Endoscopic Decompression of Spinal Cord for Adults with Sciatica or Low Back Pain (CPT 62380)

November 2017

Updated Information/Addendum

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Overview

This addendum provides an update to the October 2017 report by Ray, Thielke, and King (2017) that evaluated the evidence for the effectiveness and safety of endoscopic decompression of the spinal cord.

Key Findings

- One additional systematic review and 12 additional case series studies were identified in the updated search of the Ovid MEDLINE database.
- The fair methodological quality systematic review identified three studies that compared percutaneous endoscopic lumbar disc herniation (PELD) or microendoscopic decompression surgery (MED) to micro- or open discectomy for individuals with recurrent lumbar disc herniation (LDH). The three studies were included by the fair methodological systematic review (Li et al., 2016) previously evaluated in the October 2017 ("original") report by Ray et al. (2017).
- The 12 case series studies provide additional information on adverse events from endoscopic decompression surgery. Additional identified adverse events that were not included in the original report by Ray et al. (2017) include guide wire breakage, head and neck pain, numbness, and wound dehiscence.
- Based on the additional studies, there are no updates to the strength of evidence findings of the original report by Ray et al. (2017).

Methods

Center for Evidence-based Policy (Center) researchers searched Ovid MEDLINE for systematic reviews (with or without meta-analysis), technology assessments, and individual studies on the use of endoscopic decompression that were published between January 1, 2017 to November 20, 2017. The original report included systematic reviews and technology assessments published within the last 10 years, and updated the identified systematic reviews by including an additional search of the Ovid MEDLINE database for individual studies published between January 1, 2016, and August 9, 2017 (Ray et al., 2017). This report update is intended to identify any newly published studies since the search completed for the original report (Ray et al., 2017). Given the delay of article indexing in the PubMed database, the search dates of the original report and this update intentionally overlap.

Center researchers evaluated the methodological quality of systematic reviews and individual studies eligible for this report update using the methodology described in detail in Appendix A of the original report (Ray et al., 2017) and methodological quality assessment tools described in the New York State Department of Health's dossier process (available on pages 14 to 33 of the

Dossier Submission Form located on the New York State Department of Health website)[1]. Center researchers followed the study inclusion and exclusion criteria as described in the original report (Ray et al., 2017). See Appendix A of the original report for a full description of methods (Ray et al., 2017).

Evidence Review

Findings

Center researchers, through a search of the Ovid MEDLINE database, identified one additional systematic review relevant to the effectiveness of endoscopic decompression for recurrent LDH that met inclusion criteria (Onyia & Menon, 2017).

Center researchers identified additional 12 case series studies published after the search dates from the most recent systematic reviews identified in the original report (Ray et al., 2017). Center researchers included case series for evaluation of potential harms if they included more than 15 individuals.

Figure 1 outlines the number of articles identified by the updated Ovid MEDLINE search and the total number of studies included in this updated literature search. The search strategies and list of studies reviewed in full text form with reasons for exclusion are in Appendices A and B, respectively.

Overview of Evidence Sources

Center researchers summarized the evidence as reported by the included systematic review. Center researchers did not review the methodological quality of eligible individual studies within the systematic review unless necessary for clarification of information reported in the systematic review. The studies included by the Onyia and Menon (2017) systematic review were also included in the Li et al. (2016) systematic review that was included in the original report by Ray et al. (2017).

Systematic Reviews with Meta-analysis

Onyia and Menon (2017)

Onyia and Menon (2017) conducted a fair methodological quality systematic review that compared the effectiveness and safety of different surgical approaches for the treatment of recurrent LDH (total n = 197). The authors conducted an extensive literature search for studies published between January 1, 2000, and January 29, 2017. The authors identified three comparative studies that reported on operating time, length of stay, pain, function, blood loss,

