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Short-term effects of minimally invasive dynamic neutralization system for the treatment of lumbar spinal stenosis

An observational study

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Abstract

The aim of the study was to evaluate the safety and short-term effects of dynamic stabilization via minimally invasive system for degenerative lumbar spinal stenosis. Patients with degenerative lumbar spinal stenosis and treated with Transforaminal Lumbar Interbody Fusion via minimally invasive minimally system (mis-TLIF) were served as the control group.

From April 2011 to March 2015, 47 patients (29 male, 18 female; mean age 47.6 [range, 26–52] years) with lumbar spinal stenosis were treated with decompression and excision of herniated disk via the minimally invasive system combined with the dynamic fixation technique, and 42 patients as control group with mis-TLIF. Minimally invasive surgeries were performed via the posterior incision approach. The clinical outcomes were evaluated by comparing the Visual Analog Scale (VAS) score, Oswestry Disability Index (ODI) scores, and the ROMs of the adjacent segment before and after surgery. The postoperative complications related to the implants were identified.

A total of 83 patients (43 of Dynesys group and 40 of mis-TLIF group) were followed for an average duration of >35 months. Dynesys stabilization resulted in significantly higher preservation of motion at the index level ($P < .05$), and significantly less hypermobility at the adjacent segments. VAS for the back and leg pain and ODI improved significantly ($P < .05$) in 2 groups; however, there is no significant difference between the groups. In Dynesys group, 3 cases suffered skin flay necrosis, 1 of them had a wound infection that was treated with washing and drainage combined with antibiotic therapy. Skin flay necrosis were also observed in 2 cases of mis-TLIF group. Reoperation was performed in one case of Dynesys group for rupture of the internal fixation. No rupture of internal fixation was observed in mis-TLIF group.

The nonfusion fixation system Dynesys may be used to treat degenerative spinal stenosis without posterior element damage. This surgical technique is safe and effective. However, utilizing higher preservation of motion may lead to the failure of internal fixation.

Abbreviations: CT = computed tomography, DDD = degenerative disc disease, Dynesys = dynamic neutralization system, LDH = lumbar disc herniation, MIS = minimally invasive surgery, MRI = magnetic resonance imaging, ODI = Oswestry Disability Index, TLIF = Transforaminal Lumbar Interbody Fusion, VAS = Visual Analog Scale.

Keywords: degenerative disc disease, dynamic neutralization system (Dynesys), minimally invasive surgery (MIS), transforaminal lumbar interbody fusion (TLIF)

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1. Introduction

Degenerative disc disease (DDD) is the major course of low back pain, which places a considerable socioeconomic burden on the health system.[1,2] Lumbar spinal stenosis is one of the most common DDDs and is characterized by symptoms such as low back pain, radiating pain to the lower extremities, and decreased walking capacity.[3] In the past, the management of the spinal stenosis started with decompressive surgery and posterior stabilization. Compared with the decompression alone, vertebral fusion provides efficient outcomes.[4] However, with the wide application of rigid fusion, including posterior lumbar interbody fusion (PLIF) and transforaminal lumbar interbody fusion (TLIF), these management methods were discovered to have major drawbacks. Posterior fusion surgeries damage the spinal muscle, causing cross-sectional area atrophy and reduced muscle strength. These changes, the so-called dysfunctional paraspinal musculature, can cause acute and chronic low back pain, spinal stenosis, and degenerative spondylolisthesis.[5,6] Adjacent-segment degeneration (ASD), an accelerated degenerative process, is a serious complication incurring high costs.[7,8] Dynesys (dynamic neutralization system for the spine) is a nonfusion system consisting of titanium alloy screws connected by an elastic synthetic compound. As an alternative to fusion, the dynamic spinal stabilization technique maintains better physiological function and reduces the drawbacks inherent in rigid fusion. It has been proven that the mid-term results of Dynesys are highly comparable to that of fusion procedures. Moreover, Dynesys is less invasive and decreases the occurrence of complications such as ASD in the long term.[9] Currently, no study has reported this technique for the management of lumbar stenosis. In this study, we used the Dynesys fixation system to treat 43 cases of lumbar stenosis and identified satisfactory clinical results.

