



Original Article

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Safety Profile of Biportal Endoscopic Spine Surgery Compared to Conventional Microscopic Approach: A Pooled Analysis of 2 Randomized Controlled Trials

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Objective: To compare the safety profiles of biportal endoscopic spinal surgery (BESS) and microscopic spinal surgery (MSS) for lumbar disc herniation and spinal stenosis by analyzing the associated adverse events.

Methods: We pooled data from 2 prospective randomized controlled trials involving 220 patients (110 in each group) who underwent single-level lumbar surgery. Participants aged 20–80 years with radiating pain due to lumbar disc herniation or spinal stenosis were included in this study. Adverse events were recorded and analyzed over a 12-month follow-up period.

Results: The overall adverse event rates were 9.1% (10 of 110) in the BESS group and 17.3% (19 of 110) in the MSS group, which were not statistically significantly different ($p = 0.133$). Notably, wound dehiscence occurred in 8.2% of MSS cases but in none of the BESS cases. Both groups showed similarly low rates of complications, such as dural tears, epidural hematoma, and nerve root injury. The most common adverse event in the BESS group was recurrent disc herniation (2.7%), whereas that in the MSS group was wound dehiscence (8.2%).

Conclusion: BESS demonstrated a safety profile comparable to that of MSS for the treatment of lumbar disc herniation and spinal stenosis, with a trend towards fewer overall complications. BESS offers particular advantages in terms of reducing wound-related complications. These findings suggest that BESS is a safe alternative to conventional MSS and potentially offers the benefits of a minimally invasive approach without compromising patient safety.

Keywords: Biportal endoscopic spine surgery, Microscopic spine surgery, Lumbar disc herniation, Spinal stenosis, Adverse events



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INTRODUCTION

Endoscopic spinal surgery has advanced significantly in recent years as a minimally invasive approach for the management of various spinal diseases.¹ Conventional open microscopic surgery remains the gold standard for discectomy and decompression procedures in lumbar disc herniation and spinal stenosis,^{2,3} due to its well-established efficacy and the familiarity most surgeons have with the technique.^{4,5} The use of a microscope allows for excellent visualization of neural structures and has been associated with good clinical outcomes and lower complication rates.⁶

Endoscopic spinal surgery is a promising alternative to conventional open microscopic surgery.¹ This has led to the application of endoscopic surgery for conditions such as disc herniation, foraminal stenosis, and recurrent disc herniation, demonstrating its effectiveness and safety.⁷ The advantages of endoscopic spinal surgery, such as minimal tissue disruption, reduced blood loss, and decreased postoperative pain, have contributed to its popularity and acceptance as a viable treatment option. The continuous evolution of endoscopic techniques has enabled surgeons to manage a wide range of spinal pathologies, including lumbar stenosis, which was previously considered a contraindication to endoscopic surgery, in a minimally invasive manner.⁸

With continuous and rapid advances, biportal endoscopic spinal surgery (BESS) offers benefits such as reduced tissue dissection, reduced blood loss, shorter hospital stay, early functional recovery, and enhanced quality of life for patients.^{9,10} The expanding applications of BESS, along with the development of advanced techniques and instruments, have made it a valuable treatment option for degenerative lumbar diseases.¹¹⁻¹³ Furthermore, the ability to handle complications without requiring conversion to open surgery is an important consideration as surgeons explore the full potential of BESS.¹⁴ One of the key advantages of BESS is its similarity to microscopic techniques, which allows for two-handed endoscopic surgery. This familiarity facilitates the adoption of endoscopic techniques, and helps surgeons to overcome the learning curve associated with spinal endoscopy.¹⁴

However, as with any other surgical technique, BESS has some potential complications. A recent meta-analysis reported an overall complication rate of 5% for BESS in lumbar spinal stenosis, with dural tears being the most common complication, followed by epidural hematoma.^{15,16} Other potential complications include incomplete decompression, nerve root injury, infection, and postoperative headache.¹⁵ Although the overall incidence of these complications is relatively low, clinicians need to be aware of these complications and understand preventive

strategies.

