Systematic Review

The Efficacy of the Minimally Invasive Lumbar Decompression (MILD®) Procedure: A PRISMA-compliant Systemic Review and Meta-analysis

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Background: Lumbar spinal stenosis is the most common cause for spinal surgery of older adults. It is associated with pain in the legs and back as well as impaired ambulation. Minimally Invasive Lumbar Decompression (MILD®, Vertos Medical) is a percutaneous, image-guided lumbar decompression technique for central canal stenosis secondary to a hypertrophied ligamentum flavum. However, whether MILD can achieve adequate beneficial results in patients with lumbar spinal stenosis remains undetermined.

Objective: To assess the efficacy and complications of MILD for lumbar spinal stenosis.

Study Design: A systematic review and meta-analysis.

Methods: Electronic databases were searched to identify all clinical trials of patients undergoing MILD surgery. Primary outcomes included Visual Analog Scale scores (VAS) or Oswestry Disability Index scores (ODI) at baseline, < 6 months posttreatment, ≤ 6 months posttreatment, < one year, and ≥ one year posttreatment. Secondary outcomes included postoperative complications. For continuous variables, the treatment effects were calculated by weighted mean difference and 95% CI. The statistical significance was defined as $P < 0.05$.

Results: There were 334 trials identified; 12 of them, with data from 500 patients, were included in our analysis. MILD treatment resulted in a significant decrease in the mean pain score compared to the baseline ($P < 0.01$). There is a consistent pattern of decreased mean ODI scores following MILD compared to the baseline ($P < 0.01$).

Limitations: The included MILD clinical trials did not have the same exclusion and inclusion criteria. While all clinical trials in this study adopted conservative treatments prior to MILD, there were no standardized treatment modalities and length of time. All of the studies employed subjective outcome tools including VAS and ODI. However, these self-reported outcome tools are subject to bias.

Conclusions: Our study suggests MILD is an effective and safe surgical technique for patients with stenosis from ligamentum flavum hypertrophy. This technique resulted in significant clinical improvement, as indicated by changes in pain scores and ODI scores. In addition, adverse events were low compared to other surgical decompression techniques. To further confirm this, more well designed and powered randomized trials are needed.

Key words: Spinal stenosis, lumbar spine, decompression, stenosis, minimally invasive decompression, Visual Analog Scale score, Oswestry Disability Index, side effects

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Lumbar spinal stenosis is a degenerative condition in which narrowing of the spinal canal is caused by changes in the discs, ligamentum flavum (LF), and facet joints. This condition is associated with pain in the legs and back as well as impaired ambulation (1). Lumbar spinal stenosis (LSS) affects more than 200,000 adults in the United States; it is the most common cause of spinal surgery for people older than 65 (2).

The LF is a series of elastic tissue bands that connect the laminae and fuse with the facet joint capsules. It is also known as the yellow ligament because of the yellow coloring from its content of elastin. The LF covers the spinal canal. As we age, the LF loses elastin and can encroach upon the spinal canal. In addition, disc degeneration, which causes disc collapse, results in decreased intervertebral disc height. This can often lead to buckling of the hypertrophied LF, and cause a decrease of the spinal canal space (3). This is one of the common etiologies of central canal stenosis. Also, the etiology of LSS has a strong association for underlying spinal instability, facet joint arthropathy, and degenerative spondylolisthesis (4).

Treatments options for spinal stenosis range from conservative treatments, including physical therapy, lumbar epidural steroid injections, and pain medications, to surgical decompression. Conservative treatments, including epidural steroid injections, may provide some degree of symptomatic relief for a short period. Clinical studies have shown that these treatments have not been effective for patients with neurogenic claudication (5,6). Historically, the definitive treatment is decompression surgery after conservative treatments fail. Traditional surgical decompression carries significant risks, complications and extensive recovery times. Recently, more minimally invasive therapies for spinal stenosis have been developed and assessed by prospective, randomized trials. Minimally Invasive Lumbar Decompression (MILD®, Vertos Medical) is a percutaneous image-guided lumbar decompression technique for central canal stenosis secondary to hypertrophied LF. This is the only commercially available option that achieves spinal decompression by a set of instruments to percutaneously remove LF tissue under imaging guidance, The purpose of our study was to assess the efficacy and complications of MILD for LSS.

Methods

Search Strategy and Selection Criteria.

Our systemic review and meta-analysis were conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) Statement. It was registered with the International Prospective Register of Systematic Reviews (PROSPERO) (Registration number CRD42017067398).

We selected relevant studies published by searching Embase, PubMed, the Cochrane Library, and Web of Science. We utilized the following combined text and Medical Subject Headings (MeSH) terms as search words: "Lumbar Vertebrae" and "Minimally Invasive Surgical Procedures" and "Decompression, Surgical." The complete search used for PubMed was: ("MILD") OR (("Minimally Invasive Surgical Procedures" [MeSH]) AND ("Decompression, Surgical" [MeSH])) AND ("Lumbar Vertebrae" [MeSH]). We considered all potentially eligible studies for review and conducted a manual search on the reference lists of key articles.

