients after sequestrectomy alone (group S; $N = 40$) with primary lumbar disc herniation were compared retrospectively. Pain intensity on the visual analogue pain scale (VAS), oswestry disability index (ODI) or the patient satisfaction index (PSI) were collected. Disc signal intensity, Modic type changes, endplate reactions, anular tears and reherniations were investigated using MRI before and <18 months postoperative. Morphologic changes were correlated with clinical outcome.

There was no difference in VAS back, VAS leg or ODI/PSI after the operation although group S showed significantly more reherniations in MRI. The overall rate of repeated surgery at the same level was similar with a trend in favour of the ACD group ($P = 0.729$). Significantly more patients of the ACD group experienced endplate erosions after surgery ($P < 0.001$). Both groups experienced progression of disc signal intensity, Modic type changes, and anular tears with most MRI signs being without clinical relevance.

ACD implantation is associated with a significantly lower reherniation rate in MRI but showed a significantly higher rate of endplate erosions. The structural changes do not appear to be clinically relevant.

1. Introduction

Patients suffering from symptoms of lumbar disc herniation classically undergo open lumbar microdiscectomy or sequestrectomy alone. Regardless of the operative technique, these operations represent the most common surgical procedures in the United States performed for those patients [1]. Both techniques may lead to immediate relief of symptoms but recurrent disc herniations may cause increased pain and disability, which necessitates repeat surgery. A recent comprehensive review addressing the degree of discectomy concluded that limited discectomy may be associated with a lower incidence of long-term recurrent low back pain at the cost of an increased incidence of reherniations [2].

In order to prevent any further outward migration of nuclear material at the location of tear or rupture and thereby associated unfavourable outcome, anulus closure devices (ACDs) have been developed. They are thought to facilitate the surgeon to preserve the integrity of the entire intradiscal structures and to prevent recurrent reherniations. Preliminary effectiveness of such an ACD has been recently shown in patients at high risk of reherniation based on anular defect size [3].

However, no control group was available and imaging results were focused on the presence or absence of reherniations only. Thus, no information is available on additional pathological changes occurring inside the disc space and/or in the vertebral bodies associated with ACD implantation.

We therefore analyzed discal and non-discal changes occurring in patients of a single prospective patient cohort after limited discectomy and implantation of an ACD. These changes were compared to results of a similar patient cohort that received sequestrectomy alone. As the disc space has not been entered in

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http://dx.doi.org/10.1016/j.jocn.2016.09.013
0967-5868/

this control group, significant morphologic changes of any kind in the ACD group should be generated by the implant itself. Finally, MRI changes observed in both patient groups were investigated for clinical relevance.

2. Materials and methods

2.1. Patient selection

For the present investigation, a total of 85 patients were retrospectively screened for eligibility. Patients were only included if magnetic resonance imaging (MRI) and clinical datasets were available before and after the operation. Clinical data of the sequestrectomy alone group (Group S) originate from the sequestrectomy arm ($N = 40$) of a previously published trial [4,5], clinical data of the limited discectomy group with implantation of an anulus closure device (Group ACD) are derived from a post marketing surveillance study ($N = 45$), which represents 'Cohort B' of a recently published study [3]. Fig. 1 shows images of the device. For the present investigation, all preoperative and follow-up MRI-data of Group S and Group ACD were newly analyzed by an independent institution (Medical Metrics Inc., Houston, TX, USA). The following variables were recorded: presence and type of MRI confirmed reherniations, anular tears or fissures, disc signal intensity, Modic Changes, and endplate changes/reactions (for details, see Section 2.3). In group S, only 34 complete imaging datasets were available. Additional 5 MRI datasets had to be discarded due to insufficient imaging quality. In Cohort B, no follow-up MRI was available in 3 patients resulting in 42 datasets ready for analysis.

For both studies, informed consents and Ethics Committee approvals were available. Inclusion criteria for both studies were similar: presence of lumbar disc herniation with at least six weeks of failed conservative treatment prior to surgery; no previous surgery at index level; age above 18 and below 60; sufficient knowledge of the German language for completing the questionnaires; MRI confirmed disc herniation; and absence of concomitant spinal disease. Patients were excluded if spondylolisthesis was present at the index level; clinically compromised vertebral bodies in the lumbosacral region due to any traumatic, neoplastic, metabolic, or infectious pathology; scoliosis of greater than ten degrees; or any metabolic bone disease that has not been stabilized for at least three months.

