



Electromagnetic navigation-assisted percutaneous endoscopic foraminoplasty and discectomy for lumbar disc herniation: technical note and preliminary results

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Background: The aim of the present study was to report a new technique for electromagnetic navigation system-assisted percutaneous full-endoscopic foraminoplasty and discectomy and to evaluate the efficacy of this technology in the treatment of lumbar disc herniation (LDH).

Methods: This is a retrospective study. Seventeen patients who underwent electromagnetic navigation system-assisted percutaneous full-endoscopic foraminoplasty and discectomy in our department from September to November 2018 were included in the study. Patients' hospital charts, magnetic resonance imaging results, surgical data and follow-up records were reviewed. Outcomes were assessed by visual analog scale (VAS) score, Oswestry Disability Index (ODI), modified MacNab criteria and postoperative complications.

Results: The median follow-up time was 20.64 months (range, 19–21 months). The average operating time was 52.94±12.88 min (range, 35–78 min), including the working tube introduction time (13.59±2.89 min), decompression time (39.35±13.61 min), and the fluoroscopic time (3.65±2.52 min). Postoperative back VAS, leg VAS, and ODI were significantly improved compared with pre-operation, respectively ($P < 0.01$). The overall excellent and good rate of these seventeen patients was 94%. There were no significant complications related to the operation.

Conclusions: Electromagnetic navigation system-assisted percutaneous full-endoscopic foraminoplasty and discectomy is a safe and effective method for treating LDH and this method has the advantage of short operative time and fluoroscopic times.

Keywords: Electromagnetic navigation system; percutaneous full-endoscopic foraminoplasty and discectomy; percutaneous endoscopic lumbar discectomy (PELD); lumbar disc herniation (LDH)

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Introduction

Lumbar disc herniation (LDH) is a common degenerative disc disease, with an incidence between 3.7% and 5.1% (1). For LDH patients who have failure of conservative treatment, surgery should be performed to relieve nerve compression. Percutaneous endoscopic lumbar discectomy (PELD) is gradually becoming a new gold standard surgical procedure for LDH. Its advantages include desirable satisfactory clinical outcome, less trauma, less bleeding, less postoperative pain, and faster recovery (2-5). However, the steep learning curve is still a major technical obstacle of PELD. Multiple intraoperative fluoroscopy is needed to identify the position of the working tube for safety, and excessive X-ray exposure may expose doctors and patients to potential radiation (6).

The electromagnetic navigation-guided technique is an innovative procedure that provides navigational assistance coupled with steer ability and movability. It has been applied in neurosurgery, otolaryngology, as well as oral and maxillofacial surgery (7-9). Electromagnetic navigation has recently been applied in spinal surgery for pedicle screw placement (10,11). However, to the best of our knowledge, the application of electromagnetic navigation to guide spinal endoscopic surgery has not been reported. Therefore, we introduce a new technique of electromagnetic navigation-assisted percutaneous endoscopic lumbar foraminoplasty and discectomy using the I-See device (SEESSYS) for full visualization of the entire surgical procedure. In the present study, we describe the SEESSYS procedure, evaluate the clinical efficacy of continuous 17 cases, and outline the challenges of the widespread implementation of this new technology. We present the following article in accordance with the STROBE reporting checklist (available at <http://dx.doi.org/10.21037/apm-20-1956>).

Methods

Patient selection

Consecutive patients with clinically symptomatic LDH undergoing SEESSYS procedure from September to November 2018 were included in the study. The indication for surgery was as follows: (I) typical lower-extremity radiating pain, with or without lower back pain; (II) positive straight-leg raise test, with/without muscle strength decrease or hypoesthesia of nerve root innervation area; (III) magnetic resonance imaging and computerized

tomography (CT) scan indicating LDH; (IV) imaging manifestations were consistent with clinical symptoms in terms of the side and level of the herniated disc; (V) age >18 years; and (VI) provided informed consent to participate in the study. The exclusion criteria were as follows: (I) lumbar hyperextension and hyperflexion X-ray indicating segmental instability of the same diseased segment; (II) multiple LDHs; (III) previous surgical history of the same diseased segment; (IV) concomitant tumor, tuberculosis, infection, or fracture and other disease; and (V) patients with psychiatric disorders or those who could not complete the scale. This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013) and was approved by the ethics committees of Guangdong Provincial Hospital of Chinese Medicine (approval No. ZE2019-285-01). Written informed consent was obtained from participants.

