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A cross-sectional analysis of harms reporting in systematic reviews evaluating laminectomy

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ABSTRACT

Background Context: Laminectomy is a common vertebral decompression procedure that has multiple potential adverse events which are not always reported in SRs.
Purpose: To evaluate the completeness of harms reporting in systematic reviews (SRs) on laminectomy.
Study Design: Cross-sectional analysis.
Methods: Eligible studies were SRs that evaluated laminectomy for any indication. MEDLINE (PubMed and Ovid), Embase, Epistemonikos, and the Cochrane Database of Systematic Reviews were searched in May 2022 to locate studies for inclusion. Screening and data extraction on harms reporting and study characteristics were performed in duplicate. AMSTAR-2 was used to evaluate the methodological quality of included SRs. Corrected covered area (CCA) was calculated for SR pairs.
Results: We included 26 SRs comprising 426 primary studies. Most SRs studied laminectomy for spinal stenosis, declared harms as a secondary outcome, and lacked or did not mention funding. Two SRs completely omitted harms, 9 had between 0% and 50.0% completion of harms items, and 15 had more than 50.1% completion. AMSTAR-2 graded 25 SRs (25/26, 96.2%) as 'critically low' and 1 SR (1/26, 3.8%) as 'low'. We found a statistically significant association between completeness of harms reporting and outcome specification. No other associations were statistically significant. Three SR pairs had CCAs >50% and were compared for unique and shared harms.
Conclusions: The completeness of harms reporting in SRs was inadequate. Because SRs often serve as tools for constructing clinical practice guidelines and clinical decision making, improvements must be made to enhance and refine harms reporting.

Background

Laminectomies — both cervical and lumbar — are common treatments for compressive spinal pathology [1]. With over 450,000 laminectomies performed each year at an average 30-day total cost of 70,000 USD, this procedure is a significant financial burden for the healthcare system [2,3]. While this treatment provides clinically significant neurological symptom improvement, complications and risks are present yet not often reported [4]. Clearly presented adverse events are necessary for health care professionals, policy makers, regulators, and patients

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to make educated decisions regarding medical interventions [5]. Moreover, adverse events are increasingly pertinent as postoperative complications correlate with our aging population [6]. Due to the importance of complete and accurate reporting in medical literature, a number of harms reporting guidelines have been produced.

Harms is the encompassing term for any complications, risks, adverse reactions, and adverse events that can be rationally associated with a medical intervention [5]. The efficacy of an intervention is commonly the outcome of interest in systematic reviews (SRs), and harms are often omitted or not evaluated at all [7]. While SRs are regarded as robust sources of evidence, they are not without bias and omissions. Many clinicians look to this study type to evaluate the incidence of negative outcomes among a population, however less than 10% report harms as their primary objective [7].

In order to optimize patient outcomes, surgical interventions like laminectomies require consistent and objective reporting of both benefits and harms. Otherwise, physicians and their patients will have a biased understanding of the possible outcomes when considering operative intervention. Therefore, we investigated whether the harms-related data in SRs of laminectomies was reliable and thorough. Our hypothesis is that the harms reporting will be incomplete and unstandardized in accordance with what previous studies have located in other fields of medicine and other study designs.

Methods

Study design

In compliance with Preferred Reporting of Systematic Reviews and Meta-analyses (PRISMA) guidelines, our cross-sectional analysis investigated harms reporting in SRs evaluating laminectomy [8,9]. Because no human subjects were involved in our study, IRB approval was not required.

Search strategy, harms terminology, and search string

Our sample was obtained using a search string created by a SR librarian which has been uploaded to the Open Science Framework (OSF) [10]. Both this report and the search string included terminology from the PRISMA harms group (Fig. 1) [5]. The librarian scoured MEDLINE (PubMed and Ovid), Embase, Epistemonikos, and the Cochrane Database of Systematic Reviews for eligible studies. The combined records were uploaded into a SR screening platform: Rayyan (https://rayyan.qcri.org/). Two of us excluded duplicates and independently screened search return titles and abstracts in a masked, duplicate fashion before unmasking to resolve disagreements.

