A Novel Balloon-Inflatable Catheter for Percutaneous Epidural Adhesiolysis and Decompression

Department of Anesthesiology and Pain Medicine, Asan Medical Center, University of Ulsan College of Medicine, Seoul, Korea

Seong Soo Choi, Eun Young Joo, Beom Sang Hwang, Jong Hyuk Lee, Gunn Lee, Jeong Hun Suh, Jeong Gill Leem, and Jin Woo Shin

Epidural adhesions cause pain by interfering with the free movement of the spinal nerves and increasing neural sensitivity as a consequence of neural compression. To remove adhesions and deliver injected drugs to target sites, percutaneous epidural adhesiolysis (PEA) is performed in patients who are unresponsive to conservative treatments. We describe four patients who were treated with a newly developed inflatable balloon catheter for more effective PEA and relief of stenosis. In the present patients, treatments with repetitive epidural steroid injection and/or PEA with the Racz catheter or the NaviCath did not yield long-lasting effects or functional improvements. However, PEA and decompression with the inflatable balloon catheter led to maintenance of pain relief for more than seven months and improvements in the functional status with increases in the walking distance. The present case series suggests that the inflatable balloon catheter may be an effective alternative to performing PEA when conventional methods fail to remove adhesions or sufficiently relieve stenosis. (Korean J Pain 2014; 27: 178-185)

Key Words:
balloon, lumbar disc herniation, percutaneous epidural adhesiolysis, post lumbar surgery syndrome, spinal stenosis.

Various etiologies and pathophysiologies contribute to the development of chronic lower back pain and dictate the appropriate treatment. Epidural adhesions are considered one of the most important factors in the pathophysiologies of back pain. Epidural adhesions most commonly arise from postoperative epidural scarring and can also be seen in patients with spinal stenosis and disc herniation [1-3]. Epidural adhesions cause pain by interfering with the free movement of the spinal nerves and increasing neural sensitivity as a consequence of neural compression [4]. Although an epidural injection with a local anesthetic agent and glucocorticoid is an effective treatment for chronic lower back pain and/or radicular pain, this therapy often works for only a few weeks or may not improve the patient’s functional status [5,6]. It may be attributed to the reason that the injectate cannot spread out to the lesion...
properly due to the epidural adhesions [7]. Therefore, physicians may perform percutaneous epidural adhesiolysis (PEA) on patients who are unresponsive to existing and temporary treatments, with the goal of eliminating adhesions and allowing the delivery of injections to target sites.

PEA is commonly performed with a Racz catheter or a more steerable navigation catheter (NaviCath®, Myelotec, Inc., Roswell, GA, USA) and has proven to be effective [8,9]. However, the approach and correct placement of these catheters can be difficult in patients with severe adhesions or stenosis, leading to incomplete removal of the adhesions [10]. Moreover, the long-term effects (i.e., over more than 6 months) of this treatment are uncertain and controversial [11]. Importantly, there has not yet been any treatment developed to relieve stenosis itself through a nonsurgical method.

Previously, we have reported that transforaminal balloon treatment results in significant pain relief and functional improvement in patients with chronic refractory lumbar foraminal stenosis [12]. On the basis of this concept, a novel balloon catheter for more effective PEA and decompression was developed: the Zigzag-motion Inflatable Neuroplasty (ZiNeu®, JUVENUI, Seoul, Korea) catheter, which can be adjusted side-to-side and has an inflatable balloon attached to the end of the catheter tip (Fig. 1). In the present report, we describe four patients who suffered from persistent lower back pain radiating to the leg despite repeated conventional epidural steroid injections and other PEA modalities, and who were successfully treated with the inflatable balloon neuroplasty catheter.

**CASE REPORTS**

1. Case 1
A 75-year-old man presented to our clinic with pain in his back, both thighs, and calves that had persisted for seven months. He had a medical history of well-controlled hypertension and a depressive disorder. When he walked for 10 minutes, his pain was aggravated and accompanied by dysesthesia of the feet, and these symptoms were relieved by bending over. His pain score was 8 on the 11-point Numeric Rating Scale (NRS; 0 = no pain, 10 = worst pain imaginable), and his Oswestry Disability Index (ODI; ranging from 0–100; 0 = no disability) score was 56. No abnormal signs were seen on physical examination. Magnetic resonance imaging (MRI) of his lumbar spine revealed central stenosis at the L4-5 level due to a bulging disc, facet arthrosis, and thickening of the ligamentum flavum (Fig. 2). For two years, he had been treated with oral medication, a fentanyl patch, and five sets of epidural steroid injections. In addition, PEA had been performed three times (once with the NaviCath and twice with the

---

**Fig. 1.** The inflatable balloon neuroplasty (ZiNeu) catheter. This instrument can be adjusted from side to side and has an inflatable balloon (arrow) attached to the end of the catheter tip. It also has a channel (arrow-head) to inject drugs or to leave another catheter at the target site for two- or three-day regimens.