Surgical tools

The electromagnetic navigation system (Fiagon GmbH, Germany) included the magnetic field generator, MultiPad, MaperBrige, localizer, computer mainframe and monitor, Kirschner wire, and IseePointer (*Figure 1A,B,C,D,E,F,G*). The I-See endoscopic spine surgical system (Joimax, IseeU, Germany) included the needle, guide rod, endoscopy, and Isee-reamer with IseePointer (*Figure 1H,I,J,K*). The multifunctional plasma radiofrequency electrode system (Xi'an Surgical Medical Technology, China) was also used in the surgery.

Operative technique

All operations were performed by the same surgical team. The patient was placed in the prone position, and local anesthetic was administered. The magnetic field generator was placed near the surgical site (*Figure 2A*). After the Kirschner wire was fixed to the spinous process of the adjacent vertebra, the patient localizer was placed on the Kirschner wire and connected to the computer mainframe (*Figure 2B*). The MaperBrige was placed near the surgical section (*Figure 2C*). Anterior-posterior and lateral lumbar X-ray were taken by the C-arm, and the images were transmitted to the navigation host for auto-complete registration (*Figure 2D,E*). The Multipad was then connected to identify and calibrate the different devices (*Figure 2F*).

The puncture target point was then set up (*Figure 3A*).



Figure 1 I-See electromagnetic-navigation endoscopic spinal surgery system. (A) Magnetic field generator; (B) MultiPad; (C) MaperBrige; (D) localizer; (E) computer mainframe and monitor; (F) Kirschner wire (used to connect localizer); (G) IseePointer (navigation probe instrument for image-guided surgery); (H) needle with IseePointer; (I) guide rod with IseePointer; (J) endoscope with IseePointer; (K) IseeReamer with IseePointer.

An 18-gauge needle was used to access the target point under the guidance of the electromagnetic navigation system (*Figure 3B*). Once the guidewire reached the target position, the stepwise dilatation guiding rods were inserted

to expand the soft tissue, and the protective sheath tube was positioned (*Figure 3C*). Precise full-visualization foraminioplasty was performed using an endoscope under electromagnetic navigation guidance (*Figure 3D*). Before

