Use of Annular Closure Device (Barricaid®) for Preventing Lumbar Disc Reherniation: One-Year Results of Three Cases

Bang Sang Hahn, MD, Gyu Yeul Ji, MD, Bongju Moon, MD, Dong Ah Shin, MD, PhD, Yoon Ha, MD, Keung Nyun Kim, MD, and Do Heum Yoon, MD

Department of Neurosurgery, Spine and Spinal Cord Research Institute, Yonsei University College of Medicine, Seoul, Korea

Although lumbar discectomy is an effective treatment for lumbar disc herniation, complications exist, including postoperative disc height loss, facet joint degeneration, and recurrent disc herniation. To solve these problems, annular closure devices have been utilized in other countries, producing satisfactory results, but there has been no report of annular closure device use in our country. Here, we demonstrate the preliminary reports of Barricaid® insertion in 3 patients who underwent surgery for lumbar disc herniation.

KEY WORDS: Lumbar vertebrae · Intervertebral disc degeneration · Diskectomy.

Introduction

Since its introduction by Mixter and Barr, lumbar discectomy has become the gold standard treatment for lumbar disc herniation that is refractory to conservative treatment of a sufficient duration. Although it is a safe and effective procedure for most patients, a number of complications have been reported, including disc height loss, progressive facet joint degeneration, hemorrhage, soft tissue infection, nerve root injury, dural tear, recurrent or residual disc herniation, epidural scar formation, discitis, arachnoiditis, pseudomeningocele, facet joint fracture, spinal stenosis, and epidural hematoma.5,7 Among them, recurrent disc herniation occurs in 5–15% of patients, and is considered the factor most responsible for a patient’s decision to refuse surgery.2,3,6,7 It is also a considerable burden to surgeons.

Barricaid® (Intrinsic Therapeutics, Woburn, MA, USA), an annular closure device, has been introduced to prevent reherniation by its check-valve mechanism (Figure 1). Its mechanism is unique and considered more effective than other reherniation-preventing devices.4,8 There have been several foreign reports on the maintenance of disc height space and satisfactory clinical results after Barricaid® use, ultimately thought to prevent disc reherniation. Here, we demonstrate the preliminary reports of Barricaid® insertion in 3 patients who underwent surgery for lumbar disc herniation.

Case Report

Case 1
A 22-year-old man presented with low back and leg pain persisting for >8 months. Neurologic examination revealed limited straight leg raising below 30°. There was no neurologic compromise. Lumbar magnetic resonance imaging (MRI) showed disc herniation at the L4–5 and L5–S1 levels. Herniation was more significant at the L4–5 level and correlated with the patient’s pain dermatome; thus, the L4–5 level was considered the origin of his pain. The patient underwent bilateral partial hemilaminectomy and unilateral discectomy at the L4–5 level. Barricaid® was subsequently inserted at the discectomized side. Patient was discharged after routine post-operative care as other conventional disc-
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Case 1
A 49-year-old man presented with acute low back and leg pain that was refractory to conservative treatment. At the last follow-up, he complained no more low back and leg pain, except for negligible numbness on his leg. Radiographs taken 1 year postoperatively showed well-preserved disc height at the operated level (Figure 2).

Case 2
A 46-year-old woman presented with recurrent low back and leg pain that was refractory to conservative treatment. Two years prior, she had undergone microdiscectomy at the L5–S1 level for a left-sided ruptured disc. Lumbar MRI showed significant reherniation at the same level. The L4–5 level also showed central disc herniation. The patient underwent partial hemilaminectomy and unilateral discectomy and Barricaid® insertion at the same level. Before Barricaid® insertion, a discectomy window was made as small as possible to fit the device. Except adhesiolysis for previous surgical field, device was inserted as usual as other two cases with no additional effort. At the last follow-up, her low back and leg pain had disappeared completely (visual analog scale score=0). Radiographs taken 1 year postoperatively showed well-preserved disc height at the operated level (Figure 3).