Eligibility criteria

To satisfy inclusion criteria, a publication was required to be a SR with/without a meta-analysis evaluating laminectomy for any indication. The following types of studies were excluded from our sample: SRs not related to conventional laminectomy (e.g., SRs only evaluating laminectomy with fusion were excluded), animal studies, studies not in English, and any remaining study that did not meet inclusion criteria.

Training

An online Johns Hopkins course was completed to increase proficiency in assessing SRs and meta-analyses — see OSF for course link. Authors were briefed on data items — found in Tables 1-3 — regarding harms reporting. Next, authors extracted data from example SRs using a pilot-tested Google form. Reviewers were trained via lecture and video — see OSF for video link — to use A MeaSurement Tool to Assess systematic Reviews-2 (AMSTAR-2), which evaluates SR and meta-analysis methodological quality. Another pilot-tested Google form stated each item from the AMSTAR-2 instrument, allowing investigators to reconcile past responses if the overall quality assessments differed upon unmasking.

For both assessments above, investigators extracted example SRs in a masked, duplicate method with an additional investigator providing guidance. Authors then unmasked to review and reconcile discrepancies. Training was conducted by an expert in the field.

Table 1
Summary of characteristics of included studies (*n=26*).

Review Characteristics	No. (%)
Indications	
Spinal stenosis	12 (46.2)
Spinal myelopathy	7 (26.9)
Spinal tumor	3 (11.5)
Spondylolisthesis	1 (3.8)
Ossification of posterior longitudinal ligament	1 (3.8)
Spinal trauma	1 (3.8)
Not specified	1 (3.8)
Study mentions adherence to PRISMA[a]	
Yes	12 (46.2)
No	14 (53.8)
Intervention Favorable	
Yes	8 (30.8)
No	18 (69.2)
Was harms a primary or secondary outcome, or neither?	
Primary outcome	9 (34.6)
Secondary outcome	14 (53.8)
Neither	3 (11.5)
Conflicts of Interest	
Yes	20 (76.9)
No	3 (11.5)
Not stated	3 (11.5)
Funding Source	
Not funded	8 (30.8)
Not mentioned	8 (30.8)
Private	2 (7.7)
Public	6 (23.1)
Combination of funding NOT including industry	2 (7.7)
AMSTAR-2 Rating[b]	
High	0 (0.0)
Moderate	0 (0.0)
Low	1 (3.8)
Critically low	25 (96.2)

[a] Preferred Reporting Items for Systematic Reviews and Meta-Analyses [b]A MeaSurement Tool to Assess systematic Reviews

Data extraction

Two of us extracted study characteristics from each SR (Table 1). Investigators used methodology inspired by Mahady and colleagues [11] to extract data presented in Table 2 and methodology derived from Qureshi and colleagues [12–14] to extract data presented in Table 3. Data extraction was conducted with the masked, duplicate approach. A third author was available to resolve any discrepancies though this strategy was not used.

Additionally, we determined overlapping use of primary studies among included SRs via the corrected covered area (CCA) tool [15]. The CCA tool – a mathematical equation – calculated the extent of overlapping primary studies within two or more SRs. The equation was derived according to a table in which each SR was compared with other SRs. The equation is as follows:

$$CCA = \frac{C - U}{(U * R) - U}$$

The variables are defined: C is the total number of citations across the included SRs; U is the total number of unique citations; R is the number of SRs included in our sample. We defined a CCA greater than 50% as high overlap, between 20% and 50% as moderate overlap, and less than 20% as minimal overlap. The CCA between 2 SRs had to be