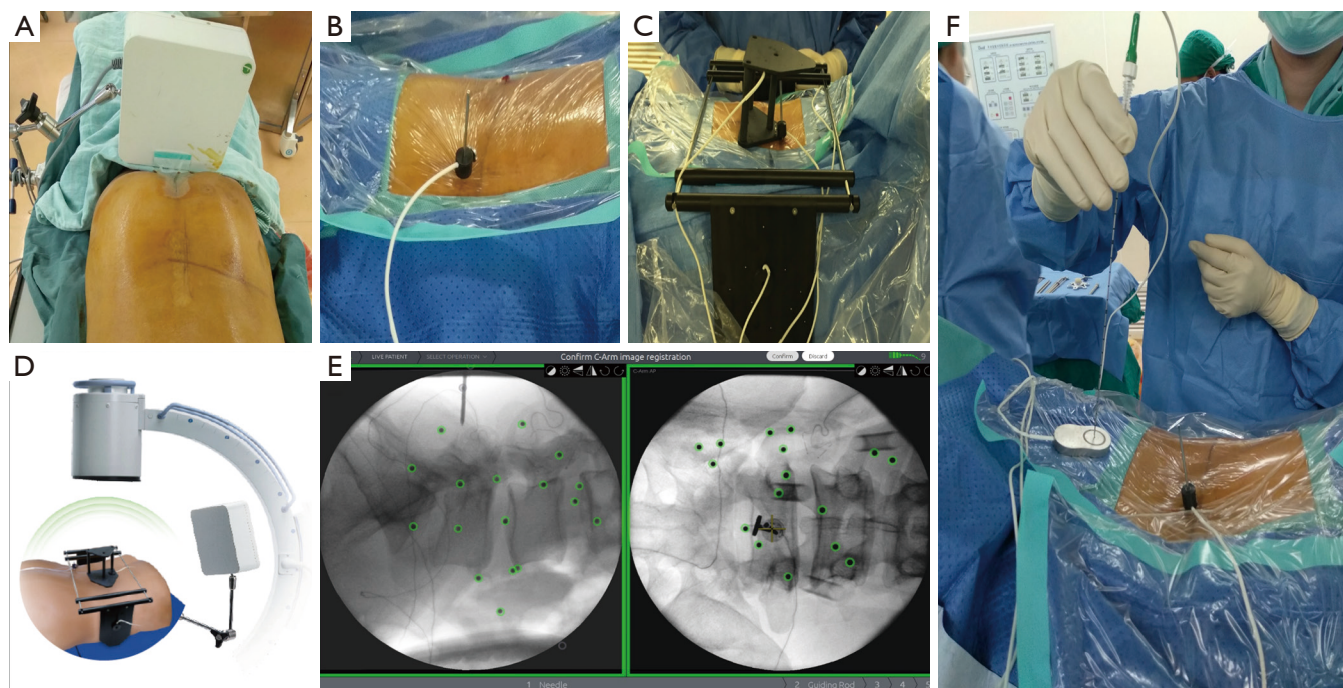


Figure 2 Surgical procedure using the I-See electromagnetic-navigation endoscopic spinal surgery system. (A) Magnetic field generator is fixed to the frame near the surgical site; (B) Kirschner wire is fixed to the adjacent spinous process of the surgical segment, and the localizer is connected; (C) MaperBrige is placed smoothly near the surgical section; (D) positive side perspective of C-arm image transferred to the navigation host; (E) auto-complete registration; (F) magnetic navigation function can be used after the surgical instruments are paired on the MultiPad.

introducing the endoscope, the reamer was placed into the protective sheath. Under the endoscope, the soft tissue around the superior articular process (SAP) was removed to clearly reveal the bony structure. The reamer's resection of the SAP could be observed under the endoscope. The path of the reamer's advancement and its depth into the spinal canal were monitored in real time by the electromagnetic navigation system until foraminoplasty completion.

Endoscopic nerve decompression was then performed, and the degenerative tissue in the disc was removed. The nucleus pulposus protruding into the spinal canal was resected first. The fiber annulus was trimmed by using a probe bipolar. The nerve root was confirmed to have been completely released. Under electromagnetic navigation guidance, the real-time position of the endoscope and the range of decompression could be clearly identified on the monitor without any additional X-ray perspective (Figure 3E,F).

Here is one of our cases that a 45-year-old woman with lower back pain and radiating pain in her left lower limb for

2 years, which was aggravated for 3 months. Preoperative magnetic resonance imaging (MRI) indicated L4-5 disc herniation (Figure 3G). She was treated with the I-See electromagnetic-navigation endoscopic spinal surgery system (SEESSYS) and underwent MRI at 6 months after operation (Figure 3H).

Outcome assessment

The overall surgical and fluoroscopic times were recorded for all cases. Outcomes of symptoms were evaluated at 1 day, 2 weeks, 3 months, 6 months, and 12 months, and the last follow-up post-operation. Leg and lower back pain were measured by patients themselves using visual analog scale (VAS) score [1–10]. Functional outcomes were assessed by the Oswestry Disability Index (ODI), and modified MacNab criteria (excellent, good, fair, poor) was measured at last follow up. ODI and modified MacNab criteria were assessed by two doctors. If there was disagreement, a third senior spine doctor was invited to assist in the evaluation to reduce the subjectivity.