Inclusion and Exclusion Criteria and Data Extraction

Studies were considered eligible for inclusion if 1) they are randomized clinical trials or cohort studies; 2) MILD was used in for treating LSS with no restrictions of procedure and duration; and 3) pain outcomes and prognoses were measured before and after MILD treatment through validated tools such as the Visual Analog Scale (VAS) or Oswestry Disability Index (ODI). System assessments, topical application designs, animal studies, and reviews were excluded.

The selected studies were assessed for quality using the Newcastle-Ottawa Scale for assessing the quality of nonrandomized studies in meta-analysis, which is a quality assessment tool that awards stars based on 3 categories. The first category focuses on the selection of the cohort, with a full star given if the cohort is truly representative and a half star if somewhat representative. The second category assesses the comparability of the study based on design or analyses. Finally, the third category evaluates the outcome of the study, with record linkage considered as data from medical records and self-report as data from interviews or questionnaires. To be included in the review, studies must have achieved at least 5 out of 9 stars.

Two independent investigators (JZ, YW) reviewed study titles and abstracts. The studies that satisfied the inclusion criteria were retrieved for full text assessment. Two independent reviewers (JL, HL) assessed risk for bias according to the PRISMA recommendations. Studies selected for detailed analysis and data extraction were analyzed by 2 investigators (XZ, JZ) with an agreement value (κ) of 98%. Disagreements were resolved by a third investigator (DW).

We extracted the following data from the selected studies:

1) Demographic and clinical characteristics: the total number of individuals, age
2) MILD and treatment intervention, side effects
3) Pain scores and ODI at baseline, < 6 months posttreatment, ≥ 6 months posttreatment, < one year, and ≥ one year posttreatment.

Outcome Measures and Statistical Analysis

To assess the effectiveness of MILD surgery for LSS, the primary outcome measurement used in our study was pain relief. Pain intensity was evaluated using 2 scales: the 0-10 VAS and the Numeric Rating Scale. Pain scores were treated as continuous variables for analysis., Two key measures were reported: 1) the absolute difference between the intraoperative and postoperative arithmetic means of pain scores. This measure provides an indication of the immediate effect of the surgery on pain relief; and 2) the mean improvement in pain scores at all follow-up intervals. This measure captures the longer-term effect of the surgery on reducing pain intensity over time.

The secondary outcome measurement used was the ODI, which is assessed on a scale of 0-100. The ODI helps determine the effect of postoperative low back or leg pain on an individual's daily life. For the analysis of follow-up outcomes in the 3 subgroups, a meta-analysis was conducted at various time follow-ups after MILD surgery. The estimates of the pain relief event rate were calculated using Stata 16.0 (StataCorp LLC) employing a random-effects model. The choice of this model was based on the significant statistical heterogeneity observed among the included studies, as well as the clinical heterogeneity resulting from differences in experimental designs.

We calculated estimates of the mean differences in pain scores between treatment and baseline groups by using a random-effects model. We assessed the possibility of publication bias by constructing a funnel plot of each trial's effect size against the SE. Assessed funnel plot asymmetry was determined using Begg's and Egger's tests. We defined significant publication bias as a P value < 0.05. We chose Cochran's Q-test to assess heterogeneity among studies; values greater than 50% were regarded as being indicative of moderate-to-high heterogeneity. We used Stata 16.0 for statistical analysis. All meta-analyses were evaluated for heterogeneity using the χ^2-based I^2 test and Q test. I^2 index estimates were calculated to evaluate for variability and heterogeneity across the included studies. If a moderate or high heterogeneity was observed, a random effects meta-analysis was conducted by the Der-Simonian and Laird method. $P < 0.05$ was considered statistically significant. Sensitivity analyses were used to assess the stability and reliability of the merge results and whether there were significant changes influenced by individual studies.

Results

Characteristics of Included Studies

As depicted in the flow chart (Fig. 1), there were 334 trials identified, of which 12 trials (7-18) were included in our analysis with data from 500 patients as shown in Table 1. All studies included in this analysis

