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Comparison of Postoperative Epidural Hematoma Formation Between Biportal Endoscopic Spine Surgery and Conventional Microscopic Surgery: A Randomized Controlled Trial

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ABSTRACTS

Background: Biportal endoscopic spine surgery (BESS) has become widely recognized as a minimally invasive method for spinal decompression and discectomy. However, postoperative epidural hematoma (POEH) presents a significant risk in spinal surgery due to its potential to compress neural elements and lead to neurological deficits. This study compares the clinical and radiological outcomes of BESS with those of conventional microscopic surgery.

Methods: In this single-center, single-blinded, actively controlled randomized clinical trial, 46 patients undergoing single-level posterior decompression or discectomy for spinal stenosis or herniated intervertebral discs were enrolled. Participants were randomly allocated to either the conventional microscopic surgery group or the BESS group. Experienced spine surgeons performed all procedures. Postoperative magnetic resonance imaging assessments were conducted following the removal of the drain system. Outcome measures included the cross-sectional area (CSA) of the dura sac and POEH, as well as the incidence of neurological deficits.

Results: The demographic and baseline characteristics of the patients were similar across the 2 groups, with 24 in the conventional group and 22 in the BESS group. There were no significant differences in the preoperative and postoperative CSA of the dura sac between the groups. However, the BESS group exhibited a significantly larger CSA of POEH (0.36 ± 0.34 cm²) compared with the conventional group (0.17 ± 0.15 cm², $P = 0.033$). Despite this higher incidence of POEH, there was no corresponding increase in neurological deficits or revision surgeries.

Conclusion: The findings indicate that while BESS achieves decompression comparable to that of conventional microscopic surgery, it is associated with a higher incidence of epidural hematomas. Importantly, these hematomas did not result in an increased rate of neurological deterioration or the need for surgical interventions. Further studies with larger sample sizes and extended follow-up are required to confirm these results and further refine the BESS technique.

Clinical Relevance: Despite a higher incidence of epidural hematomas, BESS offers comparable decompression to microscopic surgery without increased neurological risks, making it a viable, less invasive option for patient care.

Level of Evidence: 2.

Endoscopic Minimally Invasive Surgery

Keywords: biportal endoscopic spine surgery, epidural hematoma

INTRODUCTION

Biportal endoscopic spine surgery (BESS) has become widely recognized as a minimally invasive approach for spinal decompression and discectomy.[1–4] This technique presents several advantages over traditional open surgery, such as reduced muscle damage, smaller incisions, and expedited recovery times. BESS employs 2 portals—1 for visualization and the other for instrumentation—facilitating effective decompression and minimizing trauma to adjacent tissues.[5,6] However, this technique demands meticulous management of intraoperative conditions to achieve optimal outcomes.

Postoperative epidural hematoma (POEH) represents a significant risk in spinal surgery, posing a threat of compressing neural structures and potentially leading to neurological deficits.[7] The incidence of POEH is variable, encompassing both symptomatic and asymptomatic presentations, as documented in the literature.[8–10] Prompt detection and management of POEH are essential to avert serious complications.[11,12] Notably, studies suggest that minimally invasive methods like BESS

may exhibit a higher incidence of POEH than conventional surgery, possibly due to challenges associated with achieving effective hemostasis.[13,14]

The objective of this study was to assess the clinical and radiological outcomes of BESS compared with conventional microscopic surgery in patients undergoing single-level posterior decompression or discectomy. We specifically examined the occurrence and size of POEHs, the frequency of neurological deficits, and the changes in the cross-sectional area (CSA) of the dura sac. Through this analysis, we aimed to elucidate the relative safety and efficacy of BESS compared with traditional surgical methods.

METHODS

Study Design and Participants

This study was a single-center, single-blinded, actively controlled randomized clinical trial with 2 parallel groups and was conducted between July 2021 and August 2022. The surgeries were performed by experienced spine surgeons, each with more than a decade of expertise. The trial received approval from the institutional review board of Chung-Ang University Hospital.