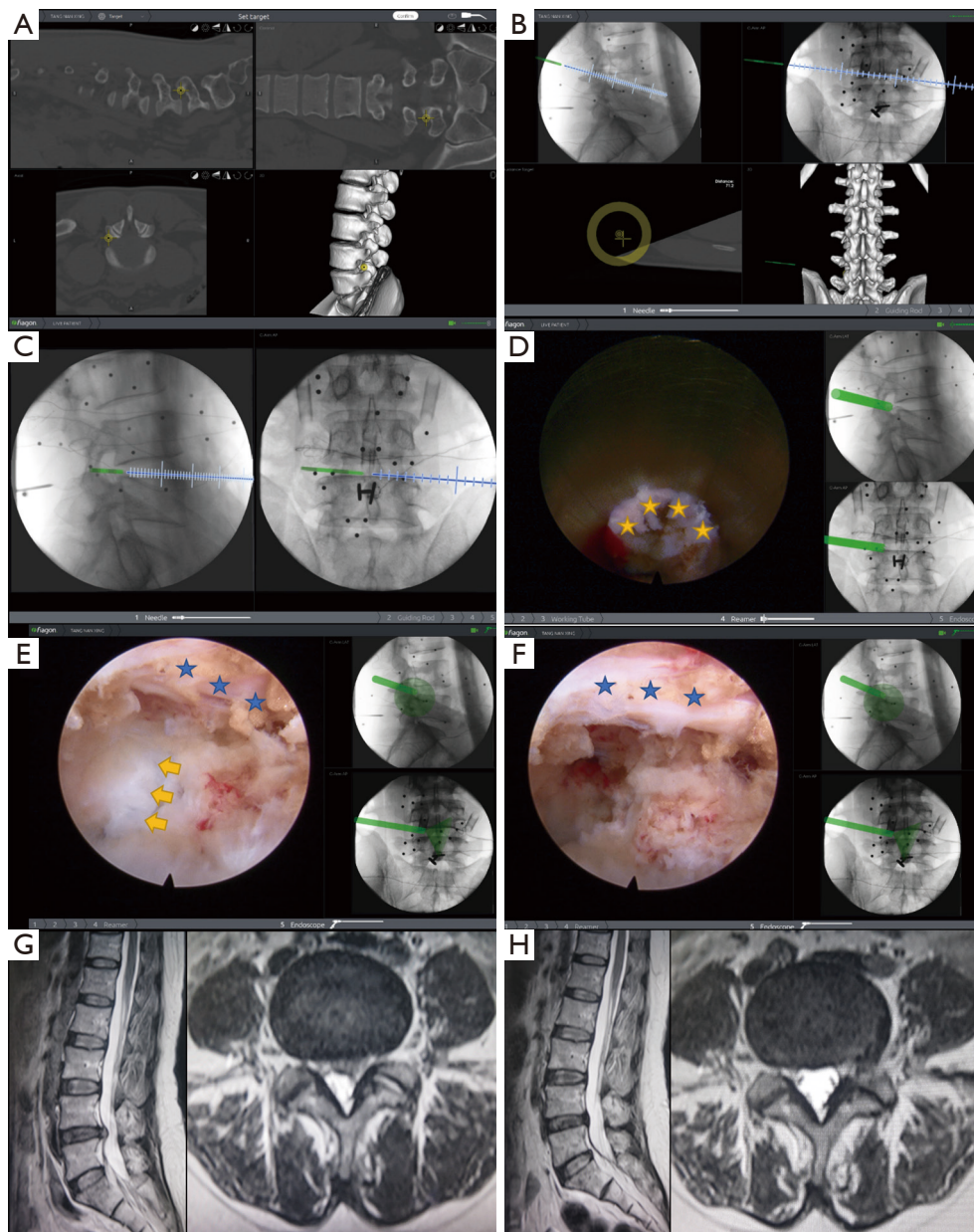


Figure 3 A 45-year-old woman with lower back pain and radiating pain in her left lower limb for 2 years, which was aggravated for 3 months. She was treated with the I-See electromagnetic-navigation endoscopic spinal surgery system (SEESSYS), as conservative treatment was unsuccessful. (A) surgical target was set to locate the L5 superior articular process; (B) direction of the needle in real time under the guidance of the electromagnetic navigation system was observed and adjusted; (C) position of the guide rod was observed when the expansion guide rod was placed; (D) under electromagnetic navigation guidance, the position of the reamer was observed in real time. Unlike the traditional transforaminal endoscopic surgical system, the entire foraminal process of the SEESSYS is visualized under the endoscope. Superior articular process (the yellow star) is clearly identified under endoscopy; (E) depth of the surgical instruments into the spinal canal can also be observed in real time. L5 nerve root (blue stars) and the herniated disc (the yellow arrow) was clear; (F) herniated disc is removed and nerve root (blue stars) is relieved completely; (G) Preoperative magnetic resonance imaging (MRI) indicated L4–5 disc herniation; (H) postoperative MRI at 6 months.

Statistical analysis

Statistical analyses were performed with SPSS version 21.0 (SPSS, Chicago, IL, USA). Continuous variables were expressed as mean \pm standard deviation. The Shapiro-Wilk test was used to check the normality of data. Paired *t*-test was used for the preoperative and follow-up parameters (VAS and ODI). The descriptive assessments and analytical statistics were performed depending on the group characteristics. Statistical significance was set at $P < 0.05$.

