Anesth Pain Med 2022;17:361-370
https://doi.org/10.17085/apm.22237
pISSN 1975-5171 • eISSN 2383-7977

Review

# Percutaneous epidural balloon neuroplasty: a narrative review of current evidence

**Doo-Hwan Kim, Jin-Woo Shin, and Seong-Soo Choi**

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

**Received** September 27, 2022
**Revised** October 13, 2022
**Accepted** October 13, 2022

**Corresponding author**
Seong-Soo Choi, M.D., Ph.D.
Department of Anesthesiology and Pain Medicine, Asan Medical Center, University of Ulsan College of Medicine, 88 Olympic-ro 43-gil, Songpa-gu, Seoul 05505, Korea
Tel: 82-2-3010-3868
Fax: 82-2-3010-6790
E-mail: choiss@amc.seoul.kr

Percutaneous epidural balloon neuroplasty (PEBN) can be used to perform balloon decompression combined with percutaneous epidural neuroplasty (PEN), leading to significant pain relief and functional improvement in patients with lumbar spinal stenosis. Several studies have demonstrated the effectiveness of PEBN and supported its relatively long-term outcomes (at least 6 months, sustained for up to 12 months). Balloon neuroplasty appears to be superior to conventional PEN. Moreover, it has been shown to be effective in patients unresponsive to conventional PEN or in those with post lumbar surgery syndrome. In addition, balloon neuroplasty achieved successful outcomes regardless of the approach used, such as retrodiscal, transforaminal, contralateral interlaminar, or caudal. Chronic lumbar radicular pain without back pain, neurogenic claudication, and minimal neuropathic component were favorable predictors of successful PEBN from a symptomatic perspective. A short duration of pain after lumbar surgery, lumbar foraminal stenosis caused primarily by degenerative disc, mild foraminal stenosis, and perineural adhesion by degenerative discs were associated with successful outcomes of PEBN from pathological aspects. Ballooning ≥ 50% of the target sites and complete contrast dispersion after ballooning seemed to be crucial for successful outcomes from a technical perspective. In addition, PEBN was effective regardless of the accompanying redundant nerve roots or a mild degree of spondylolisthesis. Studies on balloon neuroplasty have reported occasional minor and self-limiting complications; however, no PEBN-related significant complications have been reported. Given the present evidence, balloon neuroplasty appears to be a safe and effective procedure with minimal complications for the treatment of lumbar spinal stenosis.

**Keywords:** Adhesiolysis; Low back pain; Lumbar spinal stenosis; Neuroplasty; Radiculopathy.

## INTRODUCTION

Percutaneous epidural neuroplasty (PEN) involves lysis of epidural adhesions using a solution injection, such as hypertonic saline or hyaluronidase and/or by mechanical means, with a specially designed catheter or epiduroscope [1]. It can lyse friable epidural adhesions using a combination of hydrostatic and mechanical forces [2], resulting in ablation of inflamed and innervated membranes [3,4] and alleviation of perineural inflammation and edema, thereby reducing axial back pain or radiculopathy [5]. Several studies have shown that PEN is an effective treatment for chronic low back and/or lower extremity pain that does not respond to conservative treatment, including epidural injections [1,6,7]. Since the development of a specialized epidural catheter by Dr. Racz (Racz catheter; Fig. 1A) for percutane-

ous epidural adhesiolysis in the early 1980s [8,9], various epidural catheters for epidural adhesiolysis have been developed, such as a nerve stimulating catheter (EpiStim® Catheter, Sewoon Medical Co. Ltd., Korea; Fig. 1B) [10], a more steerable navigation catheter (NaviCath®, Myelotec, USA; Fig. 1C) [11], or a Zigzag-motion Inflatable Neuroplasty (ZiNeu®) catheter (JUVENUI, Korea; Fig. 1D) [12]. More invasively, lysis of adhesion can be performed by epiduroscopy with direct visualization of the pathology [5]. The effectiveness of PEN for the treatment of chronic refractory symptoms in degenerative spinal diseases is relatively well-established [1,6,13]. However, the long-term effects (i.e., over six months) of conventional PEN using Racz catheter, NaviCath, and EpiStim are uncertain and unclear [14]. In other words, the treatment effectiveness of PEN is sometimes limited in some cases of chronic refractory pain.

Among the epidural catheters for epidural adhesiolysis, a balloon-inflatable epidural catheter enables the most advanced procedure. Briefly, percutaneous epidural balloon neuroplasty (PEBN) is a combination of balloon decompression (mechanical detachment of a perineural adhesion using a balloon) and conventional PEN [12,15]. Based on a randomized study of transforaminal balloon decompression using the Fogarty catheter, which is designed for angioplasty, in patients with refractory lumbar foraminal stenosis [16,17], a balloon-inflatable catheter was developed for balloon neuroplasty [12]. It can perform a unique balloon decompression procedure in addition to conventional epidural adhesiolysis, yielding significant pain relief and functional improvement in patients with chronic lumbar radicular and/or low back pain [12,15]. Notably, these improvements were sustained up to 12 months after the procedure in a meaningful proportion of patients with chronic lumbar radicular/back pain [15,18]. Moreover, PEBN was effective in patients with chronic lumbar radicular and/or low back pain who were unresponsive to conventional PEN [19].