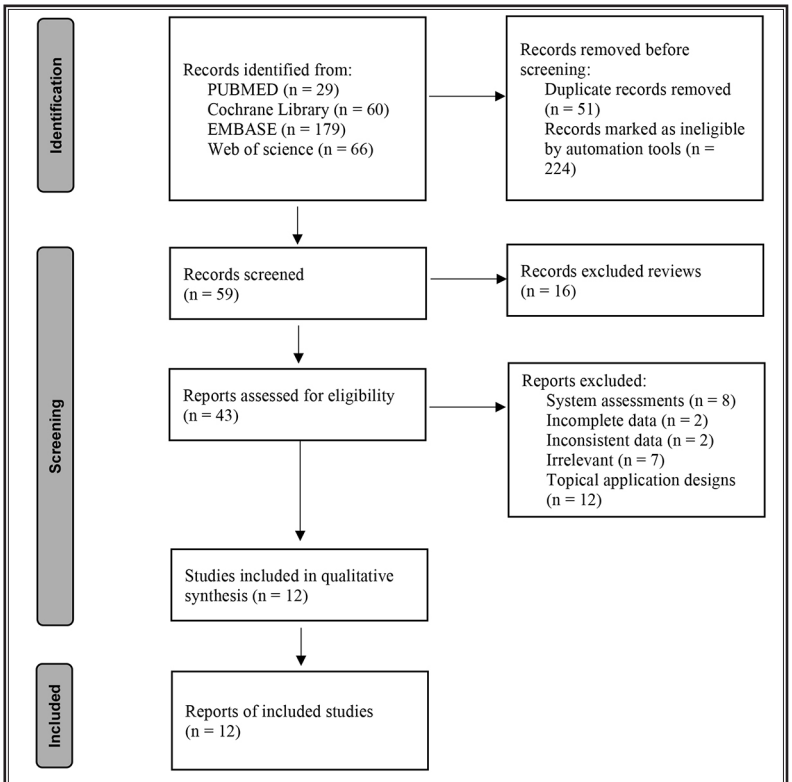

Fig. 1. *Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) flow diagram.*

Table 1. *Characteristics of included trials.*

Study	Year	*N*	Age	Baseline (VAS)	Follow-up Postoperative < 6 months	Follow-up 6 months ≤ postoperative < 1 year	≥ 1 year	*P*	Baseline (ODI)	Follow-up < 6 months treatment	6 months ≤ after treatment < 1 year	≥ 1 year	*P*	Adverse reactions
Mekhail, N et al (7)	2021	75	74.4 ± 9.1	NRS: 6.6 ± 2.2	3.4 ± 2.7	3.6 ± 2.9	3.7 ± 2.8	< 0.0001	-	-	-		< 0.0001	11 postprocedural pain, 1 ecchymosis
Durkin, B et al (8)	2013	50	73.3 ± 9.4	NRS: 7.52 ± 1.68	1 month: 5.18 ± 2.65; 3 month: 5.31 ± 3.04	5.60 ± 2.83	-	< 0.0001	40.58 ± 15.7	1 month:32.52 ± 16.37; 3 month:32.22 ± 16.06	29.24 ± 19.12		< 0.0004	Not reported
Chopko, B (9)	2013	45	70 (37-88)	7.2 (95%CI ± 0.6)	-	-	4.8 (95%CI ± 0.8)	< 0.01	48.4 (95%CI ± 4.4)	-	-	39.8 (95%CI ± 5.6)	< 0.01	Not reported
Wang, J et al (10)	2013	22	73.5 (51~91)	original data	original data	-	-	< 0.05	-	-	-			1 development of persistent bilateral leg pains
Wilkinson, J et al (11)	2012	10	64 (41~81)	7.3 ± 1.5	3.6 ± 3.2	4.2 ± 2.8	-	< 0.05	49.4 ± 13.9	37.8 ± 15.2	29.4 ± 19.8		< 0.05	1postoperative headache; 1transient worsening of left hip pain.
Mekhail, N et al (12)	2012	58	70 (45~88)	7.4 (95% CI ± 0.5)	-	-	4.5 (95%CI ± 0.8)	< 0.0001	48.6 (95%CI ± 3.8)			36.7 (95%CI ± 5.8)	< 0.0001	Not reported
Mekhail, N et al (13)	2012	40	72.2 (53~86)	7.1 (95%CI ± 0.8)	-	-	3.6 (95%CI ± 0.9)	< 0.0001	-	-	-		< 0.0001	Not reported
Brown, L et al (14)	2012	21	74.2 ± 10.4	6.3 (95% CI ± 0.7)	3.8 (95%CI ± 1.3)	-	-	< 0.0001	38.8 (95%CI ± 4.2)	27.4 (95%CI ± 7.0)			< 0.0018	Not reported
Basu, S et al (15)	2012	27	63.3 (37-83)	9.1 (95%CI ± 0.59)	-	3.9 (95%CI ± 2.25)	-	< 0.0001	55.1 (95%CI ± 6.34)	-	31.1 (95%CI ± 9.29)		< 0.0004	Not reported
Deer, T et al (16)	2012	35	66.1 (46-80)	6.9 (95%CI ± 0.6)	4.2 (95%CI ± 1.0)	4.4 (95%CI ± 1.0)	4.0 (95%CI ± 1.0)	< 0.0001	49.4 (95%CI ± 2.5)	35.1 (95%CI ± 5.6)	35.0 (95%CI ± 5.5)	32.0 (95%CI ± 5.8)	< 0.0001	Not reported
Lingreen, R etal (17)	2010	42	52~86	9.6 ± 0.42	5.8 ± 2.5	-	-	< 0.05	-	-	-			20 soreness at site; 4 left gluteal pain; 1 bleeding at incision site; 1 back spasm
Chopko, B et al (18)	2010	75	70 (37~88)	7.3 (3~10)	3.7 (0~10)	-	-	< 0.0001	47.4 (16~84)	29.5 (0~72)	-		< 0.0001	Not reported

were published within the timeframe of 2010 to 2024. A comprehensive overview of the articles is presented in Table 1. The average treatment duration in the included studies was one day. The patient mean (SD) age was 70.74 (10.81) years. Furthermore, the incidence rate of adverse reactions reported after the MILD surgical procedure was 8.2%. Table 2 indicates the quality of the included studies that passed evaluations via Newcastle-Ottawa Scale assessment.