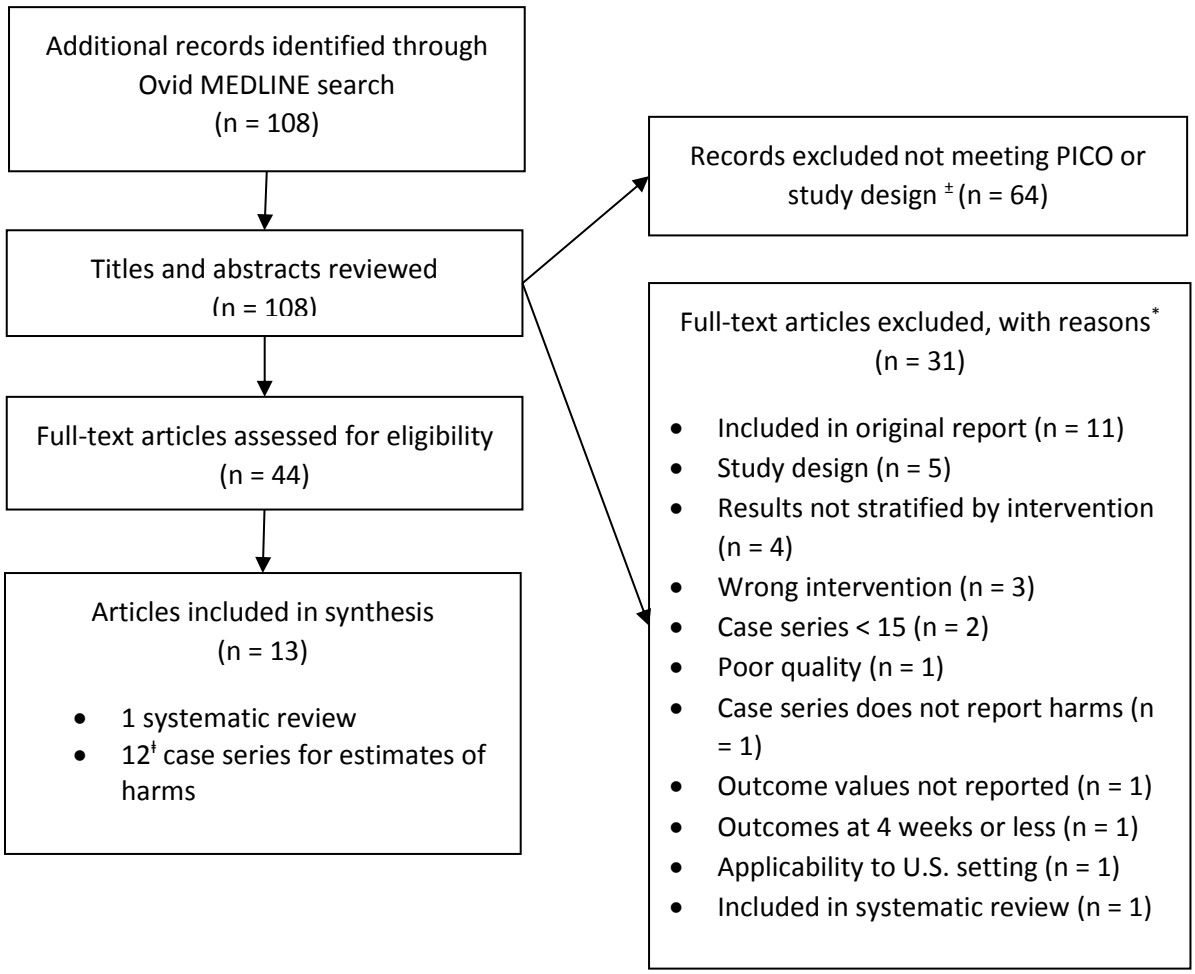
[1] Center researchers did not assess the methodological quality of the included case series. Case series studies are by definition non-comparative and are included to illustrate potential harms only. This type of study does not provide evidence of benefit. Any findings related to efficacy outcomes included in the case series studies are therefore are not included or described in this report.

and complications. The identified studies were also included by the fair methodological quality systematic review (Li et al., 2016) evaluated in the original report (Ray et al., 2017).

Individual Studies

Center researchers identified 12 case series studies from the updated search of the Ovid MEDLINE database. Because case series studies are non-comparative, these studies are included for estimates of harms only and formal methodological quality assessment was not done. There was significant heterogeneity across the included case series studies in terms of the type of endoscopic decompressive procedure used, geographic study location, patient demographics, and outcomes reported.

Figure 1. Search Results



± Articles were excluded if they did not meet predetermined inclusion criteria (e.g., PICO, study design, English language, publication date) as described in Appendix A.

ǂ Individual studies consisted of case series studies including more than 15 individuals and were included for harms only.

* Exclusion rationale provided in Appendix B.

Quality and Limitations

Center researchers rated the single identified systematic review as having fair methodological quality (Onyia & Menon, 2017). Center researchers did not assess the methodological quality of the individual studies included in Onyia and Menon (2017). Center researchers did not assess the methodological quality of the included case series studies.