Despite several studies on balloon neuroplasty providing evidence of treatment for chronic lower extremity and/or low back pain, several questions remain unanswered regarding potential responders, spine pathophysiology suit-

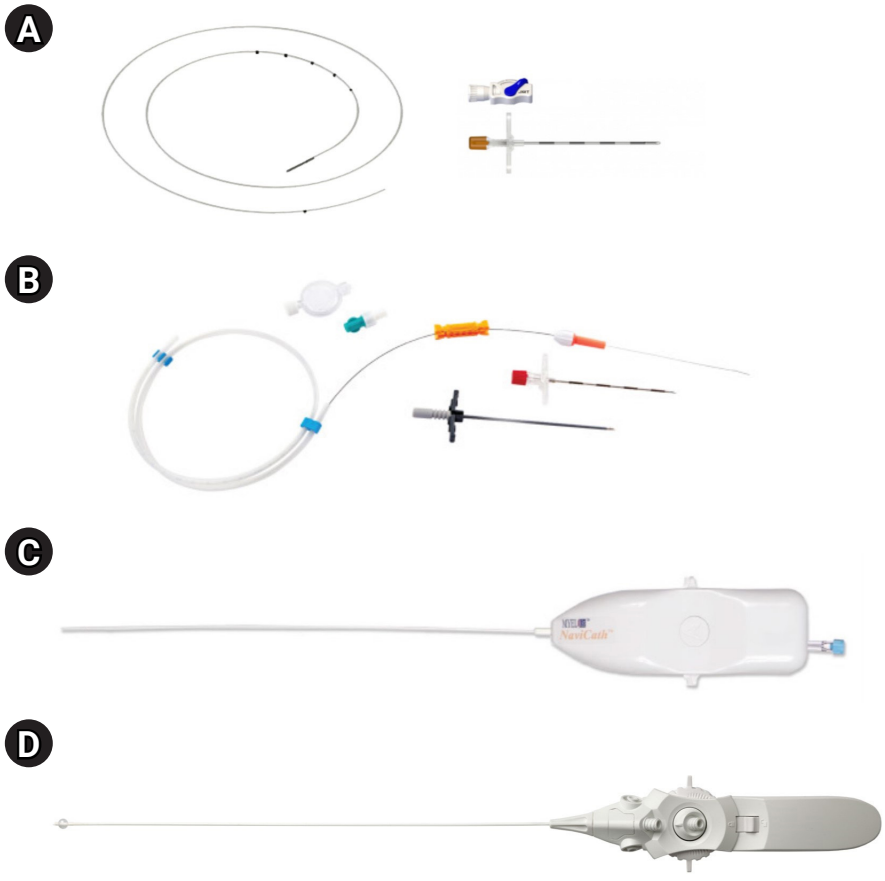


**Fig. 1.** Various epidural catheters for percutaneous epidural neuroplasty. (A) Racz catheter, (B) EpiStim® catheter, (C) NaviCath®, (D) ZiNeu® catheter.

able for the procedure, and safety of balloon neuroplasty. Although the technical details of PEBN, which are different from those of PEN, are another important issue to deal with, we will not discuss them here. Thus, this narrative review of the current evidence aimed to answer the unsolved questions regarding PEBN.

## EVIDENCE OF THE EFFECTIVENESS OF BALLOON NEUROPLASTY IN PATIENTS WITH CHRONIC LUMBAR RADICULAR AND/OR BACK PAIN

Epidural adhesiolysis with a balloon catheter to treat failed back surgery syndrome was first reported in 2004 by Song and Lim [20]. They reported that, among the various existing catheters that can inflate the balloon, the Fogarty catheter was only useful for removing epidural adhesions. Since the first randomized controlled trial of transforaminal balloon neuroplasty in patients with chronic lumbar foraminal stenosis was performed [17], several prospective and retrospective studies have been conducted to assess the effect of balloon neuroplasty in patients with chronic lumbar radicular pain and/or back pain (Tables 1, 2). Kim et al. [17] demonstrated that transforaminal balloon decompression using the Fogarty catheter leads to significant pain relief, improvement of functional status, and longer claudication distance for 3 months compared with sham in a double-blind, randomized, active controlled trial. In 2016, Choi et al. [15] showed that PEBN using the ZiNeu catheter was effective in chronic refractory spinal stenosis; successful responders who showed substantial pain relief (≥ 50% reduction from baseline) or moderate pain relief (≥ 30% reduction from baseline) with functional improvement from baseline were 72, 61, 57, and 36% of the patients at 1, 3, 6, and 12 months, respectively. The estimated mean pain intensity of leg and back pain in the 11-point numerical rating scale (NRS) was decreased from baseline 5.2 and 6.8 to 3.6 and 4.0 at 12 months after PEBN, respectively. Similar changes were observed in the Oswestry disability index evaluating functional status over 12 months after the procedure (from 47.1 to 21.6).

