A novel balloon inflatable catheter for percutaneous epidural adhesiolysis and decompression: Zineu® catheter

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A considerable number of patients complaining of pain after spinal surgery reportedly have adhesions and fibrosis in the epidural space [1, 2]. Also, patients with chronic low back pain and/or radicular pain may have perineural adhesions due to perineural and neurogenic inflammation from mechanical or chemical irritation, while they don't have any history of surgery [3, 4]. Parke et al. [5] dissected the cadavers of such patients and reported that a number of anterior epidural adhesions, which were not detached even when pulled with threads of about 60g, were found between L4 and S1. This finding indicates that the adhesions might have been the cause of chronic low back pain.

It is still unclear whether adhesions or fibrosis constitute the main cause of low back pain or whether adhesions or fibrosis are the direct cause of pain. Considering the reports currently available, although there is less evidence supporting the postulation that adhesions or fibrosis cause pain directly, it is widely accepted that they are attributed to pain in association with patient’s motion [6].

Published reports suggest that the mechanism by which adhesions or fibrosis affect pain may be a disorder of the blood and nutrient supply or repression of the mobility of the dura and dural sleeve. When persisting for a long time, such disorders may cause aggravation of neuritis, demyelination, a nerve conduction disorder, ectopic neural transmission, and, eventually, neuropathic pain [3, 5, 7-11].

Nonsurgical treatments, such as nerve block, in chronic pain patients with severe adhesions are reported to have a relatively low effect and a high risk for relapse. This may be attributed to the fact that epidural adhesions themselves are difficult to remove through such methods, and also that they interfere with effective spread of a therapeutic agent to the lesion [12].

If a simple nerve block does not have a sufficient effect in a patient with pain caused by adhesions or stenosis, it is important to confirm whether pain is associated with an adhesion and where the adhesion, suspected of being a lesion, is positioned. Once adhesions or stenosis are confirmed as a cause of pain, neuroplasty may be performed to relieve them.

Conventional neuroplasty may be divided into either chemical adhesiolysis using hypertonic saline or mechanical adhesiolysis using a catheter that can be moved laterally.

Chemical adhesiolysis is performed by placing a thin catheter, such as Racz catheter, at the adhesion site and injecting hypertonic saline. Hypertonic saline has long been used in patients with intractable chronic pain. Although it has recently been used for chemical adhesiolysis, it is unclear whether it actually relieves adhesions, and almost no reports on its effect can be found. A short-term effect of chemical adhesiolysis lasting up to 3 months has been reported, with the evidence level as high as Ⅰ to Ⅱ-1 in chronic pain patients after spinal surgery [13]. Rather than the hypertonic saline having an adhesion-eliminating effect, however, the analgesic effect of the procedure seems to be associated with a measure of relieved adhesion due to water pressure at the time of the saline injection, dilution of the algesic substances, the hyperosmolar hyperdepolarization of the hypertonic saline, and decreased pain transmission due to highly concentrated chlorine [14-16].

Koh et al. [17] performed transforaminal epidural block with hypertonic saline and steroid in intractable spinal stenosis patients for whom an epidural block effect of 50% or higher did not continue for 1 month or more. In that group, the pain relief and functional improvement effects were higher compared to a group of patients in whom 0.9% normal saline and a steroid were injected. Also, the effects were prolonged over a longer period of time. This result provides evidence that the effect of hypertonic saline used for chemical adhesiolysis arises from the analgesic effect of the agent itself rather than from an adhesion-eliminating effect.

Mechanical adhesiolysis has the theoretical advantage that the adhered region around a nerve is separated with a catheter directly. Mechanical adhesiolysis may be divided into two methods: (1) the epiduroscopicadhesiolysis method using a laterally moving video-guide catheter, and (2) the adhesiolysis method using a thin catheter without epiduroscopic guidance. Epiduroscopicadhesiolysis enables physicians
severe pain and pose risks of nerve damage when procedures are performed in intervertebral foramen with severe adhesions. Furthermore, the information obtainable through epiduroscopy is little in comparison with the high cost. When using a thin catheter instead, physician may be unable to eliminate a moderate or severe adhesion due to weakness of the catheter. In addition, the risk of re-adhesion is high. Thus, the effect of this method tends to be low or temporary. Epiduroscopic adhesiolysis has a reported evidence level of about II-1 over a short term and about III over a long term in patients experiencing pain after spinal surgery [13].