In this study, we analyzed the adverse events associated with BESS versus conventional microscopic spinal surgery (MSS) for lumbar disc herniation and spinal stenosis in a comprehensive manner. By pooling data from 2 prospective randomized controlled trials (RCTs),^{17,18} we provided a robust comparison of safety outcomes between these approaches. Our focus on adverse events emphasized the importance of safety in establishing and refining novel surgical techniques.

MATERIALS AND METHODS

1. Study Design

This study integrated data from 2 prospective RCTs comparing the safety and adverse events of BESS and conventional MSS in patients with herniated lumbar intervertebral discs or lumbar spinal stenosis. Both trials were multicenter, assessor-blinded studies designed to assess the efficacy and safety of the 2 surgical approaches (Fig. 1).^{17,18}

The study protocols for these multicenter, assessor-blinded, prospective RCTs were approved by the Institutional Review Boards of the participating hospitals (B-2102/666-007, B-2102/667-003). Before starting these trials, we registered them at cris.nih.go.kr (KCT0006191, KCT0006057).

2. Participant Population

This study included participants aged 20–80 years who presented with radiating pain in the lower extremities caused by a single-level lumbar herniated intervertebral disc or lumbar spinal stenosis. To ensure consistency across both trials, identical inclusion and exclusion criteria were applied, with the only difference being the specific diagnosis.

Participants were eligible for inclusion if they were between 20 and 80 years of age, had a confirmed diagnosis of either single-level lumbar herniated intervertebral disc disease or lumbar spinal stenosis, and experienced radiating pain to the lower extremities with a visual analogue scale (VAS) score > 4. Additionally, participants needed to be capable of understanding and providing informed consent for the research and had to be willing to adhere to the follow-up protocol. We excluded participants with spondylolisthesis of Meyer grade II or higher, those with a history of lumbar spinal surgery at the same level, and those with degenerative lumbar scoliosis with a Cobb angle > 20°. Further exclusion criteria included the presence of other spinal diseases, such as ankylosing spondylitis, spine tumors, fractures, or neurological disorders. Participants with psychological disorders,