This multicenter, single-arm, prospective observational study demonstrated that pain relief and functional improvement after PEBN might persist for up to 12 months in chronic refractory spinal stenosis, although considerable follow-up loss is a major limitation [15]. Patients who participated in these two studies presented levels 1–2 (e.g., L4-5 central, unilateral L5 foraminal, or L4-5 central with unilateral L5 foraminal) of lumbar spinal stenosis. In actual clinical practice, many patients have spinal stenosis of level 3 (e.g., L4-5 and L5-S1 central with both L5 foramina) or higher. In other words, balloon neuroplasty has many potential target sites. Therefore, a multicenter observational study was conducted to evaluate the effectiveness of PEBN in real-world clinical settings [21]. This multicenter prospective observational study showed that PEBN led to significant pain relief and functional improvement lasting at least 6 months in patients with chronic refractory spinal stenosis, with successful responders (similar to the above definition) of 66, 63, and 51% of the patients at 1, 3, and 6 months in the above 85% balloon success rate group, respectively. Different departments (anesthesiology, orthopedics, and neurosurgery) of five hospitals were included in this multicenter study with a relatively large cohort (n = 275) and the same protocol, thereby strengthening the robustness of the results. Importantly, this multicenter study suggested that a more successful balloon adhesiolysis for multiple target lesions may result in a better clinical outcome at least 6 months after treatment [21].

A question may arise as to whether there is a difference in the effectiveness of conventional PEN and PEBN. Interestingly, in 2018, a retrospective study revealed that PEBN was also effective for 6 months after the procedure in patients with intractable lumbar spinal stenosis who were unresponsive to conventional PEN [19]. A randomized controlled study can provide a clearer explanation for the difference in the effectiveness of conventional PEN and PEBN. Karm et al. [22] evaluated whether balloon neuroplasty could be more effective than conventional PEN for refractory central lumbar spinal stenosis. This randomized controlled trial comparing balloon neuroplasty with ZiNeu catheter and conventional PEN using the Racz catheter reported that successful responders were significantly higher in balloon neuroplasty than in conventional PEN (58% vs. 25%, P = 0.035) at 6 months after the procedure. However, the small number of participants (n = 44) limits the generalizability of this study. Because epidural adhesion typically occurs after spinal surgery, one may be curious about the effect of balloon neuroplasty in patients with post lumbar surgery syndrome. Moreover, PEBN was relatively effective in patients with post lumbar surgery syndrome; successful responders (similar to the above definition) after balloon neuroplasty were 32, 25, and 22% of the patients at 1, 3, and 6 months, respectively [23].

Various studies have been performed from the perspective

**Table 1.** Summary of Prospective Studies on Effectiveness of the Percutaneous Balloon Neuroplasty in Lumbar Spine

| Study | Study design | Patient* | Groups | Outcome measures | Results | Complications | Comments |
|---|---|---|---|---|---|---|---|
| Kim et al. [17], 2013 | Double-blind, active controlled RCT | Chronic unilateral lumbar radicular pain | Balloon neuroplasty (n = 32)<br>Sham (n = 30) | VAS, ODI, and claudication distance for 12 weeks | Balloon group showed better improvement in VAS, ODI, and claudication distance than sham group | Transient pain aggravation in all cases | 3D reconstruction image revealed ≈98% increased foramen volume |
| Choi et al. [15], 2016 | Multicenter, single arm, prospective observational | Chronic lumbar radicular pain and/or back pain | Balloon neuroplasty (n = 61) | NRS, ODI, GPES, MQS and responder for 12 months | Successful responders: 72, 61, 57, and 36% of patients at 1, 3, 6, and 12 months, respectively | Transient pain aggravation in some cases | Large follow-up loss<br>3D reconstruction image revealed increased foraminal volume |
| Karm et al. [22], 2018 | Assessor-blind, active controlled RCT | Chronic refractory LSS (central) | Balloon neuroplasty (n = 24)<br>Balloon-less neuroplasty (n = 20) | NRS, ODI, GPES, MQS and responder for 6 months | Successful responders: 58% vs. 25% at 6 months in balloon neuroplasty vs. balloon-less neuroplasty (58% vs. 25% at 6 months) | Temporary pain aggravation | Small sample size |
| Park et al. [21], 2019 | Multicenter cohort, prospective observational | Chronic lumbar radicular pain and/or back pain | Balloon success rate of multiple target sites:<br>Below 50% (n = 48), 50–85% (n = 79), and above 85% (n = 148) | NRS, ODI, GPES, MQS and responder for 6 months | Successful responders:<br>Below 50%, 50–85%, and above 85% balloon success groups at 6 months were 0.292, 0.468, and 0.507, respectively | Dural puncture (3.3%), subdural injection (1.8%), vascular injection (1.5%), disc injection (2.2%), hypotension (1.5%) | Five centers including OS, NS, and anesthesiology |
| Oh et al. [30], 2019 | Multicenter cohort, prospective observational | Chronic LSS (foraminal) | After 6 months balloon neuroplasty:<br>Non-responder (n = 115)<br>Responder (n = 92) | NRS, ODI, GPES, MQS and responder for 6 months | Mild stenosis may be an independent factor associated with successful response | Dural puncture (3.9%), subdural injection (1.9%), vascular injection (1.4%), disc injection (1.9%), hypotension (1.9%) | Five centers including OS, NS, and anesthesiology |
| Gil et al. [25], 2019 | Assessor-blind, RCT | Chronic unilateral L5 radiculopathy | Balloon neuroplasty to: Safe triangle (n = 13)<br>Kambin's triangle (n = 13) | Success of procedure NRS and ODI | Similar success of balloon (77% vs. 92%)<br>Both NRS and ODI significantly decreased at 3 months without group difference | Not reported | A pilot study, small sample size<br>Did not consider medication |
| Kim et al. [18], 2020 | Prospective observational | Chronic LSS | Contrast dispersion after balloon neuroplasty:<br>Complete (n = 54)<br>Incomplete (n = 46) | NRS, ODI, and GPES for 12 months | Complete contrast dispersion group after balloon neuroplasty showed more effective than incomplete dispersion group for 12 months | No adverse events | Did not consider medication |

