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Barricaid Spinal Implant Device

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Key Messages

- Horizon Scan reports provide brief summaries of information regarding new and emerging health technologies.
- These technologies are identified through the CADTH Horizon Scanning Service as topics of potential interest to health care decision-makers in Canada.
- This Horizon Scan summarizes the available information regarding an emerging technology, Barricaid — a spinal implant device for those at risk of recurrent spinal disc herniation.

Barricaid: A Bone Implant Device for Lumbar Disc Herniation

Barricaid by Intrinsic Therapeutics is a surgical implant designed for people at risk of recurrent spinal disc herniation (Figure 1) — a common source of chronic low back pain. Approximately one-fourth of patients who undergo a standard discectomy to resolve lumbar disc herniation face recurrent symptoms after surgery, demonstrating a need for the development of novel solutions to improve the procedure's success rate.[1]

How It Works

Lumbar disc herniation, also called a slipped or ruptured disc, occurs when segments of fibrous tissue cushioning the low back vertebrae bulge or break and push out their inner soft tissue.[2] Herniated discs may impinge nerve roots in the spinal cord and are the most common cause of sciatica, which is characterized by radiating pain in the hips and legs.[3] Eighty-five percent of all disc herniations resolve on their own, where the pain of nerve root compression improves without any intervention.[4] In this process of spontaneous hernia regression, the body partially or completely absorbs the herniated material.[5] However, if non-surgical treatments such as bedrest, physical therapy, and analgesics are ineffective, or there is bowel or bladder dysfunction through nerve compression by the herniated disc, patients with sciatica undergo surgical intervention in the form of a discectomy to remove the herniated disc material.[4,6] The Barricaid annular closure device is a bone-anchored implant for use during a discectomy for patients with large annular defects.[3] During the procedure, Barricaid is used to occlude defects in the outer anulus fibrosus portion of the herniated disc, which has limited healing capacity on its own.[3]

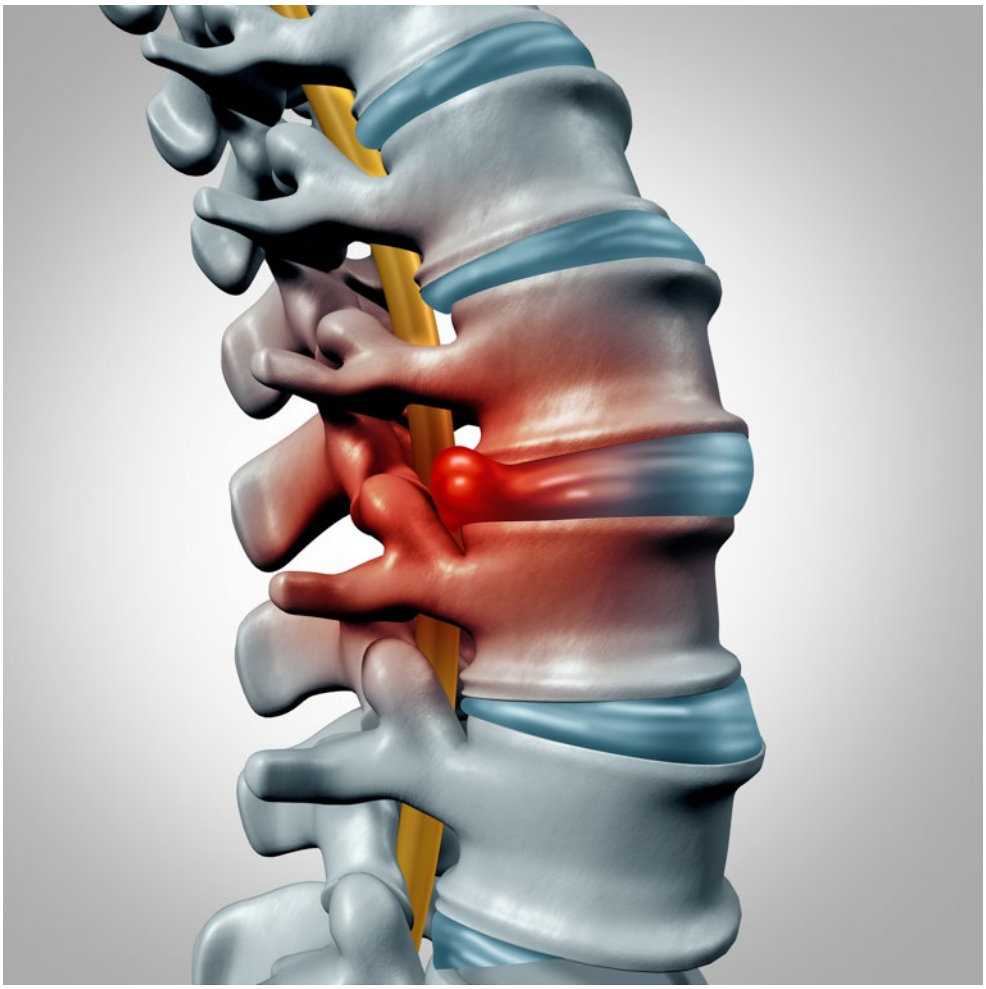
The implant consist of 2 main components: a flexible polymer mesh that covers the annular defect and mechanically prevents the inner nucleus pulposus portion of the disc from moving out of place, as well as a titanium alloy anchor that is fixed onto an adjacent vertebral body to secure the device.[7] If an annular defect is observed during discectomy, it is first measured using sizing instruments to determine if the Barricaid device is compatible with the size of the annular defect.[8]

Who Might Benefit?