Summary of the Evidence

The additional evidence is summarized in the tables below by outcomes of effectiveness and harms. Table 1 includes evidence for individuals with recurrent symptomatic LDH. Table 2 provides a summary on the incidence of adverse events reported in the additional case series studies. The adverse events reported in the additional case series studies are similar to those summarized in Table 4 of the original report by Ray et al. (2017). Incidence of infection, dural tears, nerve damage or root injury, fragment retention or incomplete decompression, dysesthesia, and hemorrhage were the most common reported adverse events in the original and additional case series studies identified. Additional adverse events that were not included in the original report by Ray et al. (2017) were reported by the additional case studies such as guide wire breakage, head and neck pain, numbness, and wound dehiscence. Several of the adverse events summarized in Table 4 of the original report by Ray et al. (2017) were not reported in the additional case series studies (e.g., bladder and bowel disturbance, paralysis, thrombosis, severe sensory radiculopathy).

Table 1. Overview of Additionally Included Studies for Symptomatic Recurrent Lumbar Disc Herniation

Citation, Study Details	# of Studies (k) Population (n) *Individual Study Quality*[a]	Study Summary and Findings	Comments
Systematic Review without Meta-analysis			
Onyia and Menon (2017) Search Dates 2000 to January 29, 2017 Eligible Study Designs Comparative studies Methodological Quality of the SR (assessed by Center researchers) Fair	k = 3 comparative studies total n = 197 *Methodological quality of included studies (assessed by the SR authors)*: Fair to poor	Comparators PELD vs. open discectomy or microdiscectomy Outcomes Author's conclusions: "Though quite few in number, each of these studies clearly demonstrate quite comparable outcomes among the various techniques evaluated, ranging from non-fusion techniques to surgeries which involved fusion. Overall results appear not to demonstrate any superiority of one method over the other for each, particularly in terms of relief of pain as a key symptom. In addition, the outcomes for the minimally invasive techniques also appear quite similar to those of the open conventional techniques." (p. 6).	The authors used the *Risk of Bias in Non-Randomized Studies of Interventions (ROBINS-I)* tool to assess study risk of bias, but do not factor this assessment into conclusions. The authors did not include studies with less than 10 participants. The included individual studies were also included by the fair methodological quality systematic review (Li et al., 2016) discussed in the original report by Ray et al. (2017).

Abbreviations. PELD: percutaneous endoscopic lumbar discectomy; SR: systematic review.

Table 2. Incidence of Adverse Events in Additional Case Series

Outcome	# of Case Series Studies Reporting Outcome	Incidence Ranges
Dural tear	9	0% to 6.4%
Nerve injury	8	0.4% to 4.0%
Surgical infections	8	0% to 1.6%
Dysesthesia	4	3.4% to 5.5%
Fragment retention or incomplete decompression	3	0.6% to 5.8%
Blood transfusion	2	0%
Numbness	2	4.0% to 7.1%
Discal cyst	1	2.0%
Guide wire breakage	1	0.8%
Head and neck pain	1	1.4%
Hematoma	1	0.7%
Paresthesia	1	3.1%
Transient motor weakness	1	3.6%
Wound dehiscence	1	2.0%

Discussion

Center researchers identified one additional systematic review on the effectiveness and harms of endoscopic decompression for recurrent LDH and 12 additional case series studies that reported on harms from endoscopic decompression surgery. The individual studies included in the newly identified systematic review were also included by a systematic review evaluated in the original report by Ray et al. (2017). The newly identified case series studies provided additional information regarding the incidence of harms. This additional evidence does not change the strength of evidence findings from the original report by Ray et al. (2017).

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Appendix A. Methods

Ovid MEDLINE Search Strategy

To ensure that the most recent data were included, Center researchers searched Ovid MEDLINE from January 1, 2017, to November 20, 2017, for systematic reviews and individual studies on the use of endoscopic decompression. The search strategy from the original report by Ray et al. (2017) was used with modifications to the date limitations.