NRS: numeric rating scale, ODI: Oswestry Disability Index, RCT: randomized controlled trial, GPES: global perceived effect of satisfaction, MQS: Medication Quantification Scale III, LSS: lumbar spinal stenosis, OS: orthopedic surgery, NS: neurosurgery, VAS: visual analog scale. *All patients had chronic (at least 3 months) severe (≥ 6 on NRS) lumbar radicular pain with or without low back pain. They were unresponsive to conservative management such as physiotherapy, exercise therapy, or analgesic medications. In addition, the effects on epidural interventions, including epidural blocks or conventional neuroplasty, were limited in these patients.

**Table 2.** Summary of Retrospective Studies on Effectiveness of the Percutaneous Balloon Neuroplasty in Lumbar Spine

| Study | Study design | Patient* | Groups | Outcome measures | Results | Complications | Comments |
|---|---|---|---|---|---|---|---|
| Kim et al. [29], 2017 | Retrospective cohort | Chronic LSS (foraminal) | After 3 months balloon neuroplasty:<br>Non-responder (n = 39)<br>Responder (n = 38) | NRS, patient-reported functional improvement, and responder for 3 months | Degenerative disc herniation as a primary cause in LSS patients may be an independent factor associated with successful response | Not reported | Did not consider medication |
| Seo et al. [24], 2018 | Retrospective, single arm | Chronic LSS caused from HIVD | Retrodiscal balloon neuroplasty (n = 22) | NRS, patient-reported functional improvement for 3 months | Significant pain reduction: 82% at 3 months<br>Functional improvement: 77% at 3 months | No adverse events | Did not consider medication<br>Case series |
| Karm et al. [19], 2019 | Retrospective cohort | Chronic intractable LSS | Balloon neuroplasty in patients with:<br>Did not undergo any neuroplasty (n = 225)<br>Unresponsive with balloon-less neuroplasty (n = 90) | NRS, ODI, GPES, and responder for 6 months | Balloon neuroplasty was effective for 6 months despite of previously unresponsive to neuroplasty | Transient pain aggravation, dural puncture, hypotension | Missing data |
| Kim et al. [26], 2020 | Retrospective, single arm | Chronic L5-S1 foraminal stenosis with high iliac crest | Balloon neuroplasty via contralateral interlaminar approach (n = 22) | NRS, patient-reported functional improvement for 6 months | Significant pain reduction: 59% at 6 months<br>Minimally important pain reduction: 82% at 6 months | No adverse events | Did not consider functional status and medication<br>Case series |
| Oh et al. [23], 2020 | Retrospective, single arm | Post lumbar surgery syndrome | Balloon neuroplasty (n = 147) | NRS, ODI, GPES, and responder for 6 months | Successful responders: 32, 25, and 22% of patients at 1, 3, and 6 months, respectively | Dural puncture (8.8%), Temporary motor weakness (0.6%), vascular injection (0.6%), coccydynia (0.6%) | Did not consider medication |
| Sim et al. [31], 2022 | Retrospective longitudinal cohort | Chronic LSS | Balloon neuroplasty in patients:<br>With redundant nerve roots (n = 572)<br>Without redundant nerve roots (n = 221) | NRS, MQS, patient-reported functional improvement for 6 months | Balloon neuroplasty was effective for 6 months regardless of accompanying redundant nerve roots in LSS | Transient motor weakness (n = 3), vascular injection (n = 2), hypotension (n = 10) | Missing data |
| Karm et al. [32], 2022 | Retrospective longitudinal cohort | Chronic LSS | Balloon neuroplasty in patients:<br>With spondylolisthesis (n = 433)<br>Without spondylolisthesis (n = 393) | NRS, MQS, patient-reported functional improvement for 6 months | Balloon neuroplasty was effective for 6 months regardless of accompanying mild spondylolisthesis in LSS | Vascular injection (n = 3), transient motor weakness (n =3), hypotension (n = 9) | Missing data |