**Fig. 2.** T2-weighted magnetic resonance images (MRI) of the lumbar spine in a 75-year-old man suffering from pain in his back, both thighs, and calves that persisted for seven months. (A) Sagittal and (B) axial views of the MRI show central stenosis at the L4-5 level caused by a bulging disc, facet arthrosis, and thickening of the ligamentum flavum.
Racz catheter). However, the therapeutic effect of these procedures did not last for more than three weeks, and the duration of pain relief was further shortened after a series of procedures. His functional status was worsening, and his ODI score increased to 72.

After obtaining the patient’s written informed consent, we performed PEA and decompression with the inflatable balloon neuroplasty catheter to reduce his pain and extend the duration of pain relief. The patient was placed in the prone position with a pillow under his abdomen to minimize lumbar lordosis. After sterile preparation for the procedure, a 10G guide needle, which was specially designed to prevent cutting and skiving of the catheter, was inserted into the epidural space through the sacral hiatus. The epidural space was identified by injection of contrast medium (Omnipaque, Nycomed Imaging AS, Oslo, Norway) under fluoroscopy. A caudal epidurogram, checked before planning the PEA, showed a filling defect from the central epidural space at the L5–S1 level to both L5 intervertebral foramina (Fig. 3A). We performed mechanical adhesiolysis and decompression of the intervertebral foramina with the inflatable balloon neuroplasty catheter in order of precedence (i.e., central anterior epidural space, lateral recess area, and each intervertebral foramen). PEA and decompression were conducted by gentle side-to-side movement of the catheter with ballooning. The balloon was filled with 0.13 ml of contrast agent, and each ballooning process was limited to 5 seconds (Fig. 3B) [12]. The extent of balloon inflation was adjusted by the degree of pain; if moderate to severe pain was noted during balloon inflation, no further attempt at treatment was made for safety reasons. The catheter moved only in the deflated state. After PEA and decompression, the contrast agent in the anterior epidural space spread upward above the level of L5–S1, suggesting that successful adhesiolysis had been achieved (Fig. 3C and 3D). Before removal of the catheter, 6 ml of a mixture of 1% preservative-free lidocaine, 20 mg triamcinolone, and 1,500 IU hyaluronidase was administered via the catheter. There were no complications during the procedure such as bleeding or damage to the dura.

Fig. 3. Serial fluoroscopic images of percutaneous epidural adhesiolysis (PEA) using the inflatable balloon neuroplasty catheter. (A) Anteroposterior view verified before the procedure showing filling defects of contrast medium at the epidural space above the level of L5–S1 and both L5 intervertebral foramina. (B) Fluoroscopic view showing the inflatable balloon neuroplasty catheter placed in the L5 intervertebral foramen and the balloon filled with contrast medium. Foraminal stenosis is visualized by the degree of distortion of the balloon (arrow). (C) Decompression is performed along the intervertebral foramen by ballooning. (D) After decompression along the pass from the lateral recess to the intervertebral foramen, the contrast agent spread well. In addition, the contrast agent in the epidural space spread upward above the level of L5–S1.
low-up monitoring after one month, the patient’s pain had been reduced from an NRS of 8 to 4. The patient could walk without pain for more than 20 minutes, and his ODI score had decreased to 36. The effect has been sustained for more than 14 months, and the patient is currently being monitored on follow-up.

2. Case 2

A 37-year-old man presented to our office with right buttock pain radiating to the leg. There was no weakness or sensory changes, and his lumbar MRI revealed a huge central disc extrusion and sequestration at central L4–5 region (Fig. 4). The patient was first treated with five epidural steroid injections (two by an interlaminar approach and the others by a transforaminal approach). Although this improved his pain level, the effect did not last for more than three weeks; the patient continued to complain of pain with a score of 7 on the NRS, and he could not walk for more than three minutes. His functional score on the ODI was 38.

