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Review article

A systematic review and meta-analysis of wound drains in non-instrumented lumbar decompression surgery

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ABSTRACT

Wound drains are routinely used in lumbar decompressive surgery (LDS). However, it remains unclear whether this practice helps to prevent symptomatic epidural hematoma formation and associated complications, particularly following non-instrumented procedures. A systematic review and meta-analysis was therefore completed to critically appraise the literature. The search protocol was conducted using the Ovid MEDLINE, EMBASE, Scopus, Cochrane Library, and Google Scholar databases. Articles meeting the following criteria were included: (i) examined patients undergoing LDS; (ii) included cases receiving post-operative wound drains; (iii) detailed adverse outcomes including symptomatic epidural hematomas or wound infection; and (iv) were published in English in a peer-reviewed journal. Pooled risk differences (RD) for adverse outcomes were calculated using Comprehensive Meta-Analysis software. Three Level 1b prospective randomized studies and five Level 2b retrospective cohort studies were included, from which 5327 cases were identified as having received a surgical drain and 773 were identified as having received no drainage following non-instrumented LDS. There was no difference between groups in the risk of symptomatic epidural hematoma (RD = 0.02; 95% CI −0.02 – 0.06, $p = 0.28$) or post-operative infection (RD = 0.00; 95% CI −0.01 – 0.01, $p = 0.91$). In conclusion, symptomatic epidural hematomas and infection are rare following non-instrumented LDS, with incidence rates unaffected by the routine use of wound drainage.

1. Introduction

A symptomatic epidural hematoma is a rare but devastating post-operative complication of spinal surgery. First described by Jackson in 1869 [1], epidural hematomas can occur in the setting of anticoagulation or use of antiplatelet agents [2–5], and are thought to be caused by rupture of the internal vertebral venous plexus of Batson [6]. The documented incidence of symptomatic epidural hematomas after spinal surgery varies across studies, from 0.1% to 0.2% of surgical cases [2,3,7,8], although spinal surgeons tend to estimate the risk to be much higher [9]. Compression of the neural structures, occurring as a consequence of epidural hematoma can result in permanent neurological damage if not rapidly detected and addressed [10]. Non-steroidal anti-inflammatory drug (NSAID) use, Rh positive blood group, age over 60 years, pre-operative coagulopathy, hemoglobin less than 10 g/dL, intra-operative blood loss greater than 1L, multi-level procedures, and an international normalized ratio greater than 2.0 in the first 48 h after surgery have all been shown to increase the risk of a patient suffering an epidural hematoma [2,7,8,11].

To help prevent formation of post-operative epidural hematomas, wound drains are commonly used in spinal surgery [12], although the evidence to support this practice remains unclear [13]. Three recent reviews investigated the relationship between wound drains and adverse outcomes following lumbar surgery [14–16]. However, five of the eight studies included in the systematic review by Zijlmans and colleagues did not use wound drains. The rationale for inclusion of such studies was unclear, and confounded conclusions that use of a wound drain does not affect the incidence of either post-operative epidural hematoma or wound infection, as the authors themselves acknowledged [15]. Liu and colleagues' meta-analysis and Waly and colleagues' systematic review also concluded wound drains in posterior spinal surgery do not influence the incidence of epidural hematoma, infection, blood loss, or neurological injury [14,16]. However, both reports included patients undergoing spinal fusion surgery,

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obscuring the impact of wound drains in non-instrumented lumbar decompressive surgery (LDS). Furthermore, as these adverse outcomes are a rare occurrence, the modest sample sizes of the included studies in all three reviews were underpowered to detect statistically significant differences for wound drainage [15,17,18].

Overall, conclusions regarding the utility of wound drains remain limited by methodological issues. The aim of the current study was therefore to re-examine the literature, applying a refined search strategy focusing exclusively on patients undergoing non-instrumented LDS, directly comparing the use of wound drains to no drainage, to identify the risk of post-operative epidural hematomas and other adverse outcomes in large patient cohorts. This protocol was expected to provide a more valid set of conclusions to inform practitioners and the patients they serve.

2. Materials and methods

The current review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement [19].

3. Data sources and search strategy

Ovid MEDLINE, EMBASE, Scopus, Cochrane Library, and Google Scholar electronic databases were searched from inception using a strategy developed by a specialist librarian (MS) to identify relevant studies. Combinations of the following subject headings and key words were used across all databases: *microdiscectomy*, *intervertebral disc*, *discectomy*, *laminectomy*, *foraminotomy*, *decompressive surgery*, *lumbar vertebrae* AND *drain*, *drainage*