2.2. Operative procedures

In both groups, a standardized microsurgical midline approach was used. In group S, patients received removal of the herniated material only without entering the disc space. Even in cases of transanular herniation, fragments were removed above the anulus-level without entering the disc space. In group ACD, a limited discectomy was performed, and annulus closure device implanted. The implant consists of a flexible woven polyester mesh (Dacron®) attached to a titanium bone anchor (Barricaid®, Intrinsic Therapeutics, Inc., Woburn, USA). Patients with defects larger than 6 mm in height or 10 mm in width were excluded from the study. For detailed surgical description, see Bouma et al. [3].

2.3. Assessment of MRI

The following findings were recorded:

- Type of MRI confirmed reherniations with (1) None, (2) Protrusion, (3) Extrusion, (4) Sequestration, (5) Indeterminate.
- Presence of anular tears or fissures were rated as (1) absent, (2) present, or (3) indeterminate.
- Disc signal intensity was graded according to Pfirrmann [6] with (1) Grade I: bright white disc, homogenous structure, clear distinction between nucleus and anulus, hyperintense signal intensity, isointense to cerebrospinal fluid, normal disc height; (2) Grade II: white disc, inhomogeneous structure with or without horizontal bands, clear distinction between nucleus and anulus, hyperintense signal intensity, isointense to cerebrospinal fluid, normal disc height; (3) Grade III: gray disc, inhomogeneous structure, unclear distinction of nucleus and anulus, intermediate signal intensity, normal to slightly decreased disc height; (4) Grade IV: dark gray disc, inhomogeneous structure, no distinction between the nucleus and anulus, intermediate to hypointense signal intensity, normal to moderately decreased disc height; (5) Grade V: black disc, inhomogeneous structure, no distinction between the nucleus and anulus, hypointense signal intensity, collapsed disc; (6) indeterminate/unable to assess: a reliable determination cannot be made from the available imaging due to technical factors, sub-optimal image quality, obscured anatomy, obstructed view due to parallax effects or other imaging artifacts. The relevant images are missing or unavailable for review, or the relevant anatomy is not visible in the field of view.
- Modic Changes with (0) None: no edematous reaction or vascular congestion induced in the adjacent bone marrow of the endplates; (1) Type I: new or increased hypointense reaction and vascular congestion in the adjacent marrows on T1-weighted MR imaging; hyperintense on T2-weighted images, new or increased relative to the previous time point; (2) Type II: bone marrow converted to a predominantly fatty marrow. Hyperin-

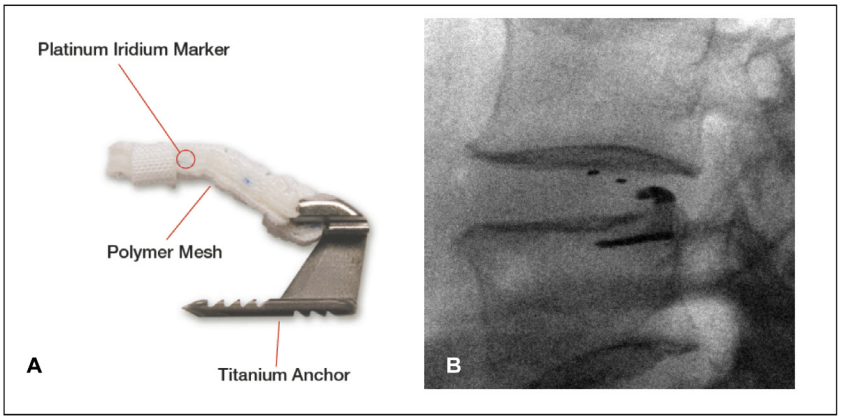

Fig. 1. Illustration of the anulus closure device (ACD). (A) Photography of the device, which consists of a polymer mesh that is attached to a titanium anchor. For better radiographic visibility, platinum iridium markers are incorporated into the mesh. (B) Lateral radiographic view of an implanted ACD.