2. Materials and methods

2.1. Ethics statement

Written informed consent was obtained from all patients before participation, and ethical approval was obtained from Human Research Ethics Committee. In addition, written consent was obtained from the patients, allowing their information to be stored in the hospital's database.

2.2. Demographics

A total of 47 patients diagnosed with spinal stenosis underwent lumbar spinal surgery with the Dynesys system via Quadrant percutaneous endoscopy from April 2011 to March 2015, with an average age of 47.6 (range, 26–59) years. Patients with spondylolisthesis or lumbar disc herniation alone were excluded. The median length of follow-up was 37.6 (range, 24–48) months. Selected cases demonstrated radiographical signs of spinal stenosis, degenerative disc disease, and/or disc herniation. Patients with spondylolysis degree >II°, scoliosis degree >10°, severe OP, severe obesity, and body mass index >35 kg/m^2 were excluded. All patients underwent preoperative examinations, including radiography, CT, and MRI.

2.3. Surgical technique

A single surgeon performed the surgeries. Surgeries were performed with the patient in the prone position under general anesthesia. The C-arm X-ray machine was used to confirm the targeted segments. In all cases, posterior midline incisions were made with blunt dissection of the erector spinae muscles of one side, providing access to the bony anatomy of the lumbar spine. To minimize tissue trauma, blunt dissection, instead of cutting the soft tissue, was carried out via endoscopic spine surgeries utilizing dilatation technology. After laminotomy or laminectomy, decompression of the nerve root was performed first, as indicated, and contralateral decompression was achieved with angulation of the endoscope. After decompression, the pedicle screws were inserted (Fig. 1). The screws anchored the Dynesys in the pedicle and vertebral body. The facet joints were preserved and there were no limitations of daily activity for patients. However, for some patients with severe stenosis and lateral stenosis, the medial border of the superior facet was partially removed for a clear view of the involved nerve root. After decompression, the polycarbonate-urethane spacers and tension cords were assembled.

2.4. Outcome measures

Radiologic follow-up was performed after the drainage tube was removed and during outpatient follow-up, using plain anteroposterior radiography of the lumbar spine. Computed tomography (CT) or magnetic resonance imaging (MRI) was also performed, if necessary. The patients were assessed in the outpatient clinic of our department at 37.6 (range, 35–48) months after surgery.

In this study, pain intensity was measured using the Visual Analog Scale (VAS) (low back pain and leg pain, respectively). The Oswestry Disability Index (ODI) was also used to evaluate clinical outcomes. Over-flexion and over-extension radiographs of the lumbar spine recorded the intervertebral angles of the frontal upright, over-flexion and over-extension positions, and calculated the ROM value. Each pair of values (before and after surgery) was compared to identify the influence of the Dynesys system on the lumbar movement of the operative segment. Preoperative, postoperative, and final follow-up symptoms, clinical signs, and sphincter function were also evaluated.

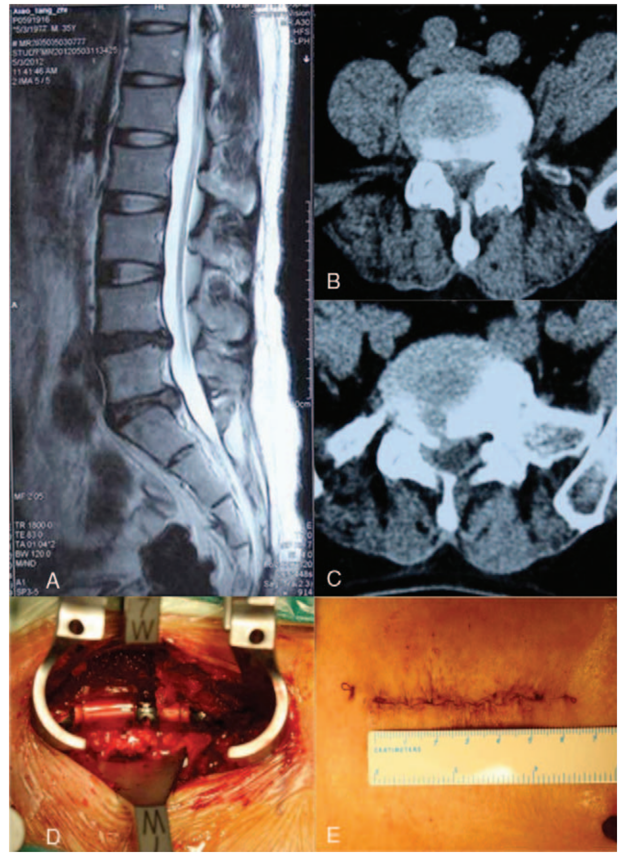

Figure 1. (A–C) The preoperative image data of patient showing lumbar disc herniation and stenosis in level L4/5 and L5/S1. (D) Remove part of lamina, decompress the canal, and insert the pedicle screws. (E) The appearance and length of the wound after closing.

