Percutaneous Image-Guided Lumbar Decompression: A Systematic Review of the Minimally Invasive Lumbar Decompression (MILD) Procedure

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PREFACE

The VA Evidence Synthesis Program (ESP) was established in 2007 to conduct timely, rigorous, and independent systematic reviews to support VA clinicians, program leadership, and policymakers improve the health of Veterans. ESP reviews have been used to develop evidence-informed clinical policies, practice guidelines, and performance measures; to guide implementation of programs and services that improve Veterans' health and well-being; and to set the direction of research to close important evidence gaps. Four ESP Centers are located across the US. Centers are led by recognized experts in evidence synthesis, often with roles as practicing VA clinicians. The Coordinating Center, located in Portland, Oregon, manages program operations, ensures methodological consistency and quality of products, engages with stakeholders, and addresses urgent evidence synthesis needs.

Nominations of review topics are solicited several times each year and submitted via the ESP website. Topics are selected based on the availability of relevant evidence and the likelihood that a review on the topic would be feasible and have broad utility across the VA system. If selected, topics are refined with input from Operational Partners (below), ESP staff, and additional subject matter experts. Draft ESP reviews undergo external peer review to ensure they are methodologically sound, unbiased, and include all important evidence on the topic. Peer reviewers must disclose any relevant financial or non-financial conflicts of interest. In seeking broad expertise and perspectives during review development, conflicting viewpoints are common and often result in productive scientific discourse that improves the relevance and rigor of the review. The ESP works to balance divergent views and to manage or mitigate potential conflicts of interest.

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Operational Partners

Operational partners are system-level stakeholders who help ensure relevance of the review topic to the VA, contribute to the development of and approve final project scope and timeframe for completion, provide feedback on the draft report, and provide consultation on strategies for dissemination of the report to the field and relevant groups.

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Technical Expert Panel

To ensure robust, scientifically relevant work, the technical expert panel (TEP) guides topic refinement; provides input on key questions and eligibility criteria, advising on substantive issues or possibly overlooked areas of research; assures VA relevance; and provides feedback on work in progress. TEP members included:

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DISCLOSURES

This report was prepared by the ESP Center located at the **Minneapolis VA Health Care System,** directed by Timothy J. Wilt, MD, MPH and Wei Duan-Porter, MD, PhD and funded by the Department of Veterans Affairs, Veterans Health Administration, Health Systems Research.

The findings and conclusions in this document are those of the author(s) who are responsible for its contents and do not necessarily represent the views of the Department of Veterans Affairs or the United States government. Therefore, no statement in this article should be construed as an official position of the Department of Veterans Affairs. The final research questions, methodology, and/or conclusions may not necessarily represent the views of contributing operational and content experts. No investigators have affiliations or financial involvement (eg, employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in the report.

Executive Summary

KEY FINDINGS

- **Key Question 1: Among adults with lumbar spinal stenosis, what is the efficacy and safety of percutaneous image-guided lumbar decompression (PILD/MILD)?**
- Safety and efficacy findings are limited by quantity, quality, and applicability of evidence.
- Individuals typically had chronic severely symptomatic lumbar spinal stenosis (LSS) due to ligamentum flavum thickening (≥2.5 mm) and failed prior nonsurgical therapies.
- There is no evidence from VHA medical centers, among individuals with less severe or shorter symptom duration, those undergoing repeat MILD, whether effects vary by patient and spine characteristics or clinicians' training, experience, and volume.
- In adults with chronic severely symptomatic LSS due to ligamentum flavum thickening (≥2.5 mm) who failed prior nonsurgical therapies, comparative effectiveness evidence from randomized controlled trial (RCT) evidence indicates that MILD compared with:
    - Conventional medical management (CMM) (*k* = 1 RCT; high RoB, *N* = 155)
        - Reduced pain severity and interference through 1 year. Mean between group improvements were modest. Reductions in the MILD group achieved minimally important changes. Adverse events did not differ between groups. Subsequent spinal interventions, including surgery, were greater in the CMM group, though >80% of interventions in the CMM group were MILD procedures (all low certainty of evidence [COE]).
    - Epidural steroid injection (ESI) (*k* = 2; 1 low RoB, *N* = 38; 1 High RoB, *N* = 302)
        - Did not reduce pain severity or interference at 6 weeks (low COE).
        - Reduced pain severity and pain interference at 6 months and 1 year (low COE). Patients in the MILD, but not the ESI, group had clinically meaningful improvements from baseline to follow-up at both 6 months and 1 year. The percentage of individuals achieving a minimally important change from baseline (responders) for both pain severity and interference was greater with MILD than ESI (low COE).
        - Resulted in fewer subsequent surgeries at 1 year and little to no difference in adverse events (low COE).
    - Laminectomy with spinal fusion (*k* = 1, high ROB; *N* = 50)
        - Resulted in little to no difference in pain severity or interference (low COE) at 1 year. Both groups and clinically meaningful improvements from baseline (low COE).
        - Evidence was very uncertain regarding subsequent surgeries or adverse events (very low COE).
- In adults with LSS who failed CMM for 6 months, Medicare claims data indicate that those who received MILD compared with those who received:
    - Lumbar laminectomy without fusion (*k* = 1, *N* = 9,343)