Participants included patients aged 18 to 80 years undergoing single-level posterior decompression surgery or discectomy due to spinal stenosis or herniated intervertebral discs. Exclusion criteria encompassed previous spinal surgery at the same level, spinal infection, malignancy, or coagulation-related pathologies. Written informed consent was obtained from all participants prior to enrollment. Demographic and clinical data collected included age, sex, height, weight, smoking history, specific diagnosis, medical comorbidities, history of anticoagulant use, surgical level, drain removal day, drain volume, and laboratory results, specifically pre- and postoperative hemoglobin levels.

Sample Size Calculation and Randomization

The primary outcome measured was the CSA of the epidural hematoma on magnetic resonance imaging (MRI). The sample size calculation was based on anticipated means derived from a pilot study conducted prior to the main study. In the pilot study, the mean CSA of the epidural hematoma in the BESS group was 0.47 cm^2 with an SD of 0.34 cm^2. The statistical parameters used for the calculation included a Type I error rate (alpha) of 0.05 and a power (1-beta) of 0.80, with an enrollment ratio set to 1. Based on these parameters, the required sample size was determined to be 20 patients per group, resulting in a total of 40 patients for the study. To account for potential dropouts, we aimed to recruit an additional 20% of the calculated sample size, resulting in a final target sample size of 48 patients.

Patients were randomized in a 1:1 ratio to either the conventional microscopic surgery group (conventional group) or the BESS group. Randomization was achieved using computer-generated sequences with a block size of 4, managed exclusively by a designated investigator through the software R version 4.0.0 (R Development Core Team, Vienna, Austria). The type of surgery—endoscopic or conventional—was disclosed to the surgeon only. Patients, outcome assessors, and data analysts were kept blinded to the allocation.

Intervention

Decompression surgery was conducted using a unilateral approach, which involved laminotomy and removal of the ligamentum flavum for bilateral decompression. Bilateral transverse roots were verified as decompressed. Discectomy was performed on the side affected by pathology through a unilateral approach, which included laminotomy and removal of herniated disc material. Surgeries in the conventional group were conducted using microscopy, whereas those in the endoscopic group were carried out using biportal endoscopic techniques. In the endoscopic group, water flow was regulated by gravitational force without a pump; a 3,000 mL saline bag was suspended 1.5 m above the surgical field to ensure constant water pressure during the procedure. All surgeries confirmed adequate water outflow prior to continuation. Meticulous control of bleeding was maintained in all patients, and a negative pressure closed drain system was employed.

Outcome Measures

Postoperative MRI was conducted on the day the drain system was removed, using a 3.0 T MRI scanner. The images had a slice thickness of 3 mm and included both sagittal and axial views. T1-weighted, T2-weighted, and T2-weighted fat suppression images were obtained. The CSA of the dura sac at the index level was measured from preoperative MRI scans at the axial cut where stenosis was most severe (Figure 1A). In the postoperative MRI, the CSA of the dura sac was measured at the same level as the preoperative scan (Figure 1B). Additionally, the CSA of the POEH was measured at the axial cut where the POEH was largest on the postoperative MRI (Figure 1C). The occurrence of postoperative neurological deficits was also evaluated. Additionally, clinical outcome measures, including Oswestry Disability Index (ODI) and visual analog

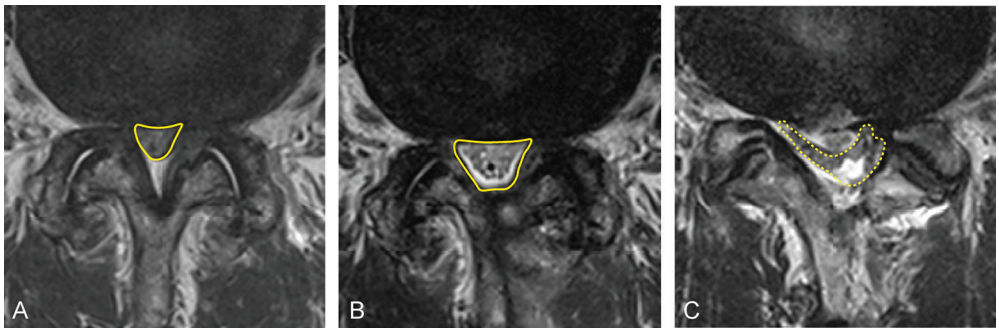

Figure 1. Measuring the cross-sectional area (CSA) of the dura sac and epidural hematoma on magnetic resonance imaging. (A and B) Pre- and postoperative dura sac CSA was measured (yellow line). (C) The CSA of the postoperative epidural hematoma was measured (yellow dotted line).

scale (VAS) scores for back and leg pain, were compared between the 2 groups preoperatively and at 3, 6, and 12 months postoperatively.