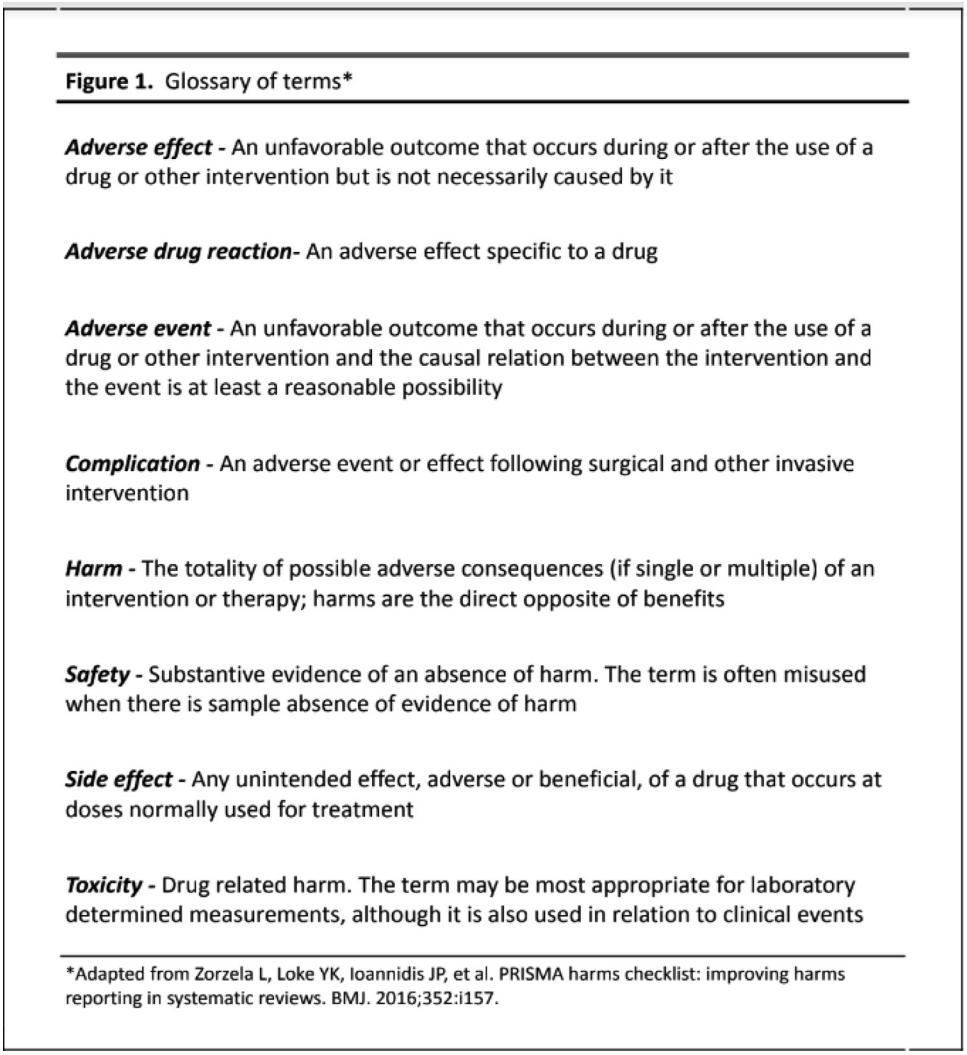

Figure 1. Glossary of terms*

Adverse effect - An unfavorable outcome that occurs during or after the use of a drug or other intervention but is not necessarily caused by it

Adverse drug reaction- An adverse effect specific to a drug

Adverse event - An unfavorable outcome that occurs during or after the use of a drug or other intervention and the causal relation between the intervention and the event is at least a reasonable possibility

Complication - An adverse event or effect following surgical and other invasive intervention

Harm - The totality of possible adverse consequences (if single or multiple) of an intervention or therapy; harms are the direct opposite of benefits

Safety - Substantive evidence of an absence of harm. The term is often misused when there is sample absence of evidence of harm

Side effect - Any unintended effect, adverse or beneficial, of a drug that occurs at doses normally used for treatment

Toxicity - Drug related harm. The term may be most appropriate for laboratory determined measurements, although it is also used in relation to clinical events

*Adapted from Zorzela L, Loke YK, Ioannidis JP, et al. PRISMA harms checklist: improving harms reporting in systematic reviews. BMJ. 2016;352:i157.

Fig. 1. Glossary of terms*.

Table 2
Mahady assessment for completion of harms reporting *(n=26)*.