NRS: numeric rating scale, ODI: Oswestry disability index, GPES: Global Perceived Effect of Satisfaction, MQS: Medication Quantification Scale III, LSS: lumbar spinal stenosis, HIVD: herniated intervertebral disc. *All patients had chronic (at least 3 months) severe (≥ 6 on NRS) lumbar radicular pain with or without lower back pain. They were unresponsive to conservative management such as physiotherapy, exercise therapy, or analgesic medications. In addition, the effects on epidural interventions, including epidural blocks or conventional neuroplasty, were limited in these patients.

of the target lesion and methodology for balloon neuroplasty. In a case series of 22 patients with chronic lumbar radicular pain, retrodiscal balloon adhesiolysis through Kambin's triangle reduced radicular pain for at least 3 months (from baseline mean NRS 7.1 ± 1.4 to 3.8 ± 2.1) [24]. A small randomized controlled trial in patients with chronic L5 radiculopathy focused on whether the approach methods for transforaminal balloon neuroplasty (Safe triangle vs. Kambin's triangle) could affect the clinical outcome; there were no significant differences in pain, functional capacity, and the success rate up to 3 months between the two approaches [25]. However, these studies had small sample sizes, which may have weakened the power of their study. Another small case series (n = 22) also showed that balloon neuroplasty was successfully achieved via the contralateral interlaminar approach, leading to significant pain reduction in 59% of patients at post-procedural 6 months [26].

## FACTORS ASSOCIATED WITH FAVORABLE OUTCOMES AFTER BALLOON NEUROPLASTY

The factors associated with outcomes after balloon neuroplasty can be classified into symptomatic, pathological, and procedural aspects, as summarized in Table 3. A previous study found that age ≥ 81 years and baseline 11-point numerical rating scale score ≤ 9 were associated with positive outcomes after conventional PEN [27]. However, chronic radicular pain without lower back pain, neurogenic intermittent claudication, and minimal neuropathic components (e.g., diabetic neuropathy) were predictive factors for favorable outcomes after balloon neuroplasty from symptomatic aspects [15,17,19,22]. A multicenter, single-arm, prospective observational study revealed that diabetes and low back pain coexisting with radicular pain were independently associated with negative outcomes after PEBN (odds ratio [OR] = 0.080 and 0.799, respectively) [15]. In post lumbar surgery syndrome, a short duration of pain (< 14 months) after laminectomy may be associated with a favorable outcome after balloon neuroplasty [23].

It is well known that lumbar spinal stenosis is caused by a combination of spinal pathologies such as decrease in the height of an intervertebral disc, thickened ligamentum flavum, facet arthritis or hypertrophy, and osteophytes [28]. Information on which component among these pathologies is related to the effectiveness of the procedure would help considerably in selecting a candidate for the procedure. In transforaminal balloon neuroplasty, factors causing stenosis other than degenerative disc herniation may be associated with poor responses 3 months after balloon neuroplasty (OR = 0.327, P = 0.018) [29]. It has been reported that chronic low back and/or leg pain in patients with lumbar spinal stenosis caused by herniated intervertebral discs can be successfully decreased by retrodiscal balloon adhesiolysis through Kambin's triangle [24]. These results suggest that perineural adhesion by degenerative discs can be successfully treated using balloon neuroplasty. Furthermore, a large multicenter prospective observational study revealed that mild (to moderate) foraminal stenosis was an independent factor associated with a successful response (OR = 2.829, P = 0.006) after PEBN [30]. Interventional pain physicians may also wonder if other spinal pathologies co-exist with lumbar

**Table 3.** Associated Factors with Favorable Outcomes after Balloon Neuroplasty

| |
|---|
| Related symptoms |
| - Chronic radicular pain without or less lower back pain |
| - Neurogenic intermittent claudication |
| - Minimal neuropathic component (e.g., diabetic neuropathy) |
| - Less than 14 months of pain duration in post-lumbar surgery syndrome |
| Pathological aspects* |
| - Lumbar foraminal stenosis mainly caused by degenerative disc |
| - Mild (to moderate) degree of lumbar foraminal stenosis |
| - Perineural adhesion by degenerative disc (e.g., herniated disc) |
| Procedural aspects |
| - Accurate balloon procedure at the target lesion site (regardless of the approach) |
| - Ballooning more than 50% target sites, if multiple target lesions to be ballooned |
| - Complete contrast dye spread after ballooning (resolution of filling defect) |

*Concomitant pathology with lumbar spinal stenosis, such as redundant nerve roots or spondylolisthesis, may not affect the clinical outcomes of balloon neuroplasty.

spinal stenosis, such as redundant nerve roots and spondylolisthesis, which may affect the effectiveness of PEBN. A recent large longitudinal cohort study of more than 1,000 patients demonstrated that PEBN alleviated pain intensity and improved functional capacity for 6 months in patients with chronic lumbar spinal stenosis, regardless of the accompanying redundant nerve roots or mild degree of spondylolisthesis ($P < 0.001$) [31,32].