Table 1 Patient demographics and intraoperative data

Characteristics	Mean \pm SD or n [%]
Gender, n [%]	
Male	8 [47]
Female	9 [53]
Age (years)	50.76 \pm 10.02
Body mass index (kg/m ²)	23.76 \pm 2.75
Symptom duration (months)	8.41 \pm 5.75
Level, n [%]	
L1–2	1 [6]
L2–3	1 [6]
L3–4	2 [12]
L4–5	10 [59]
L5–S1	3 [18]
Overall surgical time (min)	52.94 \pm 12.88
Working tube introduction (min)	13.59 \pm 2.89
Decompression (min)	39.35 \pm 13.61
Fluoroscopic time (s)	3.65 \pm 2.52
Postoperative hospital stay (days)	1.47 \pm 0.62

SD, standard deviation.

Table 2 Preoperative, postoperative, and follow-up VAS and ODI

Clinical outcomes	Preoperative	1 day postoperative	2 weeks postoperative	3 months postoperative	6 months postoperative	12 months postoperative	Last follow up postoperative
VAS of leg pain	6.59 \pm 0.87	1.53 \pm 0.51*	1.29 \pm 0.59*	0.82 \pm 0.73*	0.76 \pm 0.66*	0.47 \pm 0.62*	0.59 \pm 0.71*
VAS of back pain	3.29 \pm 0.69	1.35 \pm 0.61*	0.47 \pm 0.66*	0.59 \pm 0.62*	0.41 \pm 0.51*	0.53 \pm 0.51*	0.47 \pm 0.52*
ODI	63.88 \pm 6.91	17.76 \pm 3.15*	13.41 \pm 2.12*	11.41 \pm 1.69*	9.71 \pm 1.93*	9.41 \pm 1.91*	8.94 \pm 1.43*

*, compared with preoperative, $P < 0.01$. ODI, Oswestry Disability Index; VAS, visual analog scale.

Results

Eighteen LDH patients underwent SEESSYS and one patient was lost to follow-up. Finally, 17 patients were included in this study. The demographic and intraoperative data of the patients are shown in the *Table 1*. The mean follow-up period was 20.64 months (range, 19–21 months). The average operating time was 52.94 \pm 12.88 min (range, 35–78 min), including the working tube introduction time (13.59 \pm 2.89 min), decompression time (39.35 \pm 13.61 min), and the fluoroscopic time (3.65 \pm 2.52 min).

There was a significant decrease in back VAS, leg VAS, and ODI ($P < 0.01$, $P < 0.01$, and $P < 0.01$, respectively) at 1 day, 2 weeks, 3 months, 6 months, 12 months and the last follow up post-operation compared with pre-operation (*Table 2*). The back VAS, leg VAS, and ODI decreased significantly from 3.29 \pm 0.69, 6.59 \pm 0.87, and 63.88 \pm 6.91 preoperatively to 0.47 \pm 0.52, 0.59 \pm 0.71, and 8.94 \pm 1.43 at last follow-up ($P < 0.01$), respectively. The overall excellent and good rate was 94% (excellent in 15 patients, good in 1 patient, fair in 1 patient, and no poor patient).

There were no serious complications, such as nerve and vessel injuries or cerebrospinal fluid leakage. No wound hematomas, infections, and other perioperative complications were found.

Discussion

There are two key issues for completing PELD. One is to place working tube accurately to the target lesion; the other is to relieve the nerve roots completely from compression without new complications. Because of the complex anatomy of the intraspinal canal and the extremely limited room for maneuver, there is a high risk of damage to nerves and blood vessels if not done properly (12).