As shown in Table 3, 12 trials were used to evaluate VAS scores to compare pre- and postoperative scores, meanwhile, 8 trials (8,9,11,12,14-16,18) were used to evaluate ODI scores to compare pre- and postoperative scores.

Table 2. *Newcastle-Ottawa Quality Assessment*.

Study	Newcastle–Ottawa Quality Assessment Scale			Total Score maximum 9 stars
	Selection maximum 4 stars	Comparability maximum 2 stars	Outcome maximum 3 stars	
Mekhail, N et al 2021 (7)	★★★★	★	★★★	8
Durkin B, et al 2013 (8)	★★★★	★★	★★★	9
Chopko B 2013 (9)	★★★★	★★	★★★	9
Wang J, et al 2013 (10)	★★★★	★	★★	7
Wilkinson J, et al 2012 (11)	★★★★	★	★★	7
Mekhail Nn et al 2012 (12)	★★★★	★★	★★★	9
Mekhail N, et al 2012 (13)	★★★★	★★	★★★	9
Brown L, et al 2012 (14)	★★★★	★★	★★	8
Basu S, et al 2012 (15)	★★★★	★	★★	7
DeerT, et al 2012 (16)	★★★★	★★	★★★	9
Lingreen R, et al 2010 (17)	★★★★	★	★★	7
Chopko B, et al 2010 (18)	★★★★	★★	★	8

Table 3. Meta-analysis of primary and secondary outcomes.

Outcomes	Trials (n)	Group (n)	Heterogeneity		Analysis model	WMD/OR	95% CI	Overall effect P
			I^2 (%)	P				
VAS	12	500						
overall average < 6 mos			33.4 32.0	0.123 0.153	IV, Random IV, Random	3.11 3.06	2.82–3.40 2.75–3.37	< 0.00001 < 0.00001
6 mos ≤ MILD postoperative <one y			47.7	0.105	IV, Random	2.74	2.20–3.28	< 0.00001
≥ one y			0	0.729	IV, Random	2.88	2.44–3.32	< 0.00001
ODI	8	321						
overall average < 6 mos			35.1 32.5	0.149 0.192	IV, Random IV, Random	13.61 12.45	11.09–16.13 9.69–15.21	< 0.00001 < 0.00001
6 months ≤ MILD postoperative < one y			24.4	0.265	IV, Random	15.40	11.28–19.53	< 0.00001
≥ one y			45.3	0.161	IV, Random	13.04	9.25–16.84	< 0.00001

Note: All time periods are based on this, within 6 months after MILD surgery, 6 months (including 6 months) to 1 year after MILD surgery, and more than 1 year (including 1 year) after MILD surgery.
MILD, minimally invasive lumbar decompression; mos, month; ODI, Oswestry Disability Index; OR, odds ratio; VAS, visual analog score; WMD, weighted mean difference; y, year.

The Effect of MILD on Pain Score

As shown in Table 3, a total of 12 trials were included in our analysis of MILD's effect on VAS pain scores. Our meta-analysis revealed that this treatment resulted in a significant decrease in the mean pain score compared to baseline ($P < 0.01$) (Fig. 2). Moreover, there was no heterogeneity among the studies.

Furthermore, no publication bias was found through examining the funnel plot using Egger's test ($P < 0.05$) (Fig. 3). This indicates that the overall conclusions drawn from the meta-analysis are reliable, as all of the studies included did not show any bias. It is important to consider these findings when interpreting the results of this analysis.

The Effect of MILD on Functional Disability Assessment

In conducting a comprehensive analysis of 8 eligible studies(8,9,11,12,14-16,18), we observed a consistent pattern of decreased mean ODI scores following MILD compared to baseline ($P < 0.01$) (Fig. 4). Specifically, these 8 studies that measured ODI did not exhibit any publication bias, as demonstrated in Fig. 5 and confirmed by Begg's and Egger's tests.

Given these findings, it is crucial to interpret the results of this analysis with caution. There is a consistent trend of decreased ODI scores associated with MILD treatment; no heterogeneity or publication bias has yet been found.

The Effects of MILD on VAS Score

On Total Sample Mean Score

After carefully reviewing and analyzing the data, we found that a total of 12 trials (7-18) evaluated post-treatment pain improvement. The postoperative VAS scores decreased by an average of 3.11 points overall. Our meta-analysis results demonstrated a statistically significant difference (weighted mean difference [WMD] = 3.11; 95% CI, 2.82–3.40; $P < 0.00001$) without