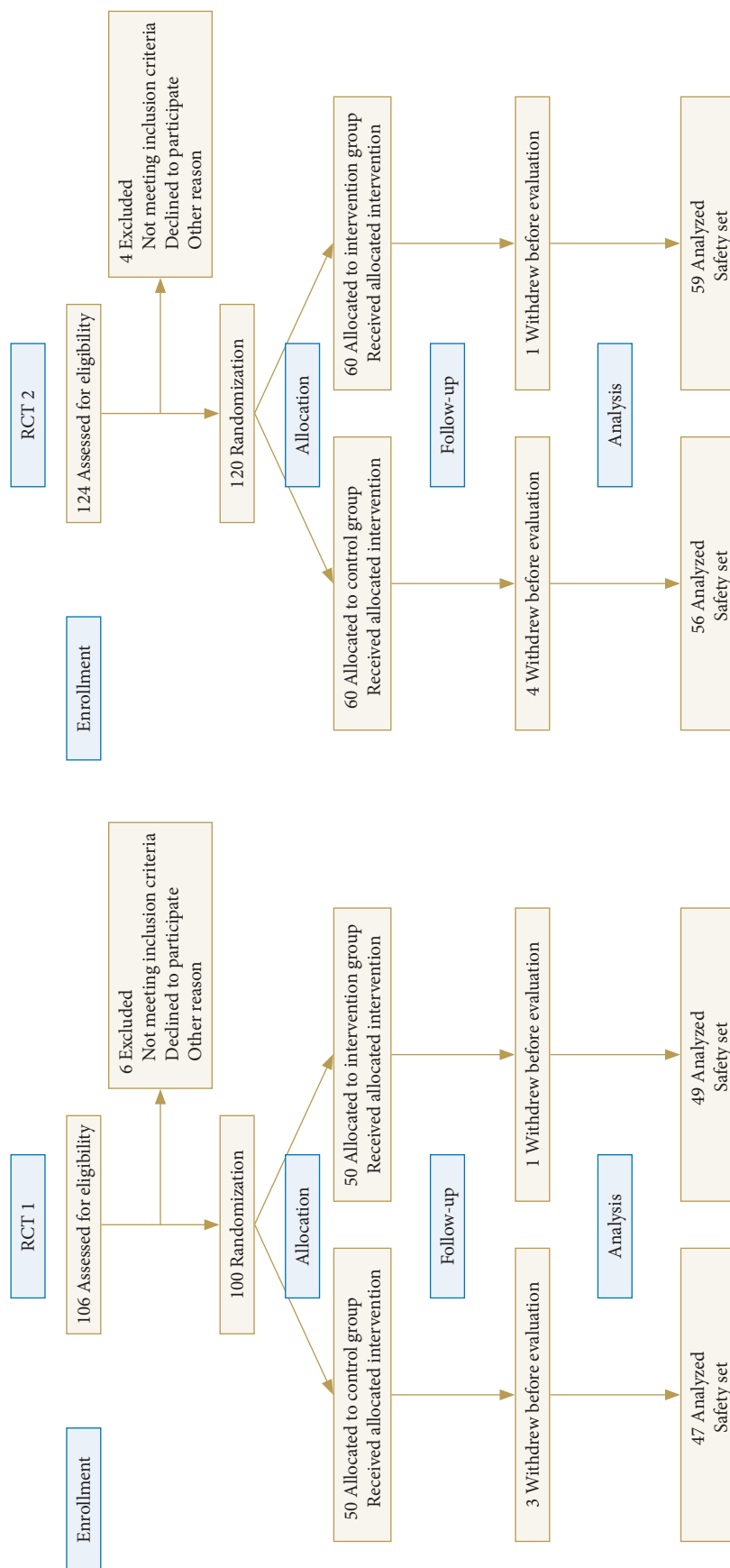


Fig. 1. Flow diagram of 2 prospective randomized controlled trials (RCTs).

including dementia, intellectual disability, and drug abuse were excluded. Finally, we excluded individuals with other disorders that the treating surgeon deemed to make them ineligible for participation.

3. Recruitment

Participants were recruited from 6 hospitals. Potential participants were those who decided to undergo a one-level discectomy for lumbar disc herniation or decompressive laminectomy for lumbar spinal stenosis. The eligible participants were identified and screened by researchers to determine their eligibility for the study. Those meeting the inclusion criteria provided written informed consent and underwent baseline testing by a blinded assessor.

4. Randomization and Follow-ups

Participants were randomized into either the control or intervention group (BESS) in a 1:1 ratio following a computer-generated randomization list with block sizes of four. The randomization lists were incorporated into a web-based electronic clinical research form platform accessible to authorized researchers. The randomization process was handled independently at each hospital, and group allocation was concealed in opaque envelopes opened immediately before surgery. Participants were followed-up for a minimum of 12 months, with assessments conducted at baseline (before surgery) and at 2 weeks, 3 months, 6 months, and 12 months after surgery.

5. Blinding

Given the nature of the surgery, the participants and surgeons were aware of the assigned procedures. However, the outcome assessors were blinded to the group assignments; thus, this was a single (assessor)-blinded trial. Blinded outcome assessors, who were trained to ensure consistency across hospitals, conducted all preoperative and postoperative assessments. Any instances of unblinding were documented in detail.

6. Interventions

1) Active intervention: BESS

BESS involved the creation of 2 small skin incisions (portals) for camera and instrument access, allowing minimal damage to normal structures. A viewing portal for the camera and working portal for the spinal instrument were created. The surgery was performed using endoscopic instruments under saline irrigation. The procedures for lumbar disc herniation and spinal stenosis were performed in accordance with the methodology out-

lined in previous studies.^{9,10,17,18}

2) Control intervention: MSS

The MSS technique has been extensively described. Both discectomy and laminectomy within the context of MSS are based on well-established methods that have been widely utilized for many years.¹⁷⁻²⁰ MSS involved a midline incision, detachment of the paraspinal muscles, laminotomy, and/or discectomy using conventional techniques. The paraspinal muscles were detached using a Cobb elevator and were retracted using a Taylor retractor. Laminotomy was performed with a burr and Kerrison punches, followed by discectomy.