        - Had more subsequent surgeries within 2 years (moderate COE).
        - Had fewer procedural complications/adverse events (moderate COE).

- ► In adults with LSS who failed CMM for 6 months, results based on Medicare claims data indicate that among those who received MILD compared with those who received:
    - Interspinous spacers (*k* = 2 cohort studies of Medicare claims data)
        - Was associated with little to no difference in subsequent surgeries but fewer procedural complications, or adverse events (all low COE).
- ► Evidence from generally small (n ≤ 75) uncontrolled observational studies reported:
    - Subsequent surgeries following MILD ranged from 0–60% over 2–60 months.
    - Zero complications or adverse events following MILD at longest follow-up time.
- ► Improvement in symptoms from baseline occurred in both the MILD and comparator groups including for therapies where previous RCT evidence indicates little to no comparative benefit (CMM beyond 3 months, ESI, and laminectomy plus fusion).
- ► Information from RCTs included individuals with severe symptomatic LSS due to ligamentum flavum hypertrophy who failed CMM and were treated by clinicians experienced with MILD.

Lumbar spinal stenosis (LSS) is due to a narrowing of the spinal canal in the lower part of the back, primarily due to age related to ligamentum flavum hypertrophy (LFH). LSS symptoms can be disabling and include numbness, fatigue, pain in the buttocks and/or legs which may increase with activity such as walking (neurogenic claudication) and relieved by sitting or bending forward. LSS prevalence in the United States is estimated to range from 11% to 39%.

Treatment for LSS includes non-steroidal anti-inflammatory medications, gabapentin, and duloxetine (a serotonin-norepinephrine reuptake inhibitor), physical therapy (*eg*, swimming, biking, stretches, strength training), manual therapy (*eg*, spinal mobilization, stretches), and epidural steroid injections (ESI). However, randomized controlled trials (RCTs) have demonstrated limited effectiveness of these options and the long-term benefits of ESI have not been demonstrated.

For patients whose symptoms do not adequately respond to nonsurgical treatments, lumbar decompression surgery (laminectomy) with or without spinal fusion is the most frequently utilized option for those over 65 years of age. Symptomatic LSS is costly, with estimated non-surgical medical management costs over $9,800 in a 2-year period. However, RCTs have found that average improvements in pain and disability due to decompression surgery are modest compared with usual care or physical therapy, and effectiveness does not differ between surgical decompression with, versus without, spinal fusion. Laminectomy without fusion, while often done in ambulatory surgery centers, requires postoperative recovery (typically 6 weeks for decompression without fusion and up to 6 months with fusion), and has risks including perioperative wound complications and mortality. These risks are higher among individuals undergoing decompression with fusion compared with those without. Finally, some patients are not surgical candidates or choose not to undergo surgery.