In previous studies on conventional PEN, there was no association between technical factors and clinical outcomes [11,27]. Two prospective observational studies of PEBN showed that ballooning more than 50% of target sites and complete contrast medium dispersion after ballooning could be of crucial importance for successful outcomes [18,21]. These results indicated that correct placement of the balloon-inflatable catheter at the target lesion and skillful manipulation of the instrument might be encouraged for achieving favorable outcomes. In addition, regardless of approaching methods, such as retrodiscal [24,25], transforaminal [17], contralateral [26], or caudal [15,19,21,22], the patient's symptoms seem to improve for at least 3–6 months if PEBN is performed on the exact target site(s).

## COMPLICATIONS

In the literature, the most common complication of conventional PEN was intravascular injection (11.6%) among minor complications [33]. Bent needle tip, intrathecal placement of the catheter, transient nerve irritation, dural puncture, torn catheter during withdrawal, and post-dural puncture headache were reported at 4.8, 4.4, 1.9, 1.8, 1.2, and 0.12%, respectively [33–35]. Profuse bleeding, epidural hematoma, meningitis, and epidural abscess among major complications were rare but occurred at 1.0, 0.1, 0.5, and 1.2%, respectively [33,35,36]. In balloon neuroplasty, the most common complication was transient pain aggravation [15,17,19], which was mainly insignificant and relieved spontaneously without any neurological sequelae. However, the patients may be uncomfortable and complain of transient pain aggravation for several postprocedural days up to weeks. In our experience, this transient pain can be reduced to some degree by appropriate opioid administration and light epidural anesthesia during the procedure. Dural puncture is an important procedural complication, because once the damage of dura mater is suspected, subsequent procedures must be stopped to prevent further complications. Two large multicenter prospective observational studies reported detailed complications after PEBN [21,30]. Dural puncture (3.3–3.9%) was the most common, followed by disc injection (2.2%). Subdural injection was observed at 1.8–1.9%. Incidence of intravascular injection (1.4–1.5%) was relatively low compared with conventional PEN. Hypotension was also observed at 1.5–1.9%. In patients with post lumbar surgery syndrome, the incidence of dural puncture (8.8%) was more than twice compared with those who have not undergone lumbar surgery [23]; the incidence was similar to that (8.7%) of conventional PEN in this specific population [37]. Although three patients underwent temporary weakness in a recent large cohort analysis, all patients completely recovered without neurologic deficits [31]. A total of 14 studies on balloon neuroplasty published until now did not report any major complication. All reported complications after balloon neuroplasty were minor and self-limiting. Therefore, PEBN can be considered a safe procedure based on the evidence to date, although external validation is necessary.

## STRENGTH AND LIMITATION

Although several review articles and meta-analyses have shown that PEN is an effective treatment for chronic refractory low back and lower extremity pain, there is a lack of evidence on spinal stenosis [1,6,7]. However, most studies on balloon neuroplasty have been conducted in chronic lumbar central and/or foraminal spinal stenosis, which could strengthen the evidence of balloon neuroplasty for the treatment of lumbar spinal stenosis. In addition, considering the unclear long-term effects of conventional PEN, PEBN provided a relatively long-term effect (at least 6 months) in most studies. Two prospective observational studies described significant pain relief and functional improvement up to 12 months [15,18]. Moreover, other pathological findings (redundant nerve roots or spondylolisthesis) accompanying lumbar spinal stenosis may have less influence on the clinical outcomes of balloon neuroplasty [31,32].

However, there are some limitations to studies on balloon neuroplasty. First, although three randomized controlled studies were conducted, the sample size was less than 30 patients per group. This could have weakened the power and validity of the results. Second, considerable follow-up loss resulted in significant limitations despite the analyses of large-cohort observational studies. Third, most studies were conducted at a single institution. Therefore, additional external validation of the effects and safety of PEBN is required

in the future. Finally, although multicenter studies were performed, confined populations, such as Koreans or patients with lumbar spinal stenosis, and the specific hospitals where the studies were conducted could limit the generalizability of the effectiveness of PEBN. Therefore, further studies are needed to verify the effects of balloon neuroplasty in other populations and hospitals.

## CONCLUSION

Balloon neuroplasty is a specialized epidural neuroplasty with a balloon-inflatable epidural catheter, which can relieve refractory radicular and/or low back pain and ensure functional improvement in patients with chronic lumbar spinal stenosis. Its effectiveness has been supported by several randomized controlled studies, multicenter observational studies, and large-cohort retrospective studies. Notably, these clinical improvements may be sustained for up to 12 months, and PEBN may be effective in patients unresponsive to conventional PEN or post lumbar surgery syndrome. Minor and self-limiting complications occurred; however, no major PEBN-related complications have been reported. Considering this evidence, PEBN seems to be a safe and effective procedure with minimal complications for the treatment of chronic refractory radicular and/or low back pain, although further research is needed. To validate and generalize the usefulness of balloon neuroplasty, well-designed randomized controlled studies with sufficient sample sizes are required.