7. Outcome Measures

The primary outcome measure was the Oswestry Disability Index (ODI) score at 12 months after surgery. The ODI is commonly used to evaluate disabilities related to lumbar conditions.²¹ Secondary outcomes included VAS scores for low back and lower extremity radiating pain, quality of life measured using the EuroQol-5-Dimension score, satisfaction with surgery, walking time, postoperative return to daily life, postoperative surgical scars, surgery-related variables, and radiographic outcomes. Safety was assessed by evaluating all adverse and severe adverse events reported by the participants to the surgeon or assessor and recorded in an electronic database. All postoperative adverse events were recorded, regardless of their relationship with the surgery. This study specifically focused on the analysis of adverse events and did not analyze primary and secondary outcomes related to efficacy measures.

8. Sample Size

The sample size for this study was calculated using Power Analysis and Sample Size software ver. 15 (NCSS, Kaysville, UT, USA). According to a previous report, the minimal clinically important difference in the ODI was 12.8,²² while in another study, the standard deviation of the ODI value 1 year after endoscopic discectomy was 17.1.²³ Moreover, a previous study has reported a standard deviation of 18.8 at 1 year after endoscopic decompressive laminectomy.¹⁰ Thus, we assumed an equivalence limit of 12.8, $\alpha = 0.05$, power = 0.90, 2-sided 95% confidence interval, and 20% loss to follow-up. Accordingly, the first RCT recruited 100 participants (50 participants in each group) to confirm the equivalence of the primary outcome analysis between the 2 groups. In the second RCT, 120 participants (60 participants per group) were recruited to confirm the equivalence of the primary outcomes between the 2 groups.

Table 1. Characteristics of the participants in both prospective randomized controlled trial at baseline

Characteristic	Herniated disc (n = 100)		Spinal stenosis (n = 120)	
	Biportal (n = 50)	Microscope (n = 50)	Biportal (n = 60)	Microscope (n = 60)
Age (yr)	57.3 ± 13.4	51.9 ± 15.1	63.3 ± 10.9	64.2 ± 9.2
Sex				
Male	28 (56.0)	34 (68.0)	32 (53.3)	31 (52)
Female	22 (44)	16 (32.0)	28 (46.6)	29 (48)
BMI (kg/m ²)	18.9 ± 5.8	20.2 ± 5.9	18.6 ± 6.9	17.1 ± 4.1
CCI score	1.7 ± 1.6	1.3 ± 1.3	2.4 ± 1.3	2.4 ± 1.3
ASA PS classification grade	2.0 ± 0.5	1.8 ± 0.5	2.1 ± 0.6	2.1 ± 0.7
Smoking status				
Non/ex-smoker	39 (76)	38 (76.0)	45 (75.0)	51 (85.0)
Current smoker	11 (22)	12 (24.0)	15 (25.0)	9 (15.0)
Alcohol consumption				
None	27 (54)	23 (46.0)	41 (68.3)	40 (66.6)
≥ 1 Drink/mo	23 (46)	27 (54.0)	19 (31.6)	20 (33.3)
Initial clinical outcomes				
VAS for back pain	5.1 ± 2.4	5.8 ± 2.7	5.1 ± 2.8	6.0 ± 2.5
VAS for leg pain	7.1 ± 2.2	7.9 ± 1.8	6.3 ± 2.2	6.8 ± 2.5
ODI	54.0 ± 19.5	53.8 ± 18.4	47.9 ± 17.1	49.8 ± 22.4
EQ-5D	0.4 ± 0.2	0.5 ± 0.2	0.5 ± 0.2	0.5 ± 0.2
Operation level				
L2–3	2/50 (4)	1/49 (2)	0/59 (0)	4/56 (7)
L3–4	5/50 (10)	6/49 (12)	18/59 (31)	10/56 (18)
L4–5	30/50 (60)	24/49 (49)	41/59 (69)	42/56 (75)
L5–S1	13/50 (26)	18/49 (37)	0/59 (0)	0/56 (0)

Values are presented as mean ± standard deviation or number (%).