There has been growing need and interest in less invasive yet effective decompressive procedural options. A new procedure for lumbar decompression for LSS secondary to LFH that has emerged is percutaneous image-guided lumbar decompression (PILD) also known as "Minimally Invasive Lumbar Decompression" (MILD). PILD/MILD is performed under indirect image guidance and involves use of specialized instruments for percutaneous limited laminectomy and thinning of the ligamentum flavum. In 2016, the Centers for Medicare and Medicaid Services expanded a National Coverage Determination which allows coverage for PILD under Coverage with Evidence Development through a prospective longitudinal study of an FDA-approved PILD device. Currently, there is 1 commercially available disposable percutaneous device available for lumbar decompression, *Mild* (Minimally Invasive Lumbar Decompression, Vertos Medical, Aliso Viejo, CA, USA).

CURRENT REVIEW

In response to a request from the Veterans Health Administration (VHA) Office of Integrated Veteran Care Clinical Determinations Unit and the Pain Management Opioid Safety and Prescription Drug Monitoring Program, we conducted a systematic review on the efficacy and safety of percutaneous image-guided lumbar decompression (*eg,* MILD procedure). This review will be used to inform development of a Clinical Determination and Indication document to help community clinicians and VHA staff determine if a Veteran meets the clinical criteria for this procedure.

A preregistered protocol for this review can be found on the PROSPERO international prospective register of systematic reviews (CRD420251076612). See Key Findings above for the Key Question.

We searched MEDLINE (Ovid), Embase (Ovid) and CENTRAL via Cochrane Library (Wiley) through April 21, 2025 using terms for *back pain, spinal stenosis, minimally invasive lumbar decompression, and percutaneous lumbar decompression.* Additional citations were sought by hand-searching reference lists and consultation with content experts. Clinical trial registries were also searched for recently completed and ongoing trials.

After removing duplicate search results, titles and abstracts were screened by 2 independent reviewers with consensus required to exclude abstracts. Included abstracts then underwent full-text review by 2 reviewers, with inclusion of papers requiring agreement of both reviewers. Disagreements were resolved by team consensus.

Effect information and population, intervention, and comparator characteristics were abstracted from all included studies by 1 reviewer and verified by a second. The internal validity (risk of bias [RoB]) of each study was rated by 2 independent reviewers and disagreements (for domains and overall) were resolved by discussion or with team consensus. RCTs were rated using Cochrane Risk of Bias 2.0. Controlled cohort studies were rated with the Cochrane Risk of Bias in Non-Randomized Studies of Interventions (ROBINS-I). Case series, case reports, and other uncontrolled study designs were assessed with elements to assess the methodological quality of case series and case reports as described by Murad et al.

Due to lack of sufficient data and variation in comparisons, quantitative meta-analysis could not be performed. We have narratively summarized the results grouped by comparator type.

We rated the certainty of evidence (COE) for priority outcomes (pain severity, pain interference, subsequent surgeries, and adverse events) based on the methodology and risks of bias of available

studies, the consistency and certainty of findings, and the directness of outcomes (with the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) approach.

We identified 4 RCTs (3 in US, 1 in Egypt) and controlled observational studies ($k = 3$). The remaining were uncontrolled case series/reports; $k = 17$). All but 2 reports, 1 small (n = 10) uncontrolled report from Canada and 1 RCT (n = 50) from Egypt, were conducted in the US. Data reported at long-term (>2 years) follow-up were sparse, and for the 2 RCTs reporting at longer term follow-up, data were only reported for the intervention group and no comparisons were made. Most identified studies were small, short-term, observational studies.

MILD COMPARED WITH CONVENTIONAL MEDICAL MANAGEMENT

One high risk of bias RCT (MOTION; $N = 155$) compared MILD plus conventional medical management (CMM) to CMM alone among adults with severely symptomatic LSS due to LFH (≥2.5 mm) who had received >3 months of CMM. Patients could not undergo recent ESI or prior spinal surgery at index level.

MILD reduced pain severity and interference through 1-year compared with CMM. Mean between-group improvements were modest. While both groups improved from baseline, reductions in the MILD group achieved a minimally important change. Adverse events did not differ between groups. Subsequent spinal interventions, including surgery, were greater in the CMM group, though >80% of interventions in the CMM group were MILD procedures (all low COE).