## FUNDING

None.

## CONFLICTS OF INTEREST

One of the authors (J.W.S.) invented the ZiNeu catheter and transferred the patent to JUVENUI Co., Ltd. before submitting this manuscript. The other authors have no conflict of interest to declare.

## DATA AVAILABILITY STATEMENT

Data sharing is not applicable to this article, as no datasets were generated or analyzed during the current study.

## AUTHOR CONTRIBUTIONS

Conceptualization: Seong-Soo Choi. Data curation: Doo-Hwan Kim, Jin-Woo Shin, Seong-Soo Choi. Methodology: Doo-Hwan Kim, Jin-Woo Shin, Seong-Soo Choi. Project administration: Seong-Soo Choi. Visualization: Doo-Hwan Kim, Jin-Woo Shin, Seong-Soo Choi. Writing - original draft: Doo-Hwan Kim. Writing - review & editing: Seong-Soo Choi. Resources: Jin-Woo Shin, Seong-Soo Choi. Supervision: Seong-Soo Choi. Validation: Jin-Woo Shin.

## ORCID

Doo-Hwan Kim, https://orcid.org/0000-0002-3875-0857
Jin-Woo Shin, https://orcid.org/0000-0003-4773-2738
Seong-Soo Choi, https://orcid.org/0000-0002-2333-0235

## REFERENCES

1. Helm S, Knezevic NN. A review of the role of epidural percutaneous neuroplasty. Pain Manag 2019; 9: 53-62.
2. Racz GB, Heavner JE, Noe CE, Al-Kaisy A, Matsumoto T, Lee SC, et al. Epidural lysis of adhesions and percutaneous neuroplasty. In: Techniques of neurolysis. Edited by Racz G, Noe C: Cham, Springer. 2016, pp 119-43.
3. Bosscher HA, Heavner JE, Grozdanov P, Warraich IA, Wachtel MS, Dertien J. The peridural membrane of the human spine is well innervated. Anat Rec (Hoboken) 2016; 299: 484-91.
4. Bosscher HA, Heavner JE. Treatment of common low back pain: a new approach to an old problem. Pain Pract 2015; 15: 509-17.
5. Yıldırım HU, Akbas M. Percutaneous and endoscopic adhesiolysis. Agri 2021; 33: 129-41.
6. Helm S 2nd, Racz GB, Gerdesmeyer L, Justiz R, Hayek SM, Kaplan ED, et al. Percutaneous and endoscopic adhesiolysis in managing low back and lower extremity pain: a systematic review and meta-analysis. Pain Physician 2016; 19: E245-82.
7. Manchikanti L, Boswell MV, Datta S, Fellows B, Abdi S, Singh V, et al. Comprehensive review of therapeutic interventions in managing chronic spinal pain. Pain Physician 2009; 12: E123-98.
8. Racz GB, Haynsworth RF, Lipton S. Experiences with an improved epidural catheter. Pain Clin 1986; 1: 21-7.
9. Racz GB, Sabonghy M, Gintautas J, Kline WM. Intractable pain therapy using a new epidural catheter. JAMA 1982; 248: 579-81.
10. Kim SH, Choi SS. Epidural neuroplasty/epidural adhesiolysis. Anesth Pain Med 2016; 11: 14-22.