Database: Ovid MEDLINE Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Ovid MEDLINE Daily, Ovid MEDLINE and Versions

Search Strategy:

1 Intervertebral Disc Degeneration/
2 Intervertebral Disc Displacement/
3 dis?opath$.tw,ot
4 spondylodiscitis.tw,ot
5 (spondylochondrosis or chondrosis).tw,ot
6 (hernia$ or perfora$ or ruptur$ or degenerat$ or displac$ or prolaps$ or protru$ or avuls$ or compress$ or extru$).tw,ot
7 1 or 2 or 3 or 4 or 5 or 6
8 Lumbar Vertebrae/
9 Lumbosacral Region/
10 8 or 9
11 Intervertebral Disc/
12 (intervertebral or intradiscal or intradiskal).tw,ot
13 11 or 12
14 10 and 13
15 (lumb$ adj (disc$ or disk$)).tw,ot
16 14 or 15
17 exp surgical procedures, minimally invasive/
18 (microdis?ectom$ or nucleotom$ or nucleoplast$ or annuloplasty or (microscop$ adj dis?oto$)).tw,ot
19 ((mini$ adj3 invas$) or mini?invas$).tw,ot
20 automated percutaneous discectomy.tw,ot
21 laser.tw,ot
22 ((percutaneous or transforaminal) adj (microendoscop$ or endoscop$ or dis?oscop$ or arthroscopy$)).tw,ot
23 transmuscular tubular.tw,ot
24 17 or 18 or 19 or 20 or 21 or 22 or 23

25 7 and 16 and 24
26 (animals not (humans and animals)).sh
27 25 not 26
28 limit 27 to english language
29 limit 28 to yr="2017 -Current"
30 limit 29 to (case reports or comment or editorial or interview or lectures or letter or personal narratives or video-audio media or webcasts)
31 29 not 30
32 remove duplicates from 31

Study Inclusion/Exclusion Criteria

Two Center researchers independently reviewed the results from the Center core sources and Ovid MEDLINE database searches at each stage of review (e.g., title and abstract, full text). Any study that was identified by at least one researcher as potentially meeting inclusion criteria was advanced to the next review level. All excluded studies were determined by two Center researchers as not meeting the predetermined inclusion criteria. Any disagreement between study reviewers regarding the inclusion of a study was arbitrated by a third Center researcher. Center researchers excluded studies that were not systematic reviews, meta-analyses, technology assessments, or individual studies (as applicable by topic); that were published before 2007; were published in a language other than English; or did not meet the specific inclusion/exclusion criteria outlined below.

Inclusion Criteria

Population: Adults with sciatica or low back pain arising from a ruptured, herniated, or bulging disc in the lumbar region, not responding to conservative management

Intervention: Endoscopic decompression of spinal cord or nerve root(s), including laminectomy, partial facetectomy, foraminotomy, discectomy and/or excision of herniated intervertebral disc, one interspace, lumbar (CPT code 62380)

Comparators: Microdiscectomy, open discectomy

Outcomes: Recovery time, change in pain (at least one year from procedure), function, quality of life, proportion of patients needing revision, adverse events (e.g., infection, bleeding, rehospitalization, morbidity, mortality), cost and cost-effectiveness

Exclusion Criteria

Study exclusion criteria included the following:

- Comments, letters, editorials, case reports
- Case series with a sample size <15 individuals
- Case series that did not report adverse events

- Studies reporting radiographic outcomes, surgery characteristics (e.g., operative time, incision size), or biological laboratory markers
- Systematic reviews that were assessed by Center researchers as having poor methodological quality
- Duplicate information from a research study published in more than one source (only the highest quality, most recent publication with outcomes of interest was included)
- Systematic reviews that included only studies summarized by more comprehensive, higher-quality, and/or more recently published systematic reviews
- Studies identified that were included in a summarized systematic review or technology assessment

Quality Assessment

Center researchers assessed the methodological quality of the included studies using standard instruments developed and adapted by the Center that are modifications of the systems in use by the Campbell Collaboration, Cochrane, the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA), the National Institute for Health and Care Excellence (NICE), and the Scottish Intercollegiate Guidelines Network (SIGN) (Campbell Collaboration, 2015; Higgins & Green, 2011; Moher, Liberati, Tetzlaff, & Altman, 2009; National Institute for Health and Care Excellence, 2014; Scottish Intercollegiate Guidelines Network, 2015). Two Center researchers independently rated all studies. In cases where there was not agreement about the quality of a study, consensus was reached through discussion.