Case 3
A 34-year-old man presented with low back and leg pain that was unresponsive to medications and pain blocks for 6 months. Seven years prior, he had undergone microdiscectomy at the L5–S1 level for a herniated disc. Until this event, he did not complain any pain or discomfort of his back or leg. This time, lumbar MRI showed diffuse disc bulging at the L3–S1 levels. At the L2–3 level, significant disc herniation was noted. The patient did not respond to conservative treatment and consequently underwent a reoperation. Barricaid® was inserted at the operated level to prevent reherniation. At the last follow-up, the patient’s low back and leg pain had decreased (visual analog scale score=2). Radiographs taken 1 year postoperatively showed well-preserved disc height at the operated level (Figure 4).

Discussion
The Barricaid® device was designed to close the annular defect. The polymer mesh is placed on the inner surface of the disc annulus, using the disc pressure to help seal the defect against leakage of nucleus. Once wound dissection and
(partial, hemi-) laminectomy have been done, discectomy is followed. However, aggressive nucleus removal has been shown to result in significant back pain and worsened clinical outcomes. After discectomy, the annular defect size is measured and the appropriate sized device is chosen. The titanium anchor is inserted into the bone (parallel to the surface of the endplate) and the mesh forms a barrier that blocks the defect (Figure 5). The device provides permanent fixation through bone anchorage and remains inside the disc. During the procedure, fluoroscopic guidance is required to ensure appropriate location of the device.

Annular closure device insertion allows more nucleus to be left inside of annulus and restores intra-discal pressure. Because only partial volume is removed from the intervertebral disc, this procedure can preserve disc height and motion and reduce facet degeneration. Recent data of annular closure device trials have shown good clinical results without severe complications. In 2-year’s prospective cohort study comparing the discectomy alone group and the Barricaid® insertion group, Parker et al.⁴ reported that Barricaid® insertion group resulted in recurrent rate of zero (0% vs. 6.5%), greater preservation of disc height, and less pain and disability. No device related morbidity was identified. They suggested that more preserved disc height results in greater foraminal height and area, leading improved radicular pain and mechanical back pain. Trummer et al.⁸ also reported that Barricaid® insertion group showed reduced rates and grades of facet joint degeneration. However, annular closure device insertion does not always present satisfactory results, however, Bouma et al.¹⁰ reported 1.4% symptomatic reherniation and 1.5% asymptomatic reherniation after Barricaid® insertion. Although it showed lower rate of reherniation compared to discectomy alone group, these results indicate that the device does not perfectly prevent disc reherniation, but reduces the rate of reherniation by preserving disc height. In our 3 cases, the procedure was even less invasive than other surgical treatment such as lumbar fusion, inducing less postoperative pain and requiring shorter duration of hospitalization. In all 3 cases, disc height at the discectomy level seemed to be preserved and neither disc reherniation nor adjacent segment degeneration appeared during the 1-year follow-up period, though it needs to be followed up after 24-months or more later. All patients showed improvement in back and leg pain, and no severe pain relapsed.

This study has some limitations. Compared with other studies, this paper reports only 3 cases and the duration of follow-up is limited to 12–13 months. Furthermore, since no computed tomography or MRI were available, and plain radiographs were the only means of follow-up, it was impossible to measure precise disc height or to detect asymptomatic reherniation like Bouma et al.¹⁰ tried.

**Conclusion**

The early experience of Barricaid® implantation in our institution showed preserved disc heights and delayed disc degeneration, and improved leg and back pain. However, greater number of cohort and longer duration of follow-up would be necessary in the future study to estimate the ef-

![Figure 4](A) Radiographs of case 3 taken preoperatively, (B) 3 months postoperatively, and (C) 13 months postoperatively.

![Figure 5](The titanium anchor is inserted into the bone (parallel to the surface of the endplate) and the mesh forms a barrier that blocks the defect (Courtesy of Intrinsic Therapeutics, Woburn, MA, USA).)
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Effectiveness and safety of this device. We hope our experience to be shared with others and helpful to future trial of Barricaid® insertion.

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