2.5. Statistical analysis

Statistical analysis was conducted with SPSS 19.0 and the statistical comparison of VAS and ODI scores before and after surgery and at the final follow-up was conducted using the paired t test. $P < .05$ was considered statistically significant.

3. Results

In Dynesys group, a total of 47 patients were included in this study, 4 patients were lost to follow-up and excluded from data

Table 1

Complications in 2 groups.

Groups	n	Never root injury	CSF leakage	Incision problems	Internal fixation broken	Reoperation
Dynesys group	43	0	2	3	1	1
Mis-TLIF group	40	0	1	2	0	0

analysis. Therefore, the results are based on the analysis of 43 patients (women 16 and men 27). The mean age was 47.6 (range, 26–52) years. In mis-TLIF group, 40 of 42 patients (women 25 and men 17) were followed up. The mean age was 49.8 (range, 28–55) years.

3.1. Surgical invasiveness and complications

No complications occurred in patients in this study during the surgery in both groups. In Dynesys group, postoperative complications were identified in 5 cases. Two patients suffered from dural tear and cerebrospinal fluid leakage. Three patients developed skin edge necrosis, and 1 patient experienced a wound infection. The wound in these 4 cases healed completely after treatment with sealing drainage an dearly irrigation combined with anti-infection therapy (Table 1). In one case, the internal fixation was broken and the patient was reoperated (Fig. 2). There were no cauda equina injuries and epidural hematoma occurrences.

In the other 39 cases, no significant complications occurred. The mean operative time for 1 level was 61.8 (range, 55–110) minutes and mean intraoperative bleeding was 81.5 (range, 50–100) mL. For the surgery of 2 intervertebral levels, the mean operative time was 92.7 (range, 60–130) minutes and mean intraoperative bleeding was 101.7 (range, 80–160) mL

In mis-TLIF group, postoperative complications were identified in 5 cases, of them 2 patients suffered from dural tear and cerebrospinal fluid leakage, 2 patients suffered from skin edge necrosis, and 1 patient experienced a wound infection. The mean operative time for 1 level was 40.5 (range, 30.5–68.2) minutes and mean intraoperative bleeding was 120.5 (range, 80–200) mL. For the surgery of 2 intervertebral levels, the mean operative time was 110.5 (range, 60–130) minutes and mean intraoperative bleeding was 180.7 (range, 120–200) mL (Table 2).

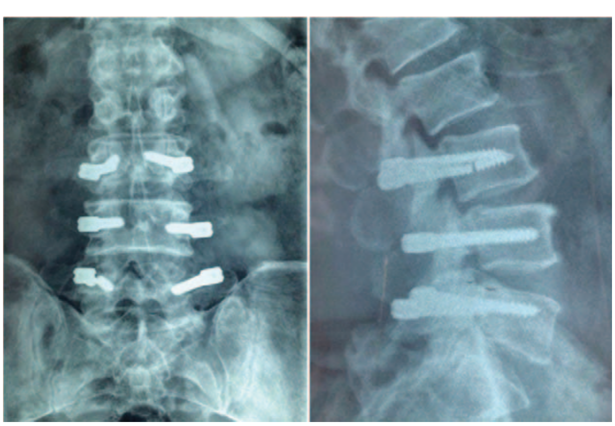

Figure 2. The internal fixation was broken, 3 years after surgery.

3.2. Clinical outcomes

There were no metal failures. VAS scores were usually used to assess postoperative pain, and ODI scores also used to evaluate clinical outcomes. The scores in the final follow-up were significantly lower than the preoperative scores ($P<.05$) (Table 3). ROM of proximal adjacent segment in mis-TLIF group is larger than that in Dynesys group ($P<.05$) (Table 4).