Each rater assigned the study a rating of good, fair, or poor, based on its adherence to recommended methods and potential for biases. In brief, good-quality systematic reviews include a clearly focused question, a literature search sufficiently rigorous to identify all relevant studies, criteria used to select studies for inclusion (e.g., RCTs) and assess study quality, and assessments of heterogeneity to determine whether a meta-analysis would be appropriate. Good-quality RCTs include a clear description of the population, setting, intervention, and comparison groups; a random and concealed allocation of patients to study groups; low dropout rates; and intention-to-treat analyses. Good-quality systematic reviews and RCTs also have low potential for bias from conflicts of interest and funding source(s). Fair-quality systematic reviews and RCTs have incomplete information about methods that might mask important limitations. Poor-quality systematic reviews and RCTs have clear flaws that could introduce significant bias.

Appendix B. Articles Selected for Full-Text Review Inclusion/Exclusion Rationale

Citation	Inclusion/Exclusion Rationale
Akinduro et al. (2017)	Exclude: Results not stratified by intervention
Casimiro (2017)	Exclude: Outcomes at 4 weeks or less
Choi, Lee, Shim, Shin, and Park (2017)	Exclude: Included in original report
Choi, Shim, Park, Lee, and Park (2017)	Exclude: Study design (case series, does not report harms)
Di Martino, Russo, Denaro, and Denaro (2017)	Exclude: Study design (narrative review)
Eun, Eum, Lee, and Sabal (2017)	Exclude: Study design (case series, does not report harms)
Fan et al. (2017a)	Included for harms
Fan et al. (2017c)	Included for harms
Fan, Wang, Gu, Zhang, and He (2017b)	Exclude: Case series n < 15
Felbaum, Stewart, Distaso, and Sandhu (2017)	Exclude: Results not stratified by intervention
Feng et al. (2017)	Exclude: Poor methodological quality
Gu, Cui, Shao, Ye, and Gu (2017)	Exclude: Included in original report
Heo et al. (2017)	Exclude: Included in original report
Hu, Pan, Fang, and Jia (2017a)	Exclude: Study design (case report)
Hu et al. (2017b)	Exclude: Intervention
Kamson, Trescot, Sampson, and Zhang (2017)	Exclude: Included in original report
Kang, Li, Cheng, and Liu (2017)	Exclude: Included in original report
Kapetanakis et al. (2017)	Exclude: Study design (case series, does not report harms)
Kim et al. (2017a)	Exclude: Applicability to U.S. setting
Kim et al. (2017b)	Included for harms
Li, Hou, Shang, Song, and Zhao (2017)	Included for harms
Liu, Chu, Yong, Chen, and Deng (2017)	Included for harms
Liu and Zhou (2017)	Exclude: Included in Onyia and Menon (2017) systematic review
Mahesha (2017)	Exclude: Included in original report
McClelland and Goldstein (2017)	Exclude: Results not stratified by intervention
Nakamura and Yoshihara (2017)	Included for harms

Citation	Inclusion/Exclusion Rationale
Oertel and Burkhardt (2017)	Included for harms
Onyia and Menon (2017)	Include
Overdevest et al. (2017)	Exclude: Intervention
Phan et al. (2017)	Exclude: Included in original report
Ren, Li, Qin, Sun, and Wang (2017)	Included for harms
Soman, Modi, and Chokshi (2017)	Exclude: Included in original report
Song, Hu, Liu, Hao, and Zhang (2017)	Included for harms
Song, Sheng, and Xu (2017)	Exclude: Outcome values not reported
Staartjes, de Wispelaere, Miedema, and Schroder (2017)	Exclude: Results not stratified by intervention
Tu et al. (2017)	Included for harms
Wang et al. (2017a)	Exclude: Intervention
Wang et al. (2017b)	Exclude: Included in original report
Wu, Zhang, Lu, Li, and Zhou (2017)	Exclude: Study design (case series, does not report harms)
Xie et al. (2017)	Included for harms
Xin et al. (2017)	Exclude: Case series n < 15
Yang and Lu (2017)	Included for harms
Yao et al. (2017a)	Exclude: Included in original report
Yao et al. (2017b)	Exclude: Included in original report

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The Center for Evidence-based Policy (Center) is recognized as a national leader in evidence-based decision making and policy design. The Center understands the needs of policymakers and supports public organizations by providing reliable information to guide decisions, maximize existing resources, improve health outcomes, and reduce unnecessary costs. The Center specializes in ensuring that diverse and relevant perspectives are considered and appropriate resources are leveraged to strategically address complex policy issues with high-quality evidence and collaboration. The Center is based at Oregon Health & Science University in Portland, Oregon.

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