Statistical Analysis

Statistical analysis was performed to compare the outcomes between the conventional and endoscopic groups. The primary outcome evaluated was the presence and size of POEH. Secondary outcomes assessed included the incidence of neurological deficits, changes in the CSA of the dura sac pre- and postoperative ODI scores, and back and leg pain VAS scores. Continuous variables were compared between the BESS group and the control group using the independent *t* test, and categorical variables were compared using the χ^2 test. Data were analyzed using appropriate statistical methods, with a *P* value of <0.05 considered statistically significant.

RESULTS

Table 1 presents the baseline demographic characteristics of the present study, which included a total of 46 patients. These patients were divided into 2 groups: 24 in the conventional group and 22 in the BESS group. The demographic and clinical characteristics assessed, such as age, sex, body mass index, diagnosis, surgical level, and comorbidities, did not differ significantly between the groups (all $P > 0.05$). Notably, 1 patient in the conventional group experienced a postoperative neurological deficit, whereas no such events were reported in the BESS group. Both groups showed improvements in clinical outcome measures, including ODI and back and leg VAS scores, up to 1 year postoperatively, with no significant differences observed between the groups at any time point (Table 1 and Figure 2). Furthermore, no significant differences were observed in coagulation parameters (prothrombin time [PT], International Normalized Ratio [INR], and activated partial thromboplastin clotting time) or preoperative and postoperative levels of creatine phosphokinase, C-reactive protein, and hemoglobin between the 2 groups (Table 2).

Table 3 and Figure 3 present the CSA measurements of the dura sac from pre- and postoperative MRI scans. Preoperatively, the CSA values were comparable between the conventional group (0.75 ± 0.37 cm²) and the BESS group (0.69 ± 0.33 cm², $P = 0.644$). Postoperatively, the dura sac CSA increased in both groups without a significant difference between them (0.97 ± 0.44 cm² in the conventional group vs 1.09 ± 0.50 cm² in the BESS group; $P = 0.412$). The change in dura sac CSA was 0.22 ± 0.47 cm² for the conventional group and 0.40 ± 0.48 cm² for the BESS group ($P = 0.253$). However, the CSA of the epidural hematoma was significantly larger in the BESS group compared with the conventional group (0.36 ± 0.34 cm² vs 0.17 ± 0.15 cm², $P = 0.033$), indicating a greater incidence of hematoma in the BESS group.

DISCUSSION

This study aimed to compare the clinical and radiological outcomes of conventional microscopic surgery with BESS for single-level posterior decompression or discectomy. The primary endpoint was the presence and size of POEH, with secondary outcomes including the incidence of neurological deficits and changes in the CSA of the dural sac. The results indicated that while the pre- and postoperative CSAs of the dural sac were similar between the 2 groups, the BESS group exhibited a significantly larger CSA of epidural hematoma compared with the conventional group. Specifically, the mean CSA of the epidural hematoma in the BESS group was 0.36 ± 0.34 cm², which was significantly larger than the 0.17 ± 0.15 cm² observed in the conventional group ($P = 0.033$). This finding suggests that

Table 1. Baseline characteristics of included patients by study group.