Patients are eligible to receive Barricaid if the annular defect measures between 4 mm and 5 mm in height, and has a width of at least 6 mm.[8] Due to the size of the annular closure device, patients with shorter disc heights or smaller annular defects would not be able to receive Barricaid.

Some patient subgroups, such as patients older than 50 who are female and patients with large annular defects, are at an increased risk of recurrent disc herniation following an initial discectomy, as seen over a long-term follow-up.[1] These subgroups could be good candidates for Barricaid to prevent reherniation. The standard surgical option for people with reherniation is a revision discectomy, either with or without the fusion of 2 or more vertebrae to provide stabilization.[9] Those who have undergone revision surgery experience poorer clinical outcomes, such as increased procedural time, length of hospitalization, and post-operative utilization of pain medication.[10] Furthermore, they are at great risk of reherniation and

Figure 1: Three-Dimensional Anatomic Diagram of Spinal Column Segment With Herniated Disc



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subsequent revision discectomies.[10] Surgical techniques and devices such as Barricaid that decrease the rate of recurrent herniation would be of benefit to this patient population.

Availability in Canada

Barricaid is not available in Canada as of this writing. In 2019, the Barricaid annular closure device received FDA approval for use during limited discectomy procedures at a single level between the L4 and S1 vertebrae.[11]

What Does It Cost?

Barricaid is designed to be used as an adjunctive supplement to conventional discectomy, with the main economic considerations for implementation being specialized surgical training, operating room resources due to a longer operation time, and the cost of the device itself. The authors of a cost-effectiveness study compared the direct health care costs of conventional discectomy to those of discectomy supplemented by Barricaid in high-risk patients with large annular defects.[12] They found that the use of Barricaid significantly reduced the rate of symptomatic reherniation over a 2-year follow-up, resulting in lower direct health care costs per patient.[12] Outside of health care costs, preventing revision discectomies may have an economic benefit because of a lower incidence of lost productivity due to chronic low back pain.

Current Practice

As most cases of disc herniation resolve without surgical intervention, patients are encouraged to wait at least 6 weeks before undergoing surgery.[4] The standard surgical procedure for disc herniation is conventional discectomy, which is generally performed as a minimally-invasive outpatient procedure called a microdiscectomy.[13] In a prospective cohort study with a 10-year follow-up, patients who underwent surgery for lumbar disc herniation tended to have worse baseline symptoms and functional status compared to patients who were initially treated non-surgically; however, patients who underwent surgery reported significantly better pain-related outcomes at 10 year follow-up.[14]

What Is the Evidence?

An ongoing follow-up of a randomized controlled trial of 554 patients is comparing the safety and clinical efficacy of Barricaid in conjunction with a limited discectomy procedure to discectomy alone.[15] The selected patient population includes those with posterior lumbar disc herniations who are eligible for a primary discectomy and have partaken in failed, conservative treatment before surgery; final results are expected in 2025.[15] Three-year results

of the randomized controlled trial have reported that Barricaid in conjunction with discectomy is associated with statistically significantly lower rates of symptomatic reherniation, reoperation, leg pain, and back pain compared to discectomy alone.[16] Participants who received the Barricaid implant also had a lower Oswestry Disability Index and higher Physical Component Summary and Mental Component Summary scores after follow-up.[16]

Safety

Discectomy with an annular closure device was associated with significantly less serious device- and procedure-related adverse events and was observed to be a relatively safe procedure compared to conventional discectomy in patients with lumbar disc herniation and a large annular defect.[3] The risk of disc reherniation, which is associated with poorer clinical outcomes as a result of revision surgeries, was significantly lower.[3] The overall risk of all-cause serious adverse events was observed to be similar.[3] Some researchers have suggested that the safety and complications profile of discectomy with Barricaid may not apply to lower volume spine surgery centres, as the clinical trial was conducted in high-volume centres, postulating that there may be additional safety concerns associated with Barricaid at lower volume centres.[17]

Intrinsic Technologies has highlighted that Barricaid carries risks additional to the standard risks associated with discectomy, such as migration of the implanted device, buildup of scar tissue, and fracture of surrounding bone.[18]

Related Developments

There are no other known annular closure devices being investigated in clinical trials. Some trials have investigated the efficacy of interspinous devices in conjunction with a microdiscectomy in patients with low back disc herniation.[19] IntraSPINE by Cousin Surgery is a device designed to fit inside the spinal column and is currently being evaluated in a randomized controlled trial that is scheduled to complete in 2023.[20]

Looking Ahead

Longer follow-up data are needed to comprehensively assess the effectiveness and safety of Barricaid. Long-term outcomes, such as post 5-year device- or procedure-related serious adverse events and post 5-year incidence of secondary surgical interventions will be reported when the ongoing randomized controlled trial is completed in 2025.[15] Repairing annular defects is a complex aspect of spinal surgery and can result in serious potential complications such as dura tears and nerve root injury. While previous attempts at repairing annular defects, such as suture-based devices, have been unsuccessful, if effective, Barricaid may fulfill this therapeutic gap in lumbar disc herniation treatment.

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