Harms assessment	Frequency (%) Yes	No
1. Are harms stated in title or abstract?	21 (80.8)	5 (19.2)
2. Are harms presented in the introduction?	20 (76.9)	6 (23.1)
3. Are harms listed and separately defined in the methods?	12 (46.2)	14 (53.8)
4. Are grades and/or severity scales used to classify harms in the methods?	0 (0.0)	26 (100.0)
5. Is there a method of harms data collection stated in the methods?	19 (73.1)	7 (26.9)
6. Is there a planned statistical analysis for harms stated in the methods?	18 (69.2)	8 (30.8)
7. Are the number of patients available for harms analyses stated in the results?	15 (57.7)	11 (42.3)
8. Are the number of treatment discontinuations in each arm reported in the results?	0 (0.0)	26 (100.0)
9. Are absolute figures for each harm in treatment and control groups presented in the results?	2 (7.7)	24 (92.3)
10. Were limitations of harms analyses discussed?	16 (61.5)	10 (38.5)
11. Is a balanced discussion of harms and benefits provided?	22 (84.6)	4 (15.4)
12. Did the authors discuss what future research would be needed to better clarify harms?	17 (65.4)	9 (34.6)
Total Systematic Reviews		
Completed 0% of items	2 (7.7)	
Completed 50.0% of items or less	9 (34.6)	
Completed over 50% of items	15 (57.7)	

high to warrant further comparison. If this threshold was met, harms extracted from each individual SR were investigated for equivalence or dissimilarity in their reporting [15].

Lastly, two investigators used AMSTAR-2 to appraise the quality of each SR [16]. AMSTAR-2 is a validated tool; it contains 16 items separately recorded as 'yes', 'partial yes', or 'no', according to the criteria specified by the AMSTAR-2 checklist which is readily available online [17]. Items 11, 12, and 15 only applied to SRs that contained a meta-analysis. If a SR did not perform a meta-analysis, then it was calculated out of 13 instead of the standard 16. Data from each SR was entered into the AMSTAR-2 quality assessment generator and subsequently graded with a quality rating of 'high', 'moderate', 'low', or 'critically low'.

Table 3
Qureshi assessment for completion of harms reporting *(n=26)*.

Harms assessment	No. (%)
1. Did the study pre-specify any harms?	
Yes	18 (69.2)
No	8 (30.8)
2a. What were the types of harms assessed?	Uploaded to OSF*
2b. What language was used to describe those types of harms?	Uploaded to OSF
2c. What were the effect estimates used to assess harms?	
Mean difference	11 (30.6)
Odds ratio	9 (25.0)
Risk ratio	5 (13.9)
None	1 (2.8)
Not applicable	10 (27.8)
3. Was a pre-specified protocol available that addressed harms?	
Yes	4 (15.4)
No	18 (69.2)
Could not find protocol	4 (15.4)
Available protocol did not address harms	0 (0.0)
4. Were any specific harms or harms language included in the search strategy?	
Yes	1 (3.8)
No	25 (96.2)
5. Was a given harm assessed qualitatively or quantitatively (i.e. within a meta-analysis)?	
Both quantitative and qualitative	1 (3.8)
Only quantitative	16 (61.5)
Only qualitative	1 (3.8)
Not applicable	8 (30.8)
6. If a given harm was assessed quantitatively, what models and assumptions were used?	
Fixed effects	5 (19.2)
Random effects	4 (15.4)
Fixed & random effects	6 (23.1)
Not applicable	11 (42.3)
7. Did the authors apply selection criteria to reported harms?	
Yes	1 (3.8)
No	25 (96.2)

*OSF = Open Science Framework

Statistical analysis

Individual item completion of general characteristics, harms reporting, and AMSTAR-2 was reported via percentages and frequencies. A bivariate analysis was performed between variables such as general characteristics and harms reporting. The characteristics of the data (e.g., statistical assumptions, distributional qualities) dictated our choice of statistical test. After processing the data, we conducted a Kruskal-Wallis equality-of-population rank test to determine if harms completion had a significant relationship with items that lacked a clear majority response (Table 1). We considered a p-value ≤ 0.05 statistically significant. Concerning the CCA, we reported the number of primary studies across all SRs in our sample, and the number of primary studies reported in only one SR, between two to five SRs, and greater than five SRs [14]. Additionally, we measured the overall CCA across included SRs. We conducted our data analyses via Stata 16.1 (StataCorp, LLC, College Station, TX) before refining data with Microsoft Excel.

Reproducibility

For transparency and reproducibility, we uploaded our study materials to OSF. Notably, our study was performed alongside other studies using a similar protocol.

Results

Study selection process and general study characteristics

Our database search yielded 2,039 returns. After removing duplicates, the remaining 1,794 returns were analyzed for exclusion/inclusion criteria. Of these, 44 studies were eligible for full-text review, which excluded an additional 18 studies. Ultimately, 26 unique SRs were included in our sample. Selection process and rationale for excluded studies are depicted in Fig. 2.