MILD COMPARED WITH EPIDURAL STEROID INJECTIONS

Two RCTs compared MILD with ESI in adults with severely symptomatic LSS due to LFH (>2.5 mm) who had not adequately responded to CMM. Patients could not have undergone prior lumbar spinal surgery or recent ESI. Brown et al was a small ($N = 38$), short-term, single-center study rated low RoB and the only trial that blinded participants to treatment assignment. However, it only reported efficacy outcomes at 6 weeks. The MiDAS ENCORE trial was a larger multi-center RCT ($N = 302$), rated high RoB and reported comparative outcomes at 6 months, 1 year, and 2 years.

Compared with ESI, MILD did not reduce pain severity or interference at 6 weeks (low COE).

Compared with ESI, MILD reduced pain severity and pain interference at 6 months and 1 year (low COE). Patients in the MILD, but not the ESI, group had clinically meaningful improvements from baseline follow-up at both 6 months and 1 year. The percentage of individuals achieving a minimally important change from baseline (responders) for both pain severity and interference was statistically significantly greater with MILD than ESI (*eg,* % achieving improvement in Oswestry Disability Index (ODI) of ≥10 points (58.0% vs 27.1%; Zurich Claudication Questionnaire [ZCQ] symptom severity >0.5 point: 51.7% vs 31.8%) (low COE). MILD resulted in fewer surgeries at 1 year and little to no difference in adverse events (low COE).

MILD COMPARED WITH LAMINECTOMY PLUS FUSION

One small ($N = 50$) high risk of bias trial conducted at 2 study sites in Egypt assessed comparative effects of MILD versus laminectomy with fusion. There may be little to no difference in pain severity and pain interference between MILD compared with laminectomy with fusion (both low COE). This trial measured pain severity via the visual analog scale (VAS) for leg pain and back pain separately,

immediately post-treatment, and at 1-year post-treatment, finding no statistically significant differences between the MILD and laminectomy with fusion groups. The improvement from baseline in both groups exceeded the minimal clinical important difference (MCID). Similarly, authors found little to no difference in pain interference between MILD compared with laminectomy with fusion at 6 months and 1 year based on ODI scores. The improvement from baseline to follow-up exceeded MCID in both groups. The evidence was very uncertain regarding comparative effects on subsequent surgeries or adverse events, primarily due to very few events and imprecise results (very low COE).

MILD COMPARED WITH LAMINECTOMY WITHOUT FUSION

One large US observational cohort ($N = 9,343$) used administrative data from the Centers for Medicare and Medicaid Research Identifiable Files to analyze subsequent surgeries/procedures/adverse effects of individuals receiving MILD compared with laminectomy without fusion. Individuals receiving MILD were older and had more comorbidities than individuals receiving laminectomy without fusion. Authors did not attempt to adjust for patient demographics or comorbidities and provided no information on clinical indications, provider experience, or efficacy outcomes. Lumbar laminectomy without fusion was associated with more subsequent surgeries and fewer procedural complications and adverse events within 2 years compared with MILD (moderate COE).

MILD COMPARED WITH INTERSPINOUS SPACERS

Two large observational cohort studies used administrative Medicare claims data from slightly different time periods and with populations that mostly overlapped. Both were industry funded (one from the manufacturer of MILD and the other from the manufacturer of interspinous spacers). There was variability in outcome definition, length of follow-up, and individual study conclusions. Nonetheless, we determined that in adults with LSS who failed CMM for 6 months, among those who received MILD, compared with those who received interspinous spacers, there was little to no difference in subsequent surgeries but fewer procedural complications, or adverse events (all low COE).

UNCONTOLLED STUDIES OF MILD

Evidence from generally small ($N \leq 75$) uncontrolled observational studies reported that subsequent surgeries in individuals having MILD ranged from 0–60% over 2–60 months. No complications or adverse events following MILD were reported at longest follow-up time.