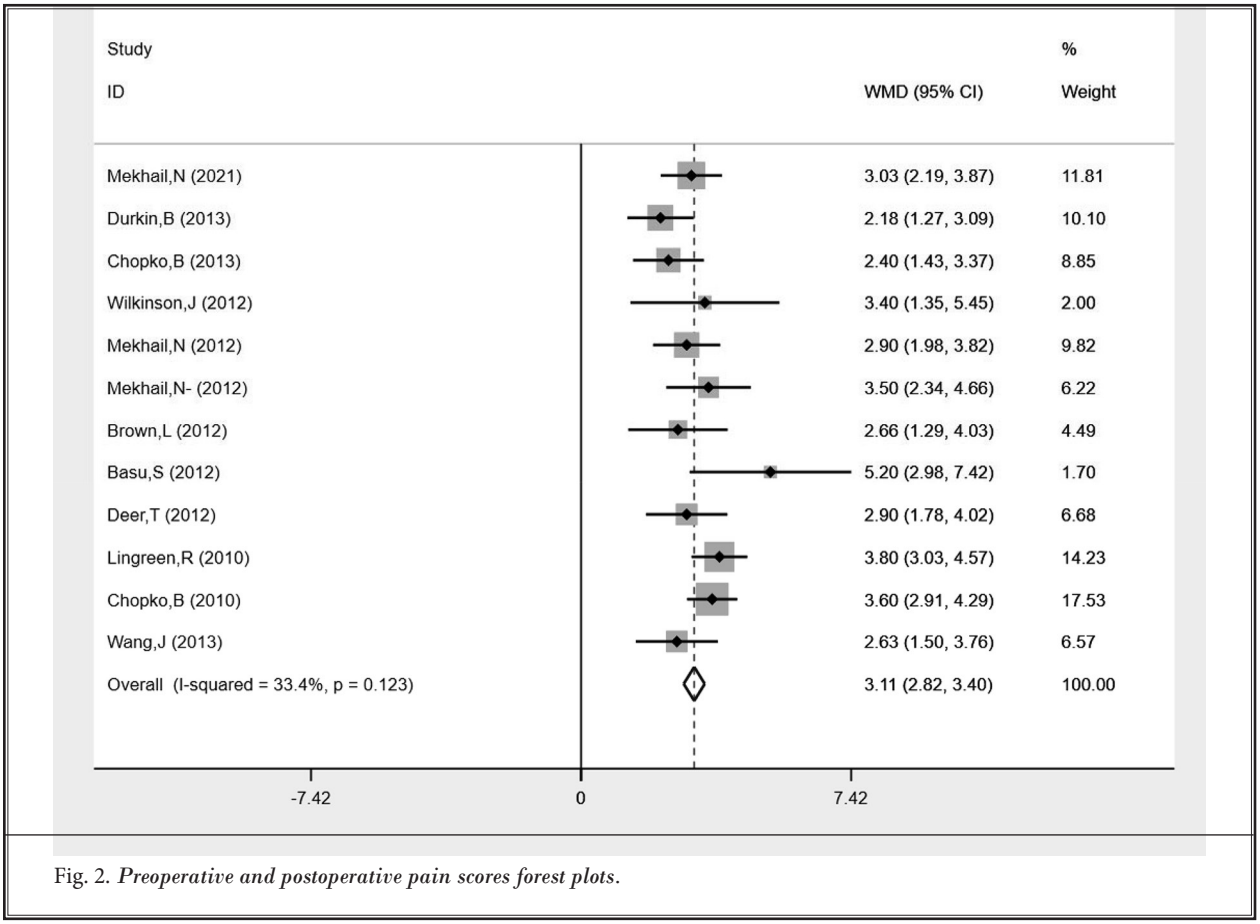

Fig. 2. *Preoperative and postoperative pain scores forest plots.*

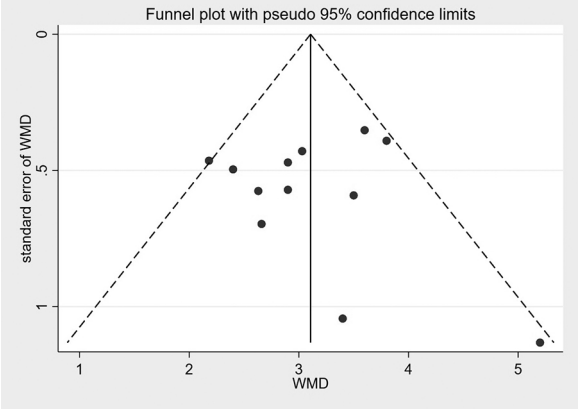

Fig. 3. *Preoperative and postoperative pain scores funnel plots.*

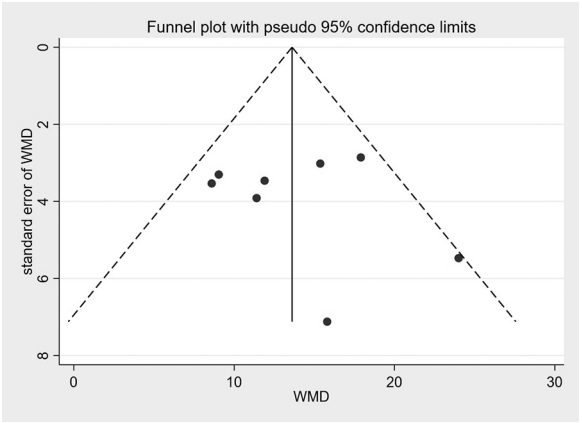

Fig. 5. *Preoperative and postoperative ODI scores funnel plots.*

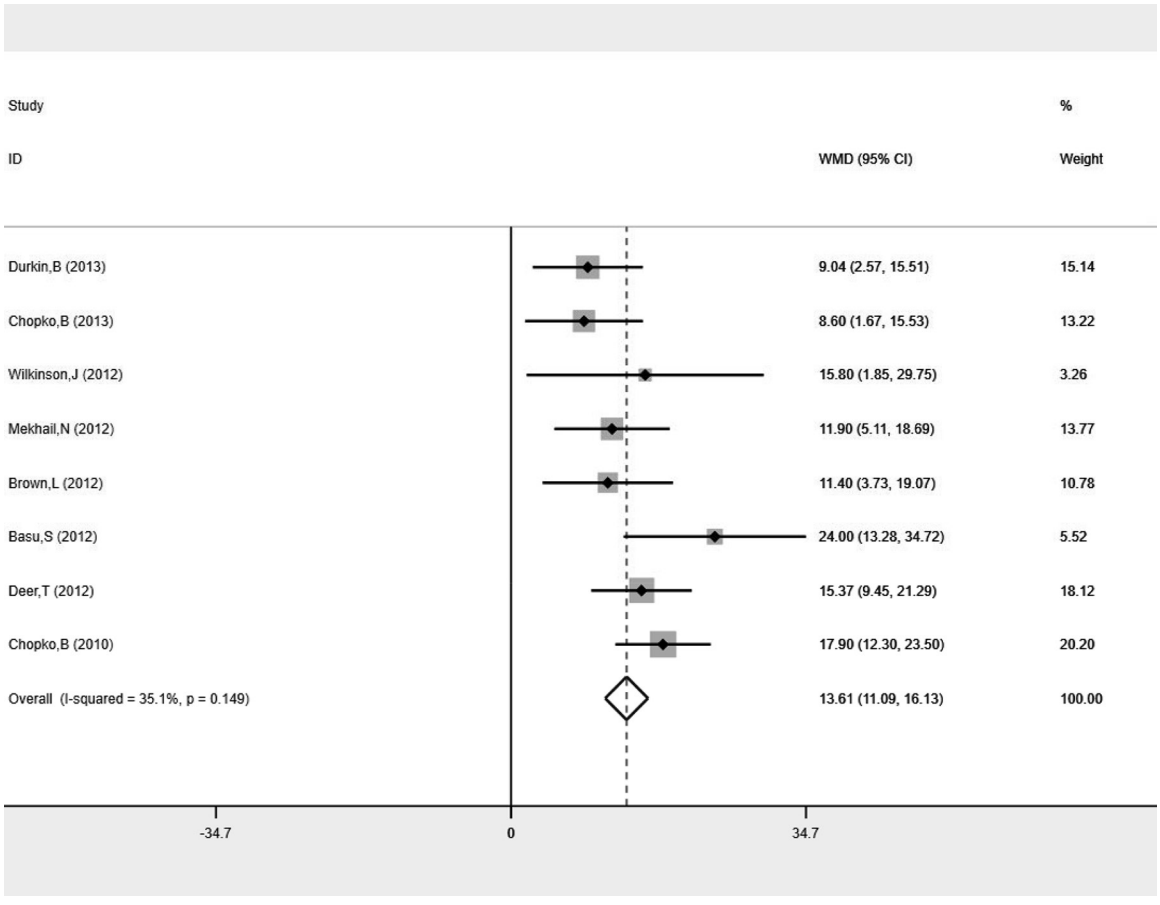

Fig. 4. *Preoperative and postoperative Oswestry Disability Index (ODI) forest plots.*

any significant heterogeneity observed among the studies (I^2 = 33.4%; *P* = 0.123).

These findings indicate that treatment with MILD is associated with a significant decrease in pain, as evidenced by the reduction in VAS scores. It is important to note that the presence of heterogeneity in the overall analysis suggests that there is no difference in the results observed across different studies.

< 6 Months MILD Postoperatively

Table 3 presents the results of 12 trials (7-18) that evaluated the pre- and < 6month postoperative scores. The meta-analysis showed a significant difference (WMD = 3.06; 95% CI, 2.75–3.37, *P* < 0.00001) without heterogeneity [I^2 = 32.0%; *P* = 0.153). These findings provide strong evidence that MILD treatment effectively relieves symptoms within 6 months postoperatively. The reduction in WMD supports this conclusion while the absence of heterogeneity in the overall analysis adds to the validity of these findings.

6 Months ≤ MILD Postoperative < 1 Year

As shown in Table 3, 12 trials compared pre- and postoperative decreased scores; the meta-analysis demonstrates a significant difference (WMD = 2.74; 95% CI, 2.20–3.28, *P* < 0.00001) without heterogeneity (I^2 = 47.7%; *P* = 0.105). Therefore, these findings suggest consistent findings across the trials. The meta-analysis showed a significant improvement in VAS scores post MILD intervention, indicating the effectiveness of this treatment in reducing pain in the one year range.