PEA and decompression with the inflatable balloon neuroplasty catheter were planned and prepared as described above. A caudal epidurogram, performed before the insertion of the inflatable balloon neuroplasty catheter, showed a filling defect in the anterior epidural space above the level of L5. When the inflatable balloon neuroplasty catheter was inserted and advanced to the level of L5, some resistance against the catheter was felt. Gentle adhesiolysis of the anterior epidural space by intermittent balloon inflation was performed as described for Case 1, and the spread of contrast medium above the level of disc herniation was confirmed. At the end of the procedure, a Perifix epidural catheter (B. Braun Melsungen AG, Melsungen, Germany) was left at the target site through the balloon catheter lumen. After test injection of 1 ml lidocaine, 6 ml of a mixture of 1% lidocaine and 1,500 IU hyaluronidase was administered through the Perifix catheter. After 10 to 15 minutes of monitoring, another 4 ml of a mixture of 10% hypertonic saline and 20 mg triamcinolone was injected through the catheter. The catheter was removed on the day of the procedure. There were no complications during the procedure. At the follow-up visit after one month, the patient’s pain was found to be reduced and was scored as a 1 on the NRS. The patient had no walking limitations, and his functional status was improved, with a change in the ODI score from 38 to 2. The effect has been maintained for more than 13 months, and the patient is currently being monitored on follow-up.

3. Case 3

A 70-year-old man presented with pain in the lower back and both legs. He had undergone a decompressive procedure...
surgery at the L4–5 level seven years previously. However, his pain had again developed six months prior to presentation. He complained of numbness and a cramping sensation in both legs and could not walk more than 100 meters because of his pain. He scored his pain as 8 on the NRS, and his functional score on the ODI was 40. Left neural foraminal stenosis at the L4–5 and L5–SI levels and right neural foraminal stenosis at the L3–4 level with degenerative spondylolisthesis, a bulging disc, and facet osteoarthritis were noted by lumbar MRI. The patient had been treated with an epidural steroid injection before visiting our clinic. However, the effect lasted for only two weeks, and his pain was reduced by only 10%.

To relieve the patient’s pain and extend the duration of pain relief, PEA and decompression with the inflatable balloon neuroplasty catheter were performed as described for Cases 1 and 2. A caudal epidurogram showed a filling defect from the central epidural space above the L5–SI level to both the L5 and SI intervertebral foramina. After anterior epidural adhesiolysis and decompression of both neural foramina by mechanical adhesiolysis and balloon inflation as described in Case 1, contrast agent spread throughout both the L5 and SI intervertebral foramina and the anterior epidural space above the L4–5 level. At the end of the procedure, 6 ml of a mixture of 1% lidocaine, 20 mg triamcinolone, and 1,500 IU hyaluronic acid was administered through the catheter. After two months, the patient’s pain scores on the NRS and ODI decreased to 4 and 36, respectively. His walking distance also increased to 500 meters. Interestingly, his pain nearly disappeared three months after the procedure, and he has been doing well without pain for more than 18 months following PEA and decompression with the inflatable balloon neuroplasty catheter.

4. Case 4

A 44-year-old female presented with pain in the lower back radiating to the right leg. Her symptoms first developed three years ago. When she walked for 10 minutes, her pain was aggravated and accompanied by numbness with a cramping sensation in the right leg. There was no weakness or sensory changes. No abnormal signs were seen on physical examination. For three years, she had been treated with oral medication and three sets of epidural steroid injections. The effect of the third epidural steroid injection did not last for more than one month, Moreover, PEA with the Racz catheter did not effectively reduce her pain level. The patient continued to complain of pain with a score of 8 on the NRS and she could not walk for more than ten minutes. His functional score on the ODI was 64. Her lumbar MRI revealed central disc extrusion at the L4–5 level with central canal stenosis, and bilateral L5 nerve root compression.