Characteristic	Conventional (*n* = 24)	BESS (*n* = 22)	Total (*N* = 46)	*P*
Age, y, mean ± SD	60.2 ± 12.8	63.0 ± 10.2	61.5 ± 11.6	0.405
Sex, man, *n* (%)	15 (62.5)	12 (54.5)	27 (58.7)	0.804
BMI, mean ± SD	25.3 ± 3.5	25.6 ± 2.8	25.5 ± 3.1	0.765
Diagnosis, *n* (%)				0.725
HIVD	13 (54.2)	14 (63.6)	27 (58.7)	
Stenosis	11 (45.8)	8 (36.4)	19 (41.3)	
Operation level, *n* (%)				0.156
L2–L3	0 (0.0)	1 (4.5)	1 (2.2)	
L3–L4	4 (16.7)	1 (4.5)	5 (10.9)	
L4–L5	18 (75.0)	14 (63.6)	32 (69.6)	
L5–S1	2 (8.3)	6 (27.3)	8 (17.4)	
Drainage, cc, mean ± SD	38.8 ± 31.5	53.2 ± 24.4	45.5 ± 29.0	0.096
Drain removal date, d, *n* (%)				0.569
0	1 (4.2)	0 (0.0)	1 (2.2)	
1	5 (20.8)	6 (28.6)	11 (24.4)	
2	16 (66.7)	15 (71.4)	31 (68.9)	
3	1 (4.2)	0 (0.0)	1 (2.2)	
4	1 (4.2)	0 (0.0)	1 (2.2)	
Drain removal date, mean ± SD	1.8 ± 0.8	1.7 ± 0.5	1.8 ± 0.6	0.525
Neurological deficit, *n* (%)	1 (4.2)	0 (0.0)	1 (2.2)	>0.99
Comorbidity, *n* (%)				
Hypertension	8 (33.3)	8 (38.1)	16 (35.6)	0.983
Diabetes mellitus	2 (8.3)	1 (4.8)	3 (6.7)	>0.99
ODI				
Preoperative	0.19 ± 0.10	0.23 ± 0.09	0.21 ± 0.10	0.174
Postoperative 3 mo	0.07 ± 0.06	0.05 ± 0.04	0.06 ± 0.05	0.324
Postoperative 6 mo	0.05 ± 0.08	0.05 ± 0.07	0.05 ± 0.07	0.955
Postoperative 12 mo	0.03 ± 0.07	0.02 ± 0.05	0.02 ± 0.06	0.711
Back pain VAS				
Preoperative	4.88 ± 2.61	4.24 ± 2.45	4.58 ± 2.53	0.405
Postoperative 3 mo	1.78 ± 1.17	1.52 ± 1.29	1.66 ± 1.22	0.488
Postoperative 6 mo	1.35 ± 1.70	1.38 ± 1.56	1.36 ± 1.62	0.947
Postoperative 12 mo	0.61 ± 1.53	0.33 ± 0.80	0.48 ± 1.23	0.454
Leg pain VAS				
Preoperative	6.17 ± 2.30	6.36 ± 2.34	6.26 ± 2.29	0.775
Postoperative 3 mo	1.50 ± 1.29	1.32 ± 0.99	1.41 ± 1.15	0.597
Postoperative 6 mo	1.00 ± 1.22	1.45 ± 1.99	1.22 ± 1.63	0.362
Postoperative 12 mo	0.79 ± 1.93	0.32 ± 0.65	0.57 ± 1.47	0.267

Abbreviations: BESS, biportal endoscopic spine surgery; BMI, body mass index; HIVD, herniated intervertebral disc; ODI, Oswestry Disability Index; VAS, visual analog scale.

BESS may be associated with a higher risk of epidural hematoma formation.

Previous research has indicated that BESS has a relatively higher likelihood of POEH compared with conventional decompression surgery, which is consistent with our findings.[1,13] The larger postoperative hematoma CSA observed in the BESS group can be attributed to several factors. First, the use of water pressure in BESS can obscure the bleeding focus, a problem previously identified by Kim et al when using infusion pumps as a risk factor. Although gravity force was employed to manage water pressure in our study, it may still have concealed bleeding sources. Therefore, maintaining appropriate water flow and carefully monitoring water outflow are critical when performing decompression surgery or discectomy using BESS to minimize the risk of POEH. Second, controlling bleeding from soft tissue or the epidural venous plexus using electrocautery or