Within these 26 articles, spinal stenosis was the most common indication for laminectomy (12/26, 46.2%), followed by spinal myelopathy (7/26, 26.9%) and spinal tumor (3/26, 11.5%). Our included SRs established harms as a secondary outcome (14/26, 53.8%), a primary outcome (9/26, 34.6%), or neither (3/26, 11.5%). Regarding funding, 8 SRs were not funded (8/26, 30.8%), 8 SRs did not mention a source of funding (8/26, 30.8%), and 6 SRs were publicly funded (6/26, 23.1%). Remaining characteristics are summarized in Table 1.

Completeness of harms reporting

Our study found 2 SRs had completely omitted harms, 9 SRs had between 0% and 50.0% harms item completion, and the 15 SRs had > 50.01% harms item completion.

In our sample, 1 SR reported a search strategy that included harms (1/26, 3.8%), No SRs used grades or scales to classify harms in the methods, and 2 SRs reported absolute figures for each harm in the results (2/26, 7.7%). Twenty-two SRs provided a balanced discussion of harms and benefits (22/26, 84.6%), 21 SRs mentioned harms in the title or abstract (21/26, 80.8%), and 18 SRs prespecified harms (18/26, 69.2%). Complete results are illustrated in Table 2 and Table 3.

CCA

Overall, none of the primary studies were cited in more than 5 of our sample SRs. Seventy-one primary studies were repeated in two to five of our included SRs, and the remaining 355 primary studies were referenced once. There were three pairs of primary studies with high overlap. The first pair — Mummaneni (2008) and Ryken (2009) — had a 72.7% overlap. Mummaneni reported 7 harms. Ryken reported 4 harms. Three of the reported harms were shared. The second pair — Tang (2021) and