LIMITATIONS

Results, conclusions, and implications for clinical practice and policy are limited in several ways. Evidence quantity is sparse and includes only 4 RCTs. None of the RCTs were large in size or provided adequate data beyond 1 year. All studies reported improvements from baseline in both the intervention and control groups; an issue commonly seen in studies of interventions evaluating patient-reported outcomes such as pain and function. This “placebo” effect makes interpretation of findings from studies without blinding of interventions challenging, and it also requires basing effectiveness decisions on changes from baseline or uncontrolled reports, particularly if interventions have harms and costs.

Only 1 trial (MILD vs ESI) was rated low risk of bias, but its reporting did not extend beyond 6 weeks. A single study compared MILD with lumbar decompression surgery. However, this trial was very

small, conducted outside the US, rated high risk of bias, and included spinal fusion, which has more harms and costs without additional benefits relative to lumbar decompression without fusion.

Individuals enrolled in RCTs had chronic and severe LSS symptoms believed due to LFH (≥2.5 mm [1”]) despite CMM. Clinicians providing MILD in RCTs were experienced and trained. It is not known how clinician training, experience, volume, and patient selection influences outcomes due to MILD. The effect of MILD on those with less severe disease and shorter symptom duration is not known. RCTs typically excluded individuals with prior surgery or MILD at the index site. The effectiveness and harms of repeat MILD are not known. Most observational studies were uncontrolled and small. None provided information on patient selection including spinal conditions, symptom duration or severity or clinician experience, training, volume, or assessed effectiveness. Observational studies are prone to important selection biases.

APPLICABILITY OF FINDINGS

Our findings are limited by quantity, quality, and applicability of evidence. Information from RCTs included individuals with severe symptomatic LSS due to LFH who failed CMM and were treated by clinicians experienced with MILD. Improvement in symptoms from baseline occurred in both the MILD and comparator groups including for therapies commonly used for symptomatic LSS where previous RCT evidence indicates little to no comparative benefit (CMM beyond 3 months, ESI beyond 6 weeks, and laminectomy plus fusion). Improvements from baseline for individuals treated with MILD exceeded established minimal clinically important differences, though treatment effects comparing MILD with other approaches studied were typically small. No studies were done in VA or reported results on Veterans. Applicability to Veterans and VA clinicians may be limited, although LSS due to LFH is a common health concern among Veterans, and VA surgical capacity may be limited. We found no evidence in individuals with less severe or shorter symptom duration, those undergoing repeat MILD, or whether comparative effects of MILD vary by patient and spine characteristics or clinicians’ training, experience, and volume.

FUTURE RESEARCH

Additional blinded randomized trials are needed to examine the benefits and harms of MILD compared with surgical laminectomy, long-term durability and repeatability of MILD, and outcomes in a broader range of individuals, including those with less severe symptoms and those treated by a wider range of clinicians, including clinicians with less advanced MILD training/experience. Ongoing surveillance should evaluate patients treated with MILD to develop and assess patient selection and clinician training criteria, long-term effectiveness and harms, need for subsequent interventions, and cost effectiveness.

CONCLUSIONS

Among individuals with severely symptomatic LSS due to LFH (≥2.5 mm), MILD may improve pain and function at 1 year versus continued CMM, though the comparative effect is modest. MILD may reduce longer-term pain severity and interference compared with ESI. Compared with lumbar decompression surgery plus fusion, MILD may have similar effects on pain and function but the effects on harms and subsequent surgeries are very uncertain. Compared with interspinous spacers, the evidence regarding subsequent surgeries is very uncertain but MILD may be associated with fewer adverse events. Clinically meaningful improvements in pain and function compared with baseline occurred in patients receiving MILD. Information from observational studies is limited by selection

bias and lack of reporting of clinical indications for procedures. However, complications and adverse events were infrequent. Most reports were small in size. There are no data in patients with less severe symptomatic LSS or versus laminectomy without fusion. Findings are limited by the quantity and quality of evidence and the magnitude of benefits versus comparators that may not be clinically meaningful. Additionally, patient selection, clinician experience, and the lack of convincing evidence of long-term effectiveness of commonly used comparator interventions in published studies limits findings.