≥ 1 Year MILD Postoperatively

According to the results presented in Table 3, 12 trials were included for VAS score analysis, all of which assessed the effect of the MILD intervention after one year. There is a statistically significant difference in the decrease of postoperative pain scores, with a WMD of 2.88 (95% CI, 2.44–3.32; *P* < 0.00001). Importantly, no heterogeneity was observed among the included studies (I^2 = 0; *P* = 0.729). These findings consistently indicate that MILD is effective in reducing pain levels, as demonstrated by the improvement in VAS scores.

The Effects of MILD on ODI Score

Total Sample Mean Score

As shown in Table 3, 8 trials (8,9,11,12,14-16,18) evaluated the pre- and postoperative ODI scores. The scores decreased by an average of 13.61 points overall. Our meta-analysis showed a significant difference (WMD = 13.61; 95% CI, 11.09–16.13; *P* < 0.00001), without heterogeneity (I^2 = 35.1%; *P* = 0.149). These results indicate that the treatment options assessed in the trials were effective in reducing ODI scores and improving patients' daily life quality by reducing leg and back pain.

< 6 Month MILD Postoperatively

As shown in Table 3, in 8 trials comparing pre- and postoperative ODI scores at less than 6 months postoperatively, our meta-analysis revealed a significant difference, with an average improvement of 12.45 points (WMD = 12.45; 95% CI, 9.69–15.21; *P* < 0.00001). Notably, there was no significant heterogeneity observed among the studies (I^2 = 32.5%; *P* = 0.192), suggesting that the treatment options consistently led to improvements in ODI scores without substantial variation among the studies.

These findings provide strong evidence that the evaluated treatment options were effective in reducing ODI scores and improving patients' quality of life by reducing leg and back pain.

6 Months ≤ MILD Postoperative < 1Year

As shown in Table 3, in 8 trials comparing pre- and postoperative ODI scores, our meta-analysis revealed a significant difference with an average improvement of 15.40 points (WMD = 15.40; 95% CI, 11.28–19.53; *P* < 0.00001). Notably, there was no significant heterogeneity observed among the studies (I^2 = 24.4%; *P* = 0.265), suggesting that MILD treatment consistently led to improvements in ODI scores without substantial variation among the studies.

≥ 1 Year MILD Postoperatively

As shown in Table 3, 8 trials evaluated the comparison of pre- and postoperative decreased scores. Our meta-analysis showed that in the WMD/OR column, ≥ one year after mild surgery, ODI scores decreased by 13.04 (WMD = 13.04; 95% CI; 9.25–16.84; *P* < 0.00001) without heterogeneity (I^2 = 45.3%; *P* = 0.161). The results from the analysis suggest that MILD treatment can significantly improve patients' quality of life by reducing leg and back pain at one year posttreatment.

Discussion

The prevalence of spinal stenosis increases with age. LSS is associated with a high risk of low back pain and disability (19). Appropriate treatments are medical-

ly necessary to improve pain and function for patients with severe neurogenic claudication. However, no clear standard has been established for treating spinal stenosis. Current treatments for LSS range from conservative management with anti-inflammatory medications, physical therapy and lumbar epidural steroid injections, to surgical decompression. For patients with moderate to severe stenosis, these conservative measures often fail to provide adequate improvement; surgical decompression of the spinal canal to relieve compression of the cauda equina and spinal nerves is required for most cases. Nonsurgical interventions including lumbar supports, exercise, and epidural corticosteroid injections have shown poor efficacy in clinical trials (1). Surgical decompression is associated with good outcomes. There is strong clinical evidence to show decompressive surgery is superior to nonsurgical treatment for selected patients with neurogenic claudication (20-23).

Traditional surgical decompressions include laminectomy, foraminotomy, facetectomy and discectomy. In some cases, fusion with instrumentation is required to preserve the stability of the lumbar spine post decompression. Although prior studies have provided evidence of good outcomes in the majority of patients, the potential complications of traditional surgeries, including local tissue trauma, postoperative pain, and nerve damage are of significant concern (24). In addition, there is a substantial number of patients with severe neurogenic claudication who are not appropriate candidates for surgery due to high surgical risks related to comorbidities or unwillingness to undergo back surgery. In these cases, a minimally invasive lumbar decompression procedure offers a safe and effective alternative option.

MILD is a minimally invasive, fluoroscopically guided percutaneous procedure designed to partially remove the thickened LF. It is generally performed under anesthesia sedation, in contrast to most spine surgeries that require major incisions, and general anesthesia. There are numerous prospective studies reporting pain and functional improvement due to MILD. However, an imaging study using magnetic resonance imaging and computed tomography at 12 weeks postoperative did not reveal an improvement in stenosis compared to preoperative imaging (11). Therefore, the mechanism of pain reduction and functional improvement from MILD remains unclear.