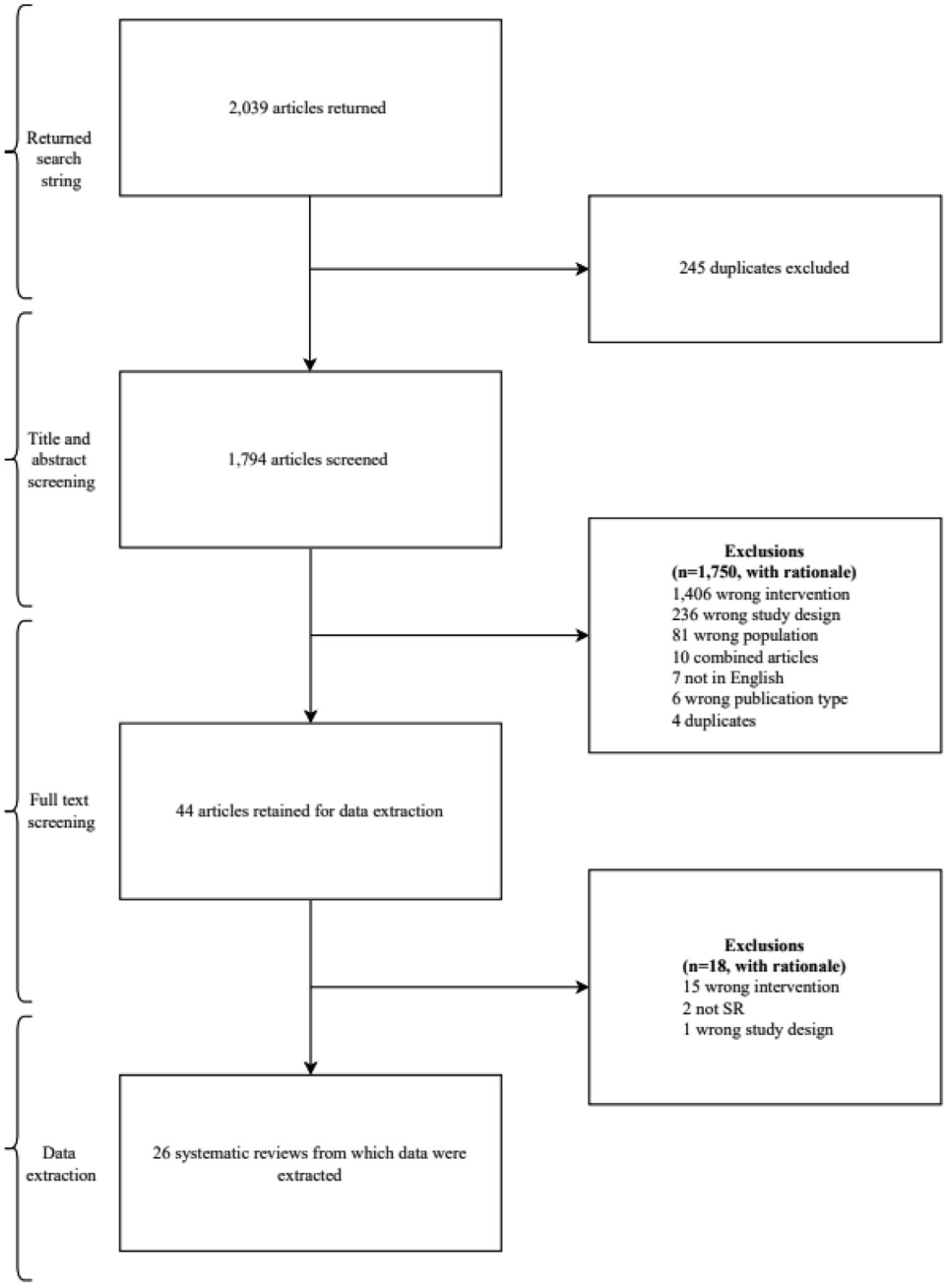

Fig. 2. Flow diagram of study selection.

Pairuchvej (2020) — had 71.1% overlap and did not report any similar harms. The third pair — Li, Z (2015) and Li, M (2020) — had 53.8% overlap and shared 2 (of 5) reported harms (Table 4).

AMSTAR-2 assessment and associations

Our AMSTAR-2 evaluation graded 25 SRs (25/26, 96.2%) as 'critically low' and 1 SR (1/26, 3.8%) as 'low'. None of the included SRs met the threshold for 'moderate' or 'high' quality designation. While one significant relationship was found between completeness of harms reporting and harms outcome specification ($p = 0.0045$), we did not perform an analysis to determine if a relationship exists between harms reporting and methodological quality due to the limited variability of the AMSTAR-2 appraisals.

Discussion

Accurate harms reporting within clinical research is essential to understand the risks and benefits of an intervention. This is particularly important for invasive procedures, which is why we evaluated harms reporting among laminectomy SRs. Our results show that approximately 8% of included SRs did not discuss harms and 42% reported ≤ 50% of the harms checklist items. With our findings in mind, it is clear that significant improvements can be made when reporting harms associated with laminectomy procedures.

We found several areas of greatest deficiency in harms reporting. First, only two SRs — Lao *et. al.*, 2013 and Osman *et. al.*, 2018 — provided a figure detailing the number of patients per stated harm. The other 22 SRs either provided no numerical evaluation of harms, or they provided a single 'complications' graph or statement. Next, only 1 SR

Table 4
Laminectomy harms reported in pairs of reviews with Corrected Cover Area (CCA) ≥ 50% (n = 2 pairs of reviews).

Harms Reported	Harms Reported	
Tang 2021 (n = 10 sources) versus Pairuchvej 2020 (n = 9 sources)		54% CCA
Transient Weakness		
Durotomy		
Dysthesia		
Hematoma	Hematoma	
Infection	Infection	
	Dural Tear	
	Root Injury	
	Instability	
Li, Z 2015 (n = 38 sources) versus Li, M 2020 (n = 27 sources)		71% CCA
Unexplained Visual Disturbance		
Spinous Process Fracture		
Epidural Hematoma		
Dural Tears		
	Lamina Penetration	
	Incorrect Pedicle Screw Placement	
	Elastic Deformation of Lamina	
	Thermal Damage to Tissue	
	Vertebral Body Displacement	
Mummaneni 2008 (n = 33 sources) versus Ryken 2009 (n = 24 sources)		73% CCA
Infection		
Pseudoarthrosis		
Hardware Failure		
Adjacent Degeneration		
Kyphosis	Kyphosis	
Postoperative Spinal Instability	Postoperative Spinal Instability	
Neurological deterioration	Neurological Deterioration	
	Spondylolisthesis	

had a search strategy that included harms-related terms, which may contribute to the poor harms reporting found in our sample. Finally, none of our SRs graded or used scales to report harms, which is concerning because the use of scales/grades qualifies the difference between a mild harm that requires no treatment and a major harm like death.