3.3. Case illustration

A 34-year-old patient had experienced low back pain, radiation pain in both legs for 5 years, and symptoms of intermittent claudication. The symptoms worsened and could not be relieved with physical therapy for 6 months. An L-spine MRI and CT were performed, and revealed lumbar disc herniation and severe lumbar stenosis (Fig. 1). In view of the long history and worsening symptoms, alaminectomy was indicated. Considering the patient's young age and the possibility of iatrogenic instability after surgery, microendoscopic decompression combined with dynamic fixation was carried out (Fig. 3A and B). After 4 years of follow-up, radiographs showed no instability over the adjacent level (Fig. 3C and D), and the patient was satisfied with the outcome.

4. Discussion

Kirkaldy-Wills and Farfan[10] divided the process of lumbar spine degradation into 3 phases: temporal dysfunction phase, unstable phase, and restabilization phase. When the process reaches a late phase or the conservative treatment fails, surgical strategies may be indicated. Rigid fusion is usually considered the surgical treatment of choice for degenerative spine disease when nonoperative therapy is unsuccessful. Previous studies have shown that 68% of patients had a satisfactory outcome after fusion, although the range was wide (16%–95%).[11] Moreover, for a long time, radiological solid fusion was thought to provide good results. However, spinal fusion treatment has several potential drawbacks, such as the sacrifice of the motion of operative segments, implant failure, or pseudoarthrosis.[12] One of the most severe complications is increased mechanical stress on the adjacent segments, which may result in failed back syndrome requiring reoperation. At the same time, it is necessary to revisit the essentials of fusion surgery. Fritzell et al[13] demonstrated that the least demanding surgical technique, which is posterolateral fusion without internal fixation, had no obvious disadvantage compared to the rigid fusion technique. Deyo et al[11] reported that patients who underwent spinal fusion showed a complication rate 1.9 times greater than did those who underwent nonfusion surgery, with more blood transfusion (5.8 times), nursing home placement (2.2 times), and hospital charges (1.5 times).

The dynamic fixation technique may be used to reduce complications, such as listhesis, instability, hypertrophic facet joint arthritis, and adjacent segment stenosis.[14] Dynesys was

Table 2

Surgical invasiveness related information.

(A) Incision lengths, operative time, and intraoperative bleeding (Dynesys group)

	Incision lengths (cm)	Operative time (min)	Intraoperative bleeding (mL)
A single segment	4.3 (3.5–5.0)	52.7 (40–100)	81.7 (50–120)
Two segments	6.2 (5.5–7.2)	82.3 (60–130)	102.3 (70–160)

(B) Incision lengths, operative time, and intraoperative bleeding (mis-TLIF group)

	Incision lengths (cm)	Operative time (min)	Intraoperative bleeding (mL)
A single segment	4.3 (3.5–5.0)	40.5 (30.5–68.2)	120.5 (80–120)
Two segments	(5.5–7.2)	110.5 (60–130)	180.7 (120–200)

Table 3

VAS and ODI evaluation results.

			ODI			VAS (low backpain)			VAS (leg pain)		
Groups	n	Follow-up/mo	Preoperation	Postoperation	Last follow-up	Preoperation	Postoperation	Last follow-up	Preoperation	Postoperation	Last follow-up
Dynesys group	43		53.1%±6.52%	25.52%±10.25*	19.4%±5.63%*	6.5±0.8	2.5±1.75	2.2±0.7	7.4±0.77	2.38±1.42*	2.12±0.68*
mis-TLIF group	40		54.2±5.48†	25.32%±9.81†	20.1%±4.98†	6.1±0.9†	2.6±2.05†	2.1±0.9†	6.8±0.92†	2.41±1.55†	2.32±0.65†

* Compared with the preoperation, $P<.05$.

† Compared with Dynesys group, no statistical difference.

Table 4

ROM of surgical segment and proximal adjacent segment.

	ROM of surgical segment		ROM of proximal adjacent segment	
	Preoperation (0)	Final follow-up (0)	Preoperation (0)	Final follow-up (0)
Dynesys group	7.2±0.9	4.3±0.8*	7.3±0.6	9.4±0.7*
Mis-TLIF group	7.3±0.7	0	7.2±0.6	12.3±0.9†

* Compared with preoperation, no statistical difference.