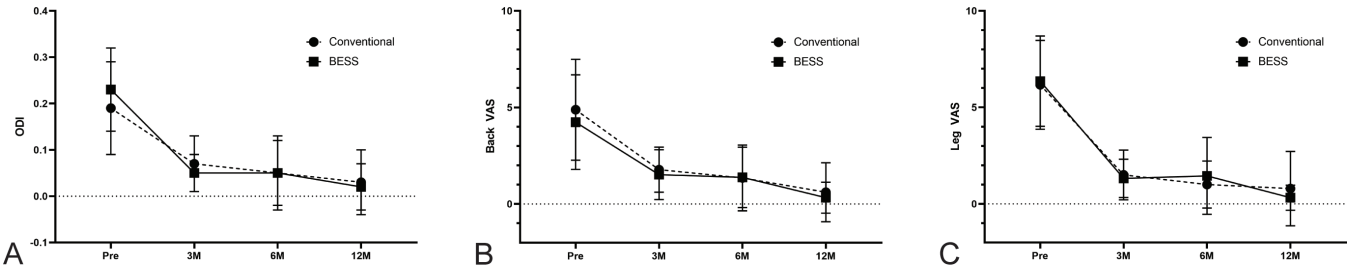

Figure 2. Comparison of clinical outcome measures between conventional and biportal endoscopic spine surgery (BESS) groups. Both groups showed improvements in clinical outcome measures up to 1 year postoperatively, with no significant differences observed between the groups at any time point. Error bars represent the SD of the mean values.

Table 2. Laboratory examination findings by study group.

Outcome Measure	Conventional (n = 24)	BESS (n = 22)	Total (N = 46)	P
Coagulation battery				
Prothrombin time, s	10.8 ± 0.6	11.0 ± 0.5	10.9 ± 0.6	0.153
Prothrombin time (INR)	1.0 ± 0.1	1.0 ± 0.0	1.0 ± 0.0	0.123
aPTT, s	31.6 ± 4.2	30.9 ± 2.7	31.3 ± 3.6	0.522
Albumin	4.4 ± 0.3	4.4 ± 0.3	4.4 ± 0.3	0.709
CPK, IU/L				
Preoperative	118.0 ± 95.7	103.7 ± 78.2	111.2 ± 87.1	0.592
Postoperative	142.4 ± 95.4	109.2 ± 79.9	126.6 ± 88.9	0.221
CRP, mg/L				
Preoperative	2.1 ± 3.2	2.6 ± 7.4	2.3 ± 5.6	0.782
Immediate postoperative	2.1 ± 3.8	1.0 ± 0.8	1.6 ± 2.9	0.190
Hemoglobin, g/dL				
Preoperative	14.1 ± 1.4	13.8 ± 1.1	14.0 ± 1.3	0.552
Immediate postoperative	13.5 ± 1.3	13.0 ± 1.2	13.3 ± 1.2	0.155
Postoperative day 1	12.9 ± 1.2	12.3 ± 1.1	12.6 ± 1.2	0.088

Abbreviations: aPTT, activated partial thromboplastin clotting time; BESS, biportal endoscopic spine surgery; CPK, creatine phosphokinase; CRP, C-reactive protein.
Note: All values presented as mean ± SD.

thrombin-soaked gelfoam is inherently more challenging in endoscopic surgery compared with conventional techniques. These factors likely contributed to the increased incidence of POEH observed in the BESS group.

While this study demonstrated that the BESS group exhibited larger POEH, this did not correlate with an increased rate of neurological deterioration or adverse clinical outcomes. Notably, the conventional group recorded 1 case of neurological deficit, while the BESS group reported none. Additionally, neither group required revision surgeries for POEH. Leonardi et al[15] reported that early POEH occurred in 42.5% of patients without symptomatic presentation. They further noted that even though early POEH may compress the dura sac, significant neurological symptoms are unlikely unless there is moderate to severe stenosis. They suggested that a CSA of the dura sac below 75 mm² significantly increases the likelihood of symptoms arising from severe stenosis. Therefore, while POEH is commonly detected on early postoperative MRI, it typically does not cause significant symptoms.[11] Nonetheless, if the hematoma is extensive, it may lead to neurological deterioration and symptoms, underscoring the importance of meticulous bleeding control, particularly in patients with predisposing risk factors.

Despite a higher incidence of hematomas in the BESS group, both surgical approaches effectively increased the CSA of the dura sac postoperatively, confirming the efficacy of both techniques in achieving decompression. This finding is consistent with prior research, which suggests that endoscopic methods can provide sufficient decompression while also offering potential benefits such as reduced muscle damage and faster recovery times.[4–6] Additionally, both groups showed improvements in clinical outcome measures, including ODI and back and leg VAS scores, up to 1 year postoperatively, with no significant differences observed between the groups at any time point (Table 1 and Figure 2). This indicates that the endoscopic approach is not only effective in decompressing the dura sac but also equally beneficial in improving clinical outcomes as the conventional method.