The above deficiencies are concerning for several reasons. First, an incomplete picture of associated harms is portrayed when a dichotomy between intention to report and actual items reported exists within a SR. Noting the exact population that experiences a given harm is crucial, as this knowledge may influence treatment decisions [11]. Next, if SR authors do not specifically search for papers that include harms in their titles and abstracts, then it is unlikely that the database will return articles which discuss harms [18]. These search strategy limitations might contribute to poor harms reporting and may further impair clinician ability to identify causal relationships between surgical intervention and harms [12]. Lastly, the use of scales and/or grades is important because it helps portray the full extent of an associated harm. For example, one study followed 75 anterior cervical discectomy and fusion patients to compare incidence and severity of postoperative dysphagia between two steroid groups and a control group in the year after the surgery. They scored patient symptoms with a standardized criteria that labeled the dysphagia as mild, moderate, or severe. The severity scale enabled the description and differentiation of harms that was crucial to the study implementation [19].

Reporting deficiencies continue beyond laminectomy to all aspects of orthopedics. This is highlighted by Ayling, *et. al.*, who found that while the rate of major harms did not vary greatly between studies of lumbar spine surgery, the reporting methods and the reporting of minor harms varied substantially [20]. Discrepancies between major and minor harms reporting inhibit complete understanding of a given procedure. Furthermore, a recent study evaluating the harms reporting of 173 randomized control trials (RCTs) — all cited as primary evidence for osteoarthritis of the hip and knee clinical practice guidelines — found that nearly 45% of the articles did not adhere to even a third of the harms checklist [21]. With our results and the above articles considered together, better harms reporting may be needed in all subspecialties of orthopedics.

To improve the reporting of harms in spine surgery we provide the following suggestions: We encourage journals that publish SRs to consider formally endorsing the harms checklist. Research demonstrates that the endorsement of reporting guidelines by journals results in greater adherence to these guidelines, and thus improved methodological quality [22,23]. In addition, we recommend funding agencies endorse the use of reporting guidelines such as the harms checklist for submitted research proposals, thus creating greater motivation for researchers to prospectively incorporate these methodological safeguards into their research design. Furthermore, due to insufficiencies in using objective scales to report harms, journals could endorse orthoSAVES (Orthopaedic Surgical Adverse Events Severity System) and/or SAVES (Spine Adverse Events Severity System). Both checklists include grades for severity — ranging from Grade 1 which does not require treatment to Grade 6 which can cause death [6]. Street *et. al.* compared two groups of harms reporting in patients with traumatic spinal cord injuries; one group used the SAVES tool and one group used the international classification of diseases, tenth revision (ICD-10) codes system. They found that the SAVES tool identified twice as many harms per patient than the ICD-10 system [24]. By providing a collection of possible harms and their severity classifications, these standardized tools make harms reporting more straightforward and an attainable expectation for submitted manuscripts.

Strengths and limitations

Regarding strengths, we conducted our research in a masked, duplicate fashion for both SR selection and data extraction in accordance with the Cochrane Handbook [25]. Due to the subjective nature of some harms assessment items, authors underwent robust training in harms reporting and SR methodology to mitigate misinterpretations. Furthermore, our protocol was uploaded to OSF a priori to foster reproducibility and accountability. Concerning limitations, we only included conventional laminectomy procedures and SRs written in English. Further, our small sample size and cross-sectional study design limit the generalization of our results. Lastly, our included SRs all had poor quality, which may have influenced our results.

Conclusion

Our study supported the notion that harms reporting in SRs of laminectomy lacks completeness. Therefore, we suggest journals endorse or incorporate harms reporting checklists into their submission requirements. More extensive and accurate harms information in SRs may enhance the reliability of SRs as a tool for clinicians. Further research into harms reporting of primary studies and their ensuing SRs is suggested to encourage evidence-based medicine and improve patient safety.

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Declarations of Competing Interests

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Supplementary materials

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