† Compared with Dynesys group, no statistical difference.

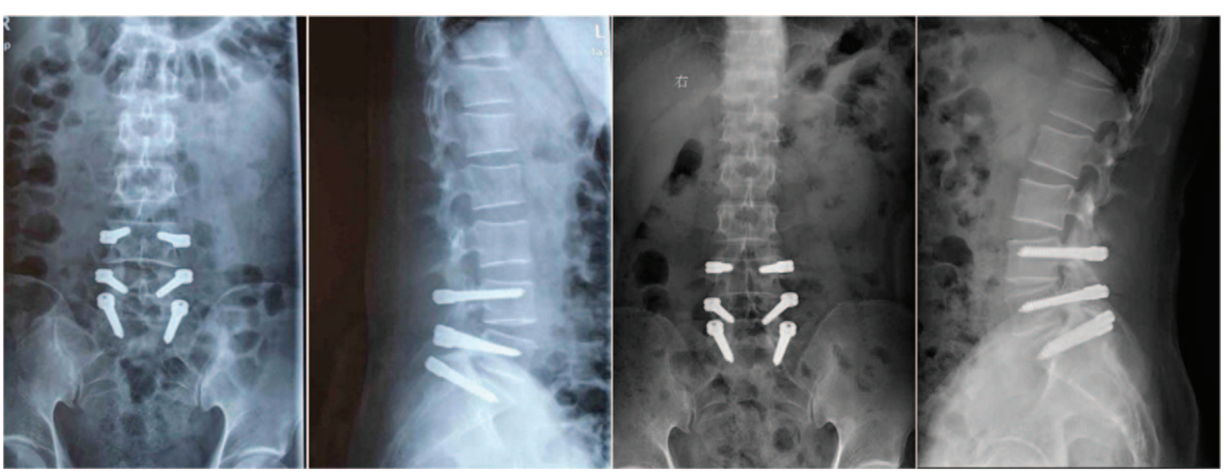

Figure 3. (A, B) Postoperative radiograph; (C, D) radiograph at 4 years of follow-up.

first developed by the French scholar Gilles Dubios as a type of posterior nonfusion spinal fixation technique in 1991. This system can theoretically reduce the load on the disk in extension, avoiding posterior annulus-related compression.[15] Rather than locking the facet in extension, Dynesys uses polyurethane spacers to limit extension, and a threaded cord, to control flexion.[16] Since 1994 when Dynesys was clinically introduced, many studies have been conducted to evaluate the effect of this dynamic fixation technique. Yu et al[17] compared the radiographic and clinical outcomes of Dynesys and PLIF for the treatment of multisegment disease with a 3-year follow-up. They revealed that the Dynesys group had a better outcome according to clinical evaluation. Lee et al[18] retrospectively compared facet joint degeneration between the dynamic stabilization using the Dynesys system and TLIF with pedicle screw fixation. They concluded that the Dynesys group had a greater preventative effect on facet joint degeneration than did the fusion group. However, they also indicated that the Dynesys system resulted in facet joint degradation at the instrumented segments and above. The biomechanical effect of pedicle-based dynamic stabilization has been studied, revealing that contact force on the facet joint in extension increased with an increase of moment.[19] This mechanism may contribute to facet joint degeneration at the instrumented segments and the unusual postoperative back pain. Poor outcomes of Dynesys have also been reported in some studies. Grob et al[20] studied a series of 31 patients and concluded that the Dynesys system was not superior to posterior rigid fusion. St-Pierre et al[21] evaluated the long-term outcomes of Dynesys system, and concluded that Dynesys technique did not prevent ASD despite maintaining a low fusion rate. In our study, the fact that ROM of the surgical segment changed from 7.2° to postoperative 4.3° revealed that Dynesys system was able to maintain the mobility of the fixed lumbar segments and the integrity of the anatomical stracture. One the other hand, ROM of proximal adjacent segment in both groups increased, but ROM in Synesys was less, this result confirmed that the Dynesys system had no significant adverse effects on ASD. As unfavorable results were published and reviews emerged pointing out the lack of evidence for Dynesys use in ASD prevention, the Food and Drug Administration (FDA) advisory committee recommendation disapproved Dynesys and restricted its use in North America. However, the multicenter randomized control trial conducted by FDA remains unpublished. Despite the fact that its outcome is still controversial and the mechanism of action is still unclear; this system is now widely applied in Europe[20] and other countries[22,23] worldwide.

