A Prospective Randomized Controlled Multicentre Study Of ProDisc–C Versus Anterior Cervical Discectomy And Fusion For The Surgical Treatment of Symptomatic Cervical Disc Disease In Asian Population: A Four-year Outcome

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Background: The current standard surgical treatment option managing symptomatic cervical disc disease(SCDD) is anterior cervical discectomy and fusion(ACDF). Despite ACDF having high clinical success and low complications, it could lead to hypermobility and increased intradiscal pressure at adjacent levels secondary to rigid immobilization at fused vertebral levels, resulting in adjacent disc degeneration. ProDisc–C is a cervical total disc replacement (TDR) designed to potentially preserve the motion at involved cervical vertebral segment, while reducing pain and neurological symptoms. Current literatures comparing ProDisc–C with ACDF in Asian population is limited. It was found that race plays an important component that influences complication rate, length of hospital stay and mortality after cervical spine procedures.

Objectives: Our study aims to evaluate safety, efficacy, and the overall success of ProDisc-C versus anterior cervical discectomy and fusion (ACDF) at 48-months post-surgery in Asian patients in treating single-level symptomatic cervical disc disease (SCDD).

Methods: This multicentre, prospective, randomized controlled trial was conducted with patients with single-level SCDD involving C3-C7-vertebral segments. The study was initiated in January 2008 after obtaining ethical approval at nine centres in China, Hong Kong, Korea, Singapore and Taiwan. The patients were randomized into group-A treated with ProDisc-C and group-B with ACDF (treated with standalone cage with bone autograft) at 2:1 ratio. A total of 120 patients consisting of 80 patients in group-A (ProDisc-C) and 40 in group-B (ACDF) were enrolled in the study. Assessments were planned to be conducted at baseline, 6-weeks, and 3-, 6-, 12-, 18-, 24-, 36- and 48-months post-surgery and annually thereafter till 84 months. The overall success at 48-months was composed of: (1) >20% improvement in neck disability index (NDI); (2) neurological success (maintained/improved); (3) absence of secondary surgery at index level; and (4) absence of device-related adverse events.

Results: Of the total of 120 patients, 76-patients in group-A and 37-patients in group-B were treated as per protocol (PP). Overall success in PP last observation carried forward (LOCF) analysis was 79% in group-A and 75.7% in group-B at 48-months (p=0.0122), demonstrating non-inferiority of ProDisc to ACDF. Additionally, ProDisc-C demonstrated non-inferiority to ACDF at 18-months (81.6% vs 83.8%, p=0.0398) and at 36-months (80.3 vs 78.4, p=0.0156). The overall success in the intent to treat LOCF analysts were 78.2% in group-A (n=81) and 73.7% in group-B (n=39) at 48-months (p=0.0086). Furthermore, at 18-months (80.8% vs 81.6, p=0.0284) and 36-months (79.5% vs 76.3, p=0.0109), ProDisc-C demonstrated non-inferiority to ACDF. Both groups had similar results in (i) NDI success (97.2% in group-A vs 100% in group-B), (ii) neurological success (83.3% in group-A vs 87.5% in group-B), (iii) absence of secondary surgery at index level (97.2% in group-A vs 100% in group-B) and (iv) absence of device-related adverse events (97.2% in group-A vs 193.75% in group-B) at 48-months (pp). Both the groups had similar secondary outcomes such as VAS-pain scores and SF-36. However, the range of motion was preserved in group-A and was significantly reduced in group-B at 48-months.

Conclusion: The use of ProDisc-C is feasible, safe, and effective for treatment of SCDD in Asian population. ProDisc-C demonstrated non-inferiority to ACDF in overall success at 18, 36 and 48-months. Both the groups had similar secondary outcomes. Future large-scale studies focusing on Asian population are required to establish clear non-inferiority of ProDisc-C to ACDF in terms the secondary outcomes in addition to the overall success.