BMI, body mass index; CCI, Charlson Comorbidity Index; ASA PS, American Society of Anesthesiologist physical status; VAS, visual analogue scale; ODI, Oswestry Disability Index; EQ-5D, European quality of life-5 dimensions.

9. Statistical Analysis

Statistical analyses were performed using Stata/MP 17.1 (Stata Corp., College Station, TX, USA). Statistical significance was defined as a 2-sided p-value of < 0.05. The Shapiro-Wilk test was used to assess data distribution. Continuous variables are presented as mean and standard deviation, while categorical variables are presented as numbers and percentages. To analyze the adverse events according to the type of surgery, we combined data from both studies. Therefore, all participants from both studies who underwent BESS were included in the BESS group and all participants who underwent MSS were included in the MSS group. This approach allowed a more comprehensive analysis of the safety outcomes of the 2 surgical techniques across a larger combined cohort of patients. Fisher exact test was used to analyze categorical variables, ensuring robust results even with small sample sizes.

RESULTS

1. Participants' Characteristics

Between July 13, 2021, and April 6, 2023, 220 participants from 6 hospitals were enrolled, with 110 in the MSS group and 110 in the BESS group. No crossover was observed for any of the randomized surgical strategies. Nine participants were excluded from the safety analysis: 3 because of violation of the surgery randomization protocol and 6 because of consent withdrawal. The baseline clinical characteristics (Table 1) of the study participants were similar among the 4 groups ($p > 0.05$).

The baseline characteristics of the 2 groups are summarized in Table 2. Overall, 220 participants were included in the study: 110 each in the BESS group and 110 participants in the MSS group. The mean age of the groups did not differ significantly ($p = 0.26$), and the sex distribution was similar, with slightly more

Table 2. Characteristics of the participants between groups at baseline

Variable	Biportal endoscopy (n = 110)	Microscopy (n = 110)	p-value
Age (yr)	60.6 ± 12.4	58.6 ± 13.6	0.261
Sex			
Male	60 (54.5)	65 (59.1)	0.498
Female	50 (45.5)	45 (40.9)	
BMI (kg/m ²)	18.7 ± 6.4	18.5 ± 5.2	0.772
CCI score	2.1 ± 1.5	1.9 ± 1.4	0.337
ASA PS classification grade	2.1 ± 0.5	2.0 ± 0.6	0.120
Smoking status			
Non/ex-smoker	84 (76.1)	89 (80.9)	0.394
Current smoker	26 (23.9)	21 (19.1)	
Alcohol consumption			
None	68 (61.8)	63 (57.3)	0.528
≥ 1 Drink/mo	42 (38.2)	47 (42.7)	
Initial clinical outcomes			
VAS for back pain	5.4 ± 2.7	5.9 ± 2.6	0.130
VAS for leg pain	6.9 ± 2.2	7.3 ± 2.3	0.159
ODI	50.6 ± 18.4	51.6 ± 20.7	0.711
EQ-5D	0.48 ± 0.19	0.47 ± 0.21	0.704
Operation level			
L2–3	2 (1.8)	5 (4.8)	0.333
L3–4	23 (21.1)	16 (15.2)	
L4–5	71 (65.1)	66 (62.9)	
L5–S1	13 (11.9)	18 (17.1)	

Values are presented as mean ± standard deviation or number (%). BMI, body mass index; CCI, Charlson Comorbidity Index; ASA PS, American Society of Anesthesiologist physical status; VAS, visual analogue scale; ODI, Oswestry Disability Index; EQ-5D, European quality of life-5 dimensions.

than half being males ($p = 0.50$). The mean body mass index was also not significantly different between the groups ($p = 0.77$). Moreover, the distribution of the operation levels was not significantly different between the groups. All of the disc herniation patients ($n = 100$) underwent ipsilateral decompression followed by discectomy, and all of the spinal stenosis patients ($n = 120$) underwent bilateral decompression.