Some studies have already indicated that, despite the outstanding benefits of this minimally invasive technique,

the learning curve of the transforaminal endoscopic surgical system is steep (12-14). For beginners, it is difficult to position the working tube into the spinal canal precisely through the safe triangle. For surgeons who are already proficient in this procedure, it should be performed with the assistance of multiple X-ray photography for optimal safety. Intraoperative X-ray-guided puncture and catheterization is the most commonly used method in current clinical practice. Although it has the benefit of higher image resolution and more accurate localization, CT navigational assistance has the drawback of greater radiation, which has been also reported in previously published studies on endoscopic surgery (15,16). Radiation damage to doctors and patients as a result of X-rays has been gradually gaining attention (17). Mastrangelo *et al.* reported that there was an increase in tumor development among orthopaedical surgeons exposed to routine radiation (18). Moreover, neither CT- nor X-ray-guided surgical procedure can display the instrument position in real time, and the process of catheterization is a blinded operation, which depends on the skill level of the surgeon. Therefore, some new technologies have been introduced in recent years, such as intraoperative ultrasonic monitoring and guidance (19,20). Although ultrasound navigation is known to reduce radiation injury, its accuracy is still questionable, because ultrasonic perspective is susceptible to bone and air interference. In addition, its blind spot could induce unpredictable noxious stimulation to nerves and blood vessels. Although combining CT and ultrasonographic imaging can provide real-time image data, it has not widely used in the clinical setting.

Previous studies have showed that electromagnetic navigation could reduce surgical complications and minimize surgical time (8,21). Electromagnetic navigation has also been used in the placement of fiducial markers for stereotactic radiotherapy and accurate navigation to target lesions (22). The electromagnetic navigation system generates a magnetic field, which is used to transmit and receive electromagnetic signals to determine the spatial position of the target. The basic principle is to use the magnetic field of known spatial distribution to realize the positioning of objects in the magnetic field according to the data obtained by the sensor (23,24). Through the intraoperative real-time positioning system, the position of the surgical instrument in the field is accurately positioned. The operator can observe the actual position of the instruments by referring to the horizontal, coronal, and sagittal three-dimensional images displayed on the

computer monitor (7,8,21-23). Using electromagnetic navigation in percutaneous full-endoscopic surgery, surgeons can observe the farthest safe position that surgical tools can reach at real time, and maximally remove the lesion for a thorough decompression effect. The use of electromagnetic navigation guidance and the I-See (full-visualization) endoscopic system produces highly accurate and safe results. In comparison with optic navigation, electromagnetic navigation reduces fluoroscopic time from X-ray radiation and ease of convenience. It is a useful tool for the surgeon for precise catheterization, faster decompression, and safety.

Although there were no complications in this study, there was still the possibility of complications if the operation was improper. The potential complications of SESSYS are the same as those of traditional percutaneous endoscopic lumbar foraminoplasty and discectomy including vascular injury, nerve root injury, dural tear, incomplete decompression, postoperative infection, hematoma and other complications (25). The potential clinical application risk is that the navigation may be not accurate if the localizer moves or its sensitivity decreases. In order to reduce risks, the localizer is fixed to the spinous process of the adjacent vertebra to increase the stability and fluoroscopy can be performed to verify its accuracy, especially for beginners. Once the deviation is found, it should be re-registered immediately. It is also important to note electromagnetic navigation system can be affected if the metal in the patient is ferromagnetic. But titanium alloy, the most commonly used materials for biomedical applications, is nonmagnetic and does not affect electromagnetic navigation system. If the metal material is not clear, the sensor can be placed near the metal and it will display whether the electromagnetic navigation system is affected. When there is an interference, electromagnetic navigation should not be used. The main limitations of this feasibility study are its small sample size and potential selection bias. However, the influence from selective bias in the study is possibly limited because a high participation rate of 94% (17/18 patients) was attained. Therefore, future larger-scale studies with long-term follow-up are needed to corroborate these findings and extend them to a wider population.

Conclusions

Electromagnetic navigation provides accurate guidance for percutaneous spinal endoscopy, displaying the anatomical

position of the surgical instrument in real time. This technique could help the spinal surgeon maximally remove the lesion for a thorough decompression effect, and possibly reduce the occurrence of surgical complications, which has great clinical application value. Moreover, this system can reduce fluoroscopic time to doctors and patients. At present, the results with this technique are still preliminary, but are encouraging. We believe that the combination use of the electromagnetic navigation system and endoscopic surgery will further develop the accuracy, safety, and efficiency of percutaneous endoscopic surgery.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at <http://dx.doi.org/10.21037/apm-20-1956>

Data Sharing Statement: Available at <http://dx.doi.org/10.21037/apm-20-1956>

Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/apm-20-1956>). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study involving human participants were in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the ethics committees of Guangdong Provincial Hospital of Chinese Medicine (approval No. ZE2019-285-01). Written informed consent was obtained from participants.

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