

腰椎椎間板ヘルニアに対するバイポータル内視鏡視下椎間板切除術と顕微鏡視下椎間板切除術の有効性および安全性の比較：多施設共同前向き判定者盲検無作為化比較試験 Comparing the efficacy and safety of biportal endoscopic discectomy with microscopic discectomy for lumbar herniated intervertebral disc: a multicentre, prospective, assessor-blinded, randomized controlled trial

By S-M. Park, MD, PhD*, K-S. Song, MD, PhD, D-W. Ham, MD, M-S. Kang, MD, K-H. You, MD, PhD, C-K. Park, MD, J-S. Kim, MD, PhD, and H-J. Park, MD, PhD**

Aims:

The aim of this study was to compare the efficacy and safety of biportal endoscopic discectomy (BED) with microdiscectomy (MD) in patients with a single-level lumbar disc herniation, and to determine whether BED gives similar clinical outcomes to MD but with potential additional benefits.

Methods:

Included in this multicentre, prospective, assessor-blind, randomized controlled trial were patients with a single-level lumbar disc herniation requiring surgical intervention. These were recruited from six hospitals between 13 July 2021 and 16 September 2022, and followed up for 12 months. The interventions were either BED (n = 50) or MD (n = 50). The primary outcome was the Oswestry Disability Index (ODI) at 12 months postoperatively.

Results:

In total, 100 patients were randomized into the BED and MD groups based on computer-generated allocation. The analysis included 41 and 46 patients from the MD and BED groups, respectively. At 12 months, the mean ODI scores were comparable between the BED (10.92; SD 12.93) and MD (10.32; SD 12.55) groups (mean difference 0.61 (95% CI -4.47 to 5.68); $p = 0.816$). No serious adverse event was seen in either group. Compared to the MD group, the BED group showed slightly lower surgical site pain at 24 ($p = 0.004$) and 48 hours postoperatively ($p = 0.014$), lower serum creatine phosphokinase (CPK) ($p = 0.003$), better scar quality at three ($p = 0.002$) and six months ($p = 0.007$), and a significantly lower rate of wound dehiscence ($p = 0.018$).

Conclusion:

BED is as effective as MD in treating single-level lumbar disc herniation but has distinct advantages in terms of postoperative wound complications. Additionally, BED may offer potential benefits in terms of early postoperative surgical site pain, scar aesthetics, and muscle preservation as indicated by CPK levels. These findings suggest that BED is a safe and effective alternative to MD, offering the benefits of minimal invasiveness while maintaining clinical efficacy.

目的:

この研究の目的は、単椎間の腰椎椎間板ヘルニア患者に対するバイポータル内視鏡視下椎間板切除術(BED)と顕微鏡視下椎間板切除術(MD)の有効性および安全性を比較し、BEDは、MDと同程度の臨床アウトカムに加えて、さらなる潜在的利益をもたらすかどうかを明らかにすることである。

方法:

多施設共同前向き判定者盲検無作為化比較試験に、外科的介入を必要とする単椎間の腰椎椎間板ヘルニア患者を組み入れた。これらの患者は2021年7月13日～2022年9月16日に6病院で登録され、12ヵ月間の追跡が行われた。介入はBED(50例)またはMD(50例)であった。主要評価項目は術後12ヵ月の時点でのOswestry Disability Index(ODI)とした。

結果:

コンピュータによる割付けに基づき、100例をBED群とMD群に無作為に割り付けた。解析対象はMD群の41例とBED群の46例であった。12ヵ月の時点での平均ODIスコアはBED群(10.92、標準偏差[SD] 12.93)とMD群(10.32、SD 12.55)で同程度であった(差の平均 0.61 [95%信頼区間 -4.47～5.68]、 $p = 0.816$) [独立標本 t 検定]。両群とも重篤な有害事象は認められなかった。BED群はMD群と比較して、術後24時間と48時間の時点での手術部位の痛みのわずかな軽減(それぞれ $p = 0.004$ 、 $p = 0.014$) [反復測定の変数混合モデル]、血清クレアチンホスホキナーゼ(CPK)の低下($p = 0.003$) [独立標本 t 検定]、術後3ヵ月と6ヵ月の時点での良好な癒合の質($p = 0.002$ 、 $p = 0.007$) [反復測定の変数混合モデル]、創離開率の有意な低下($p = 0.018$) [χ^2 検定]を認めた。

結論:

単椎間の腰椎椎間板ヘルニアの治療においてBEDはMDと同程度の有効性を示すが、術後創合併症の点で明確な優位性を認める。また、BEDは術後早期の手術部位の痛み、癒合の審美的性、CPK値で示される筋肉温存の点で潜在的利益をもたらす可能性がある。これらの知見から、BEDはMDに代わる安全かつ有効な手術であり、臨床的有効性を維持しつつ侵襲性を最小限にとどめるという利点をもたらすことが示唆される。

*Department of Orthopaedic Surgery, Spine Center, Seoul National University College of Medicine, Seoul National University Bundang Hospital, Seongnam, South Korea.
**E-mail: phjfrog@gmail.com

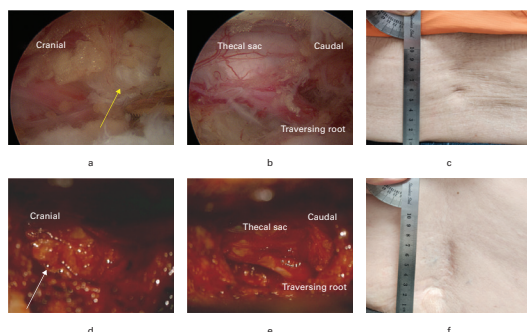


Fig. 2

L4-5 discectomy performed via two methods (biportal endoscopic and microscopic, a left-side approach). a) Biportal endoscopic view showing an extruded disc (yellow arrow) at the axillary region of the root. b) Decompressed root following discectomy. c) Postoperative scar at one year after biportal endoscopic discectomy. d) Microscopic view showing an extruded disc (white arrow) at the shoulder region of the root. e) Decompressed root following discectomy. f) Postoperative scar at one year after microscopic discectomy.