11. Lee JH, Lee SH. Clinical effectiveness of percutaneous adhesiolysis and predictive factors of treatment efficacy in patients with lumbosacral spinal stenosis. Pain Med 2013; 14: 1497-504.
12. Choi SS, Joo EY, Hwang BS, Lee JH, Lee G, Suh JH, et al. A novel balloon-inflatable catheter for percutaneous epidural adhesiolysis and decompression. Korean J Pain 2014; 27: 178-85.
13. Kim HJ, Rim BC, Lim JW, Park NK, Kang TW, Sohn MK, et al. Efficacy of epidural neuroplasty versus transforaminal epidural steroid injection for the radiating pain caused by a herniated lumbar disc. Ann Rehabil Med 2013; 37: 824-31.
14. Manchikanti L, Abdi S, Atluri S, Benyamin RM, Boswell MV, Buenaventura RM, et al. An update of comprehensive evidence-based guidelines for interventional techniques in chronic spinal pain. Part II: guidance and recommendations. Pain Physician 2013; 16(2 Suppl): S49-283.
15. Choi SS, Lee JH, Kim D, Kim HK, Lee S, Song KJ, et al. Effectiveness and factors associated with epidural decompression and adhesiolysis using a balloon-inflatable catheter in chronic lumbar spinal stenosis: 1-year follow-up. Pain Med 2016; 17: 476-87.
16. 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.
17. Kim SH, Choi WJ, Suh JH, Jeon SR, Hwang CJ, Koh WU, et al. Effects of transforaminal balloon treatment in patients with lumbar foraminal stenosis: a randomized, controlled, double-blind trial. Pain Physician 2013; 16: 213-24.
18. Kim DH, Ji GY, Kwon HJ, Na T, Shin JW, Shin DA, et al. Contrast dispersion on epidurography may be associated with clinical outcomes after percutaneous epidural neuroplasty using an inflatable balloon catheter. Pain Med 2020; 21: 677-85.
19. Karm MH, Yoon SH, Seo DK, Lee S, Lee Y, Cho SS, et al. Combined epidural adhesiolysis and balloon decompression can be effective in intractable lumbar spinal stenosis patients unresponsive to previous epidural adhesiolysis. Medicine (Baltimore) 2019; 98: e15114.
20. Song SO, Lim HJ. Clinical experience of epidural adhesiolysis in patients with failed back surgery syndrome. Korean J Anesthesiol 2004; 47: 547-52.
21. Park JY, Ji GY, Lee SW, Park JK, Ha D, Park Y, et al. Relationship of success rate for balloon adhesiolysis with clinical outcomes in chronic intractable lumbar radicular pain: a multicenter prospective study. J Clin Med 2019; 8: 606.
22. Karm MH, Choi SS, Kim DH, Park JY, Lee S, Park JK, et al. Percutaneous epidural adhesiolysis using inflatable balloon catheter and balloon-less catheter in central lumbar spinal stenosis with neurogenic claudication: a randomized controlled trial. Pain Physician 2018; 21: 593-606.
23. Oh Y, Shin DA, Kim DJ, Cho W, Na T, Leem JG, et al. Effectiveness of and factors associated with balloon adhesiolysis in patients with lumbar post-laminectomy syndrome: a retrospective study. J Clin Med 2020; 9: 1144.
24. Seo DK, Lee S, Lee G, Lee MS, Yoon SH, Choi SS, et al. Retrodiscal epidural balloon adhesiolysis through Kambin's triangle in chronic lumbar spinal stenosis: a retrospective analysis and technical considerations. Medicine (Baltimore) 2018; 97: e12791.
25. Gil HY, Jeong S, Cho H, Choi E, Nahm FS, Lee PB. Kambin's triangle approach versus traditional safe triangle approach for percutaneous transforaminal epidural adhesiolysis using an inflatable balloon catheter: a pilot study. J Clin Med 2019; 8: 1996.
26. Kim CS, Moon YJ, Kim JW, Hyun DM, Son SL, Shin JW, et al. Transforaminal epidural balloon adhesiolysis via a contralateral interlaminar retrograde foraminal approach: a retrospective analysis and technical considerations. J Clin Med 2020; 9: 981.
27. Hsu E, Atanelov L, Plunkett AR, Chai N, Chen Y, Cohen SP. Epidural lysis of adhesions for failed back surgery and spinal stenosis: factors associated with treatment outcome. Anesth Analg 2014; 118: 215-24.
28. Lee S, Lee JW, Yeom JS, Kim KJ, Kim HJ, Chung SK, et al. A practical MRI grading system for lumbar foraminal stenosis. AJR Am J Roentgenol 2010; 194: 1095-8.
29. Kim DH, Cho SS, Moon YJ, Kwon K, Lee K, Leem JG, et al. Factors associated with successful responses to transforaminal balloon adhesiolysis for chronic lumbar foraminal stenosis: retrospective study. Pain Physician 2017; 20: E841-8.
30. Oh Y, Kim DH, Park JY, Ji GY, Shin DA, Lee SW, et al. Factors associated with successful response to balloon decompressive adhesiolysis neuroplasty in patients with chronic lumbar foraminal stenosis. J Clin Med 2019; 8: 1766.
31. Sim JH, Sim KC, Kim Y, Kim DH, Lee I, Shin JW, et al. Effectiveness of epidural balloon neuroplasty in patients with chronic spinal stenosis accompanied by redundant nerve roots: a longitudinal cohort study. Pain Physician 2022; 25: E841-50.
32. Karm MH, Kim CS, Kim DH, Lee D, Kim Y, Shin JW, et al. Effectiveness of percutaneous epidural neuroplasty using balloon catheter in patients with chronic spinal stenosis accompanying mild spondylolisthesis: a longitudinal cohort study. Korean J Pain. Forthcoming 2022.
33. Lee F, Jamison DE, Hurley RW, Cohen SP. Epidural lysis of adhesions. Korean J Pain 2014; 27: 3-15.
34. Manchikanti L, Malla Y, Wargo BW, Cash KA, Pampati V, Fellows B. A prospective evaluation of complications of 10,000

fluoroscopically directed epidural injections. Pain Physician 2012; 15: 131-40.
35. Talu GK, Erdine S. Complications of epidural neuroplasty: a retrospective evaluation. Neuromodulation 2003; 6: 237-47.
36. Fishchenko I, Piontkovskyi V, Zlativ V. Complications of epidural adhesiolysis. J Educ Health Sport 2016; 6: 183-9.
37. Kim JY, Lee YH, Yoo S, Kim JY, Joo M, Park HJ. Factors predicting the success of adhesiolysis using a steerable catheter in lumbar failed back surgery syndrome: a retrospective study. J Clin Med 2021; 10: 913.