The common treatment methods for lumbar stenosis are open decompressive laminectomy with or without facetectomies, dynamic fixation, or fusion surgery. However, previous studies have shown that open decompressive laminectomies are effective for lumbar stenosis, but may also disrupt the native anatomic support structures, which may lead to muscleatrophy.[24] This technique has also been demonstrated to caused estruction of the surrounding tissues, and lead to postoperative low back pain and secondary muscle atrophy.[25,26] Thus, in recent years, minimally invasive spine surgery (MISS) has been introduced to focally access the diseased structures but minimize disruption of normal anatomic structures. MISS techniques may reduce postoperative wound infections as much as 10-foldcompared with other large, modern series of open spinal surgery published in the literature.[27] Yong-Hing and Kirkalady-willis[28] first described the surgical technique of spinous process osteotomy decompression. This technique affords excellent visualization and a wide access for Kerrison use. Recently, the MISS technique has become common in spinal surgery. Previous studies compared minimally invasive TLIF (MITLIF) and open techniques and indicated that MITLIF allowed for safe and efficient minimally-invasive treatment of DDD.[29,30] Because there is no muscle in the surgical field, muscle removal or detachment is unnecessary. Reduced invasiveness on the paravertebral muscle is one of the advantages of the microendoscopy technique. Previous studies have reported that iatrogenic injury of the paravertebral muscle is closely related to muscle strength weakness, muscle atrophy,and failed-back syndrome.[31] Microscopic or microendoscopic techniques involve unilateral retraction, ipsilateral decompression, and contralateral decompression. Hamasaki et al evaluated multi-MISS approaches and indicated that a unilateral MISS approach for bilateral decompression with intact facets maintains up to 80% of the native anatomic mic "stiffness" compared to large bilateral decompressions with facetectomies.[32] In this study, we used bilateral decompression with a unilateral pedicle construct. In this study, ODI scores decreased notably in both the early and late follow-up, and the VAS scores improved significantly in the early follow-up; however, there was no difference between the early and late follow-up. Ko et al[33] reported radiographic evidence of screw loosening occurrence in 19.7% of patients and 4.6% of screws in dynamic stabilization for 1- and 2-level lumbar spondylosis at a mean follow-up of 16.6 months. In our study, the incidence of screw loosening was 2.3% (1/43). Nonetheless, there was no adverse effect on the patient's clinical improvement.

In our study, one case occurred the internal fixation broken and the patient was reoperated (Fig. 2). Although we used a screw as long as possible to reduce the effect on the facet joints and, performed bone grafting in the screw channel, and the fixed cortex when implanting a screw for the second time, the internal fixation broken also arose. The reason may be that the patient is a postmenopausal female. Preoperative bone mineral density measurement revealed that she suffered moderate osteoporosis. The relationship between the Dynesys system and fixation stability needs to be declared through a larger sample multicenter study. There is no study concerning this point until now.

Several limitations exist in the present study. First, the study was conducted at a single institution, and the surgery was performed by a single surgeon. Second, since we performed a retrospective analysis and it is likely that information bias exists. Furthermore, the case series was small and there was no control group. Despite these limitations, our study revealed that microendoscopic bilateral decompression via a unilateral approach combined with dynamic fixation technique for lumbar spinal stenosis showed good mid-term clinical outcomes. To further determine the benefits of this technique, more randomized studies with long-time follow-up are needed in the near future.

The Dynesys system combined with Mast-Quadrant is a therapeutic option for lumbar spinal stenosis. The early clinical effects of this system are satisfactory, but its long-term effect needs further observation.

Author contributions

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Project administration: Wei Liu, Yukun Zhang, Shuhua Yang.
Resources: Wei Liu, Yu Song.

Software: Ji Tu, Wenbin Hua, Wentian Li, Wei Liu, Liang Kang, Kun Wang.
Supervision: Cao Yang.
Validation: Kun Wang.
Writing – original draft: Ji Tu.
Writing – review and editing: Shuhua Yang, Cao Yang.

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