We planned PEA and decompression with the inflatable balloon neuroplasty catheter, and prepared as described above. A caudal epidurogram showed a filling defect from the central epidural space at the L4–5 level to both L5 intervertebral foramina (especially the preganglionic area). Gentle adhesiolysis of the preganglionic area at the right L5 level by intermittent balloon inflation was performed as described above, and the preganglionic spread of contrast medium was confirmed. At the end of the procedure, a Perifix epidural catheter was left at the target site through the balloon catheter lumen. After test injection of 1 ml of lidocaine, 6 ml of a mixture of 1% lidocaine and 1,500 IU hyaluronanidase was administered through the Perifix catheter. After 10 to 15 minutes of monitoring, another 4 ml of a mixture of 10% hypertonic saline and 20 mg triamcinolone was injected through the catheter. The Perifix catheter was left in place for a 2-day drug injection. The catheter was then removed on the second day of the procedure, after injection of the same drugs, including the hypertonic solution. There were no complications during the procedure. At the follow-up visit after two months, the patient’s pain was found to be reduced and was scored as a 2 on the NRS. The patient reported an improvement in her walking distance, and her functional status was also improved, with a change in the ODI score from 64 to 26. The effect has been maintained for more than seven months, and the patient is currently being monitored on follow-up.

**DISCUSSION**

Epidural adhesions or fibrosis commonly develop after surgery, as well as in patients with spinal stenosis or disc herniation [1–3]. Several animal models of post-lumbar laminectomy syndrome have shown epidural and perineural scarring and nerve root adherence to the underlying disc and pedicle [13,14]. Furthermore, degenerative changes in the discs, facet joints, and ligamentum flavum cause a disruption of the epidural venous plexus in patients with
spinal stenosis [1]. These derangements in the epidural space lead to recurrent and clinically insignificant microbleeds, which are believed to be the origin of epidural fibrosis [1,2]. In addition, leakage of disc materials into the epidural space following an annular tear leads to acute inflammation, consequent fibrocyte deposition, and epidural adhesions in patients with disc herniation [3]. An epidural adhesion itself is not painful, but it causes pain by trapping spinal nerve roots so that they are placed under tension by movement. In addition, compression of the nerve roots and/or adjacent veins leads to perineural edema and nutritional deficiency. As it progresses, aggravation of neuritis, demyelination, conduction disability, and ectopic neural transmission can occur, eventually leading to the development of neuropathic pain [4].

Hence, PEA has been designed to treat lower back and leg pain originating from an adhesion of the epidural space by removing this adhesion [8]. PEA is performed widely with a shearing-resistant catheter, the Racz catheter [15]. Evidence suggests that PEA is effective in treating refractory lower back pain due to post–lumbar surgery syndrome or spinal stenosis [16]. Recently published experimental biomechanical evaluations of PEA have reported that when performed with the Racz–type catheter, this procedure may be suitable for the targeted application of highly concentrated epidural medications and may have a lysis effect in reducing local inflammatory substances, but it does not exert a true mechanical lysis of adhesions [10]. In order to control the direction of the catheter during the procedure, other instruments have been developed. Among them, the NaviCath, which is more steerable and can be bent to only one side, has been reported to be clinically effective in the treatment of chronic lower back pain that is not responsive to transforaminal epidural injection [9]. However, this procedure has some limitations in patients with a severe degree of adhesion or severe spinal stenosis because of the difficulty in placing the catheter at the target area. In addition, the NaviCath–type catheter cannot be used for additional administration of drugs during 2– or 3–day procedures. A systematic review of spinal endoscopic adhesiolysis has suggested that this procedure is effective in treating post–lumbar surgery syndrome patients who have failed other modalities, including PEA [17]. Nevertheless, epiduroscopic adhesiolysis has not been widely accepted as a treatment due to safety concerns and its high cost [18]. Furthermore, as there are technical is-
In conclusion, our current report is the first case series describing the use of the inflatable balloon neuroplasty catheter for PEA and decompression. Our report demonstrates efficacy in all four patient subjects. Although we have provided only anecdotal evidence, our four cases suggest that the inflatable balloon neuroplasty catheter may be an effective alternative for performing PEA when other conventional methods fail to remove adhesions or sufficiently relieve stenosis. Randomized controlled trials with larger sample sizes to assess the effects of this treatment modality on pain improvement, the patient’s functional score, and claudication distance are currently underway.