Limitations

The study has several limitations that warrant mention. The small sample size may restrict the generalizability of the results. Additionally, the follow-up period was limited to the immediate postoperative phase for MRI evaluations, and longer-term

Table 3. CSA of pre- and postoperative magnetic resonance imaging.

CSA, cm^2	Conventional (n = 24)	BESS (n = 22)	Total (N = 46)	P
Preoperative dura sac	0.75 ± 0.37	0.69 ± 0.33	0.72 ± 0.35	0.644
Postoperative dura sac	0.97 ± 0.44	1.09 ± 0.50	1.03 ± 0.47	0.412
ΔCSA of dura sac	0.22 ± 0.47	0.40 ± 0.48	0.31 ± 0.48	0.253
Hematoma	0.17 ± 0.15	0.36 ± 0.34	0.26 ± 0.28	**0.033**

Abbreviations: BESS, biportal endoscopic spine surgery; CSA, cross-sectional area.
Note: All values presented as mean ± SD.

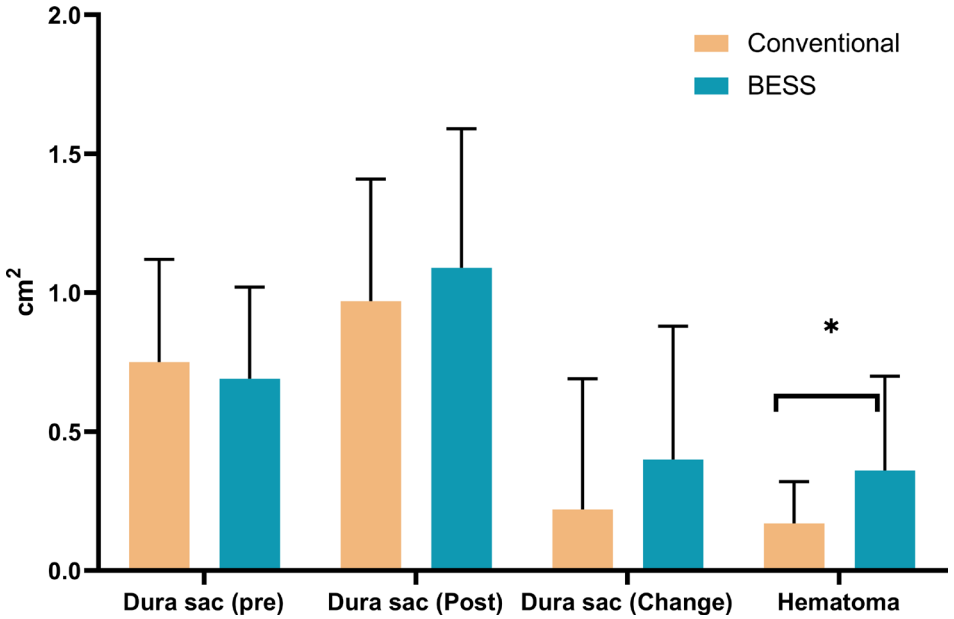

Figure 3. Comparison of pre- and postoperative cross-sectional areas of the dura sac between the conventional and biportal endoscopic spine surgery (BESS) groups, including changes in the dura sac and the epidural hematoma. *Statistically significant at $P = 0.033$.

outcomes were not assessed. Future research should include larger sample sizes and extended follow-up periods to validate these findings and assess the long-term clinical outcomes associated with BESS.

CONCLUSION

The present study demonstrates that although BESS achieves decompression comparable to that of conventional microscopic surgery, it is associated with a higher incidence of epidural hematomas. Clinicians should recognize this risk and implement strategies to minimize hematoma formation, such as maintaining appropriate water flow and ensuring effective hemostasis. Despite the increased incidence of hematomas, there was no higher rate of neurological deterioration or need for revision surgery in the BESS group. Future research with larger sample sizes and extended follow-up periods is necessary to confirm these findings and refine BESS techniques.

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