Although the aforementioned conventional procedures are applied frequently, each has distinct advantages and drawbacks. Therefore, it is necessary to develop procedures and tools for epidural adhesiolysis that are more effective and safer.

We hypothesized that the balloon dilatation used for the relief of vascular stenosis may be applied to the epidural space to enable relief of spinal stenosis by more extensive epidural adhesiolysis and by expansion of the marginal space around the nerve as much as possible in the stenotic intervertebral foramen. We also hypothesized that balloon dilatation enables minimization of the nerve damage during adhesiolysis [18, 19]. Based on the aforementioned premises, we conducted the following clinical study. The subjects included patients with only intractable neural foraminal stenosis who were nonresponsive to conventional transfemoral epidural block or whose alleviation of pain did not continue for 1 month or more. We compared two procedures: in one group, a 3Fr Fogarty catheter was inserted to the intervertebral foramen, balloon dilatation was performed, and a steroid was injected; in the control group, the same procedure was performed excluding the balloon dilatation. When conventional transfemoral block is performed in patients with severe neural foraminal stenosis or having epidural adhesions, a contrast agent is sometimes not introduced into the epidural space through the intervertebral foramen. In that case, even the trial to insert and withdraw a thin catheter may introduce the contrast agent into the epidural space. The reason may be that the action of inserting and withdrawing the catheter partially relieves stenosis and eliminates epidural adhesions. The control group procedure without balloon dilatation might be more effective than conventional transfemoral block in the sense that the catheter was inserted into and withdrawn. Nevertheless the pain relief and functional improvements were much greater in the group in which the balloon dilatation was performed, with the effects lasting for 3 to 4 months after the procedures. In addition, the ratio of patients whose pain decreased by more than 50% for 1 year or more was 18.8% in the group with balloon dilatation and 0% in the group without balloon dilatation.

In cases of spinal stenosis, most conventional nonsurgical procedures have shown good short-term analgesic effects; however, functional improvement has not been enough [20, 21]. The procedure used in our study has a great clinical significance in the sense that it greatly improved not only pain but also functions such as neurogenic claudication in even cases of intractable spinal stenosis. In the control group, where balloon dilatation was not performed, the catheter was inserted into and withdrawn from the intervertebral foramen in a manner similar to mechanical adhesiolysis in conventional neuroplasty. The fact that such a powerful procedure was less effective than the procedure with balloon dilatation indicated that balloon dilatation is likely more effective than pre-existing procedures.

To test whether the positive outcome was in fact the result of marginal space expansion in the intervertebral foramen by balloon dilatation, as well as to examine how the marginal space around nerve may expand, the spread of contrast agent in the intervertebral foramen before and after balloon dilatation were reconstructed three-dimensionally in four patients. Comparing the degree of expansion of the marginal space showed that the diameter of the region where the contrast agent spread was increased by 28% and the diffusion volume was increased by 98% after the procedure. The intervertebral foramen normally covers about 29% of the intervertebral foramen; this does not matter when there is no foraminal stenosis. However, it may exacerbate the foraminal stenosis following progression of degenerative changes [22]. The balloon dilatation may contribute to the expansion of the marginal space in the intervertebral foramen by breaking or lengthening the thin transfemoral ligament.

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Based on the finding that balloon dilatation in the epidural space can relieve not only adhesions but also stenosis, a novel catheter (Ziazag-Inflatable Neuroplasty: ZiNeu, JUVENUI, Korea) was developed by adding the balloon dilatation function to the same type of video-guide catheter used for conventional epiduroscopy. As this catheter has the additional function of balloon dilatation, it may eliminate an adhesion more effectively, causing less neural damage or dural injury. It may even be used to relieve the neural foraminal stenosis. Moreover, as this catheter has the function of leaving a thin other epidural catheter for precise drug injection at the target lesion, it may be used to perform chemical adhesiolysis on once.[23-24]

More extensive and continuous studies need to be conducted in order to establish balloon dilatation in the epidural space as an effective and safe procedure overcoming the limits of pre-existing procedures for neuroplasty.
Reference