The hypotheses of improvement from MILD are reduction of intraligament or intra spinal canal pressures without an effect on spinal canal diameter, placebo effect, and increased use of pain medications in the postoperative period. To further clarify the mechanism of improvements in pain and function, a randomized double-blind placebo controlled trial would be ideal. However, it is impractical to conduct such a trial due to hospital stay, the complexity of randomization, blinding, anesthesia, and ethical issues related to invasive procedures. Therefore, we conducted this meta-analysis to confirm the efficacy of the MILD procedure.

Our meta-analysis of 12 trials compared pre- and postoperative effects. All trials showed that MILD produced statistically significant improvements in pain and function compared to baseline. The pain score improvement was 3.06 at < 6 months postoperative, 2.74 at 6 months to one year postoperative, and 2.88 at > one year postoperative. The longest follow-up study was 5 years. These data indicate sustained clinically meaningful improvement from the MILD procedure. According to studies reporting pain scores, a reduction of 2 or more points is considered clinically meaningful improvement (25,26). As to functional outcome, ODI is one of the measurement tools with good validity and reliability (27,28). Clinically meaningful improvement of ODI was defined as ≥ a 10-point improvement from baseline to follow-up (26,29). Our study revealed a reduction of 12.45 points at < 6 months postoperative, 15.40 points at 6 months to one year postoperative, and 13.04 at > one year postoperative, which indicates long-term functional improvement from MILD.

Open surgical decompression is a good option and often required for certain patients. MILD can be considered for patients who are poor candidates for open surgeries due to comorbidities as well as patients with stenosis primarily from LF hypertrophy at one or 2 levels. It is worth noting that MILD is a percutaneous, minimally invasive procedure that causes minimal tissue injuries and scar formation. It also does not affect future open surgical options if it is required. Spinal surgeries carry a low but definite rate of neurological deficits despite the improvement in surgical techniques and equipment. The reported average rate of iatrogenic neurological deficit post-LSS is 9% (SD, 0.46%–24%) (30). Other common complications associated with spinal decompression are bleeding and dural tears, with estimated incidences of 14.3% and 9.4% respectively (21). In our meta-analysis, comprising 500 patients, there were no reported cases of postoperative neurological deficit or dural tear. The most common complication was soreness at the operation site. These data suggest that the MILD procedure has an excellent safety profile when compared to open decompression spine surgeries.

Spinal stenosis has many contributing factors, including intervertebral disc herniation or spondylolisthesis and hypertrophy of facet joints or congenital short pedicles, and LF hypertrophy. MILD can only decompress the central canal by debulking a hypertrophied LF. Ideally, future studies should be designed to enroll patients who have central canal stenosis due to a hypertrophied LF. While most clinicians in the studies in our meta-analysis developed inclusion and exclusion criteria in an attempt to enroll patients with stenosis primarily from LF hypertrophy, the presence of other contributing factors were not excluded. In a prospective study by Deer, et al (16), the inclusion criteria were neurogenic claudication primarily caused by LF hypertrophy, preoperative magnetic resonance imaging or computed tomography that revealed radiologic evidence of hypertrophic LF > 2.5 mm, and a clearly reduced central canal cross-sectional area. But the presence of other, less predominant contributing factors was not exclusionary. Staats, et al (31) used similar inclusion criteria that patients who had central canal stenosis with neurogenic claudication and LF hypertrophy of greater than 2.5 mm thickness were enrolled. One of the limitations of our meta-analysis is the clinical trials on MILD that we included did not have the same exclusion and inclusion criteria. However, conceivably more stringent inclusion and exclusion criteria will achieve improved patient selection and lead to better data and conclusions.

Limitations

There are other limitations in our meta-analysis. One is the lack of standard conservative treatments. While all clinical trials in our meta-analysis adopted conservative treatments prior to performing MILD, there were no standardized treatment modalities and follow-up times. It is conceivable that clinicians adopt various treatment modalities into their daily practice. However, if we need to know the effect of conservative treatments, and compare it to other treatments, it is necessary to define a set of standard conservative treatments. Another limitation of our meta-analysis is the lack of objective outcome tools. All the included studies employed subjective outcome tools, including VAS and ODI scores. These self-reported outcome tools are subject to bias. There are objective pain assessments available, such as functional magnetic resonance imaging and electroencephalogram. However, these assessments are still in the development stage, and require more validation before they can be used in clinical practice (32). With respect to objective measurements of function, there are tests such as self-paced walking capacity and accelerometer (33,34). These are validated tests that can be used to measure the functional status of patients with spinal stenosis in order to decrease subjective bias in clinical trials.

In addition, this meta-analysis has other limitations, such as including retrospective studies, the high heterogeneity of the included trials, and publication bias, all of which render our study susceptible to the influence of bias; additional prospective and standardized multicenter studies are needed to confirm our conclusions.

Conclusions

Our meta-analysis calculated VAS pain scores and ODI scores as well as complications and adverse events across the pooled patients. We found MILD resulted in significant clinical improvement, as indicated by the changes in VAS and ODI scores. In addition, adverse events were low compared to other surgical decompression techniques. We conclude MILD is an effective and safe surgical technique for patients with stenosis from LF hypertrophy. However, additional prospective and standardized multicenter studies are needed to confirm this conclusion.

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