REFERENCES
1. Berthelot JM, Le Goff B, Maugars Y. The role for radicular veins in nerve root pain is underestimated: limitations of imaging studies. Joint Bone Spine 2011: 78: 115–7.
2. Cooper RG, Freemont AJ, Hoyland JA, Jenkins JP, West CG, Illingworth KJ, et al. Herniated intervertebral disc-associated periarticular fibrosis and vascular abnormalities occur without inflammatory cell infiltration. Spine (Phila Pa 1976) 1995: 20: 591–8.
3. Kobayashi S, Baba H, Uchida K, Kokubo Y, Kubota C, Yamada S, et al. Effect of mechanical compression on the lumbar nerve root: localization and changes of intradiscal inflammatory cytokines, nitric oxide, and cyclooxygenase. Spine (Phila Pa 1976) 2005: 30: 1699–705.
4. Anderson SR, Racz GB, Heavner J. Evolution of epidural lysis of adhesions. Pain Physician 2000: 3: 262–70.
5. Armon C, Argoff CE, Samuels J, Backonja MM: Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Assessment: use of epidural steroid injections to treat radicular lumbosacral pain: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2007: 68: 723–9.
6. Hong JH, Lee YC, Lee HM, Kang CH, An analysis of the outcome of transfemoral epidural steroid injections in patients with spinal stenosis or herniated intervertebral discs. Korean J Pain 2008: 21: 38–43.
7. Manchikanti L, Bakht CE. Percutaneous lysis of epidural adhesions. Pain Physician 2000: 3: 46–64.
8. Manchikanti L, Singh V, Bakht CE, Fellows B. Interventional techniques in the management of chronic pain: part 1.0. Pain Physician 2000: 3: 7–42.
9. Lee JH, Lee SH. Clinical effectiveness of percutaneous adhesiolysis using Navicath for the management of chronic pain due to lumbosacral disc herniation. Pain Physician 2012: 15: 213–21.
10. Birkenmaier C, Baumert S, Schroeder C, Jansson V, Wegener B. A biomechanical evaluation of the epidural neurolysis procedure. Pain Physician 2012: 15: E89–97.
11. Manchikanti L, Abd S, Attiri S, Benyamin RM, Boswell MV, Buenaventura RM, et al. An update of comprehensive evidence–based guidelines for interventional techniques in chronic spinal pain. Part I: guidance and recommendations. Pain Physician 2013: 16: 549–283.
12. Kim SH, Choi WU, Suh JH, Jeon SR, Hwang CJ, Koh WU, et al. Effects of transformaminal balloon treatment in patients with lumbar foraminal stenosis: a randomized, controlled, double-blind trial. Pain Physician 2013: 16: 213–24.
13. Massie JB, Huang B, Malkmus S, Yakhsh TL, Kim CW, Garfin SR, et al. A preclinical post laminectomy rat model mimics the human post laminectomy syndrome. J Neurosci Methods 2004: 137: 283–9.
14. Hoq I, Cruz–Almeida Y, Siqueira EB, Norenberg M, Green BA, Levi AD. Postoperative fibrosis after surgical treatment of the porcine spinal cord: a comparison of dural substitutes. Invited submission from the Joint Section Meeting on Disorders of the Spine and Peripheral Nerves, March 2004. J Neurosurg Spine 2005: 2: 50–4.
15. Heavner JE, Racz GB, Raj P. Percutaneous epidural neuroplasty: prospective evaluation of 0.9% NaCl versus 10% NaCl with or without hyaluronidase. Reg Anesth Pain Med 1999; 24: 202–7.

16. Helm SS, Benyamin RM, Chopra P, Deer TR, Justiz R. Percutaneous adhesiolysis in the management of chronic low back pain in post lumbar surgery syndrome and spinal stenosis: a systematic review. Pain Physician 2012; 15: E435–62.

17. Helm S, Hayek SM, Colson J, Chopra P, Deer TR, Justiz R, et al. Spinal endoscopic adhesiolysis in post lumbar surgery syndrome: an update of assessment of the evidence. Pain Physician 2013; 16: SE125–50.

18. Kim JD, Jang JH, Jung GH, Kim JY, Jang SJ. Epiduroscopic laser disc and neural decompression. J Neurosurg Rev [serial on the Internet] 2012 Mar [2012 Mar 22]. Available at http://neurosurgicalreview.com/2012/03/epiduroscopic/.

19. Song SO, Lim HJ. Clinical experience of epidural adhesiolysis in patients with failed back surgery syndrome. Korean J Anesthesiol 2004; 47: 547–52.

20. Kim SH, Koh WU, Park SJ, Choi WJ, Suh JH, Leem JG, et al. Clinical experiences of transforaminal balloon decompression for patients with spinal stenosis. Korean J Pain 2012; 25: 55–9.