2. Adverse Events

The adverse events observed during the follow-up period are shown in Table 3. Ten participants (9.1%) in the BESS group and 19 (17.3%) in the MSS group experienced adverse events, with no significant intergroup difference ($p = 0.133$). Specific

Table 3. Adverse events of the participants between groups during the follow-up period

Variable	Biportal endoscopy (n = 110)	Microscopy (n = 110)	p-value
Adverse events	10 (9.1)	19 (17.3)	0.133
Incidental durotomy	0 (0)	1 (0.9)	
Epidural hematoma	2 (1.8)	1 (0.9)	
Recurrent disc herniation	3 (2.7)	3 (2.7)	
Surgical site infection	0 (0)	1 (0.9)	
Wound dehiscence	0 (0)	9 (8.2)	
Nonspecific back pain	2 (1.8)	2 (1.8)	
Compression fracture	0 (0)	1 (0.9)	
Dyspnea	1 (0.9)	0 (0)	
Gastrointestinal trouble	0 (0)	1 (0.9)	
Skin rash	1 (0.9)	0 (0)	
Stroke	1 (0.9)	0 (0)	

Values are presented as number (%).

adverse events included incidental durotomy, epidural hematoma, recurrent disc herniation, surgical site infection, wound dehiscence, nonspecific back pain, compression fracture, dyspnea, gastrointestinal trouble, skin rash, and stroke. The MSS group experienced more instances of specific adverse events, such as wound dehiscence, more frequently requiring wound closure interventions.

DISCUSSION

This study pooled data from 2 prospective RCTs to compare the safety of BESS with that of MSS in 220 patients with lumbar disc herniation and spinal stenosis (110 patients in each group). Analysis of postoperative adverse events revealed that 10 patients (9.1%) in the BESS group and 19 patients (17.3%) in the MSS group experienced adverse events, although the difference was not statistically significant. Notably, wound dehiscence was significantly more common in the MSS (9 cases [8.2%]) than in the BESS group (no cases). This finding highlights the potential advantages of using a minimally invasive approach for reducing wound-related complications.

As a minimally invasive approach, BESS offers several significant advantages for spinal surgery.^{6,12} It utilizes 2 small incisions, typically 1 cm each, for the insertion of an endoscope and surgical instruments. This approach minimizes damage to healthy tissues, particularly the paraspinal muscles, which can lead to reduced postoperative pain, faster recovery, and shorter hospi-

tal stay.^{9,10,24-26} The use of continuous saline irrigation during the procedure ensures excellent visibility and helps in hemostasis, potentially reducing the risk of postoperative hematoma.¹² In the blurred vision, achieving hemostasis is challenging. Furthermore, the pressure of the water may mask the occurrence of bleeding, which could potentially result in the formation of a postoperative hematoma.^{27,28} Additionally, BESS shares similarities with conventional microscopic techniques in terms of the surgical view and instrument handling, potentially easing the transition for surgeons who are familiar with open procedures.¹² This familiarity can help flatten the learning curve associated with the adoption of new minimally invasive techniques.²⁵

However, BESS has some limitations. The learning curve for the new technique may initially result in longer operation times and potentially higher complication rates in early cases.^{7,16,25} BESS also carries risks of specific complications, such as dural tears, particularly during the early learning phase, and incomplete decompression may potentially occur, particularly in cases of severe stenosis or in the presence of complex anatomy.^{7,16,25}

Previous studies have reported varying complication rates for both BESS and MSS, thus providing a context for our findings.^{15,16} For BESS, a meta-analysis reported an overall complication rate of approximately 5% in lumbar spinal stenosis cases, with dural tears being the most common complication (2% incidence), followed by epidural hematoma (1% incidence).¹⁵ Other reported complications include nerve root injury (0.5%–1%), incomplete decompression (1%–2%), and postoperative headache (1%–3%). Although the complication rates vary across studies, several recent meta-analyses and large-scale studies have suggested that BESS may offer comparable or lower complication rates than do traditional open procedures.^{15,29,30} A large-scale study on open lumbar discectomy reported a complication rate of 16.4%; complications included dural tears (4%), surgical site infections (2%), and nerve root injuries (1%). However, it is important to note that complication rates for both techniques can vary significantly based on factors such as surgeon's experience, patient selection, and specific surgical indications. Several studies on the learning curve of BESS have suggested that complication rates tend to decrease significantly after surgeons have performed 30–50 cases, highlighting the importance of experience with this technique.^{25,31,32} Additionally, BESS may offer lower complication rates than those of open procedures, particularly in terms of surgical site infections and dural tears, although these findings are not uniform across all studies.^{15,16}

In our study, although the overall adverse event rate was lower in the BESS group (9.1%) than in the MSS group (17.3%), the

difference was not statistically significant ($p = 0.133$). The lower complication rate in the BESS group is consistent with that of many recent studies showing that minimally invasive techniques may be safer than traditional open surgeries. Notably, we observed no cases of dural tears in the BESS group, as compared to 1 case (0.9%) in the MSS group. This is particularly interesting, given that dural tears are often cited as a concern in biportal endoscopic procedures. The most frequent adverse event in the BESS group was recurrent disc herniation (2.7%), which is comparable to rates reported in other studies. In contrast, the MSS group showed a higher rate of wound-related complications, with wound dehiscence being the most common (8.2%). This difference could be attributed to smaller incisions used in BESS. Additionally, the continuous saline irrigation throughout the surgical procedure may be demonstrated to diminish the prevalence of postoperative wound complications.³³ Other adverse events, such as epidural hematoma, surgical site infection, and nonspecific back pain, occurred at low rates in both groups. These findings suggest that, although BESS may offer a favorable safety profile, particularly in terms of wound-related problems, it may not completely eliminate the risk of other spinal surgery-related adverse events.

This study had some limitations that should be considered when interpreting the results. First, we pooled 2 RCTs that differed only in whether the procedure included a discectomy to ensure an adequate sample size. However, despite pooling data from the 2 trials, our sample size of 220 patients may have been insufficient to detect small differences in adverse events rates, particularly for rare adverse events. This may explain why some differences, although clinically notable, were not statistically significantly different between groups. Secondly, the follow-up period was limited to 12 months, which may not have captured long-term complications. Third, the surgeons' experience with BESS varied, which could have influenced the complication rates. Some studies have suggested that the complication rates for BESS decrease significantly after surgeons have performed 30–50 cases. However, in our study, all participating surgeons had over 5 years of experience with endoscopic surgery. Therefore, we believe that the learning curve-related adverse events was not a significant factor in our results. Nevertheless, we did not explicitly control for individual surgeons' experience, which could still be considered when interpreting our findings. Fourth, while we focused on adverse events, we did not analyze other important outcomes, such as pain reduction, functional improvement, or patient satisfaction, which are crucial for comprehensively comparing these techniques. Fifth, this study's

sample size was not specifically calculated for comparing complication rates, as it was based on data from RCTs primarily designed to compare clinical outcomes. While this may limit the study's power to detect small differences in complication rates, our analysis of adverse events from 2 well-designed RCTs still provides valuable insights into the safety profiles of these surgical techniques. Future studies specifically designed to compare complication rates may offer additional information on the relative safety of these procedures. Finally, our study included patients with lumbar disc herniation and spinal stenosis, which may have introduced heterogeneity into the patient population, although it increased sample size. These conditions present different technical challenges and may have different risk profiles for complications.

CONCLUSION

Our study demonstrated that BESS is a safe alternative to MSS for the treatment of degenerative lumbar spine diseases. Although we observed a trend towards fewer overall complications in the BESS than in the MSS group, this difference was not statistically significant. Notably, BESS showed particular advantages in reducing wound-related complications, with no cases of wound dehiscence, as compared to the MSS group. Both techniques demonstrated similarly low rates of major complications, such as dural tears, epidural hematoma, and nerve root injury. These findings suggested that BESS can be performed with a safety profile comparable to that of conventional MSS while potentially offering the benefits of a minimally invasive approach.

NOTES

Conflict of Interest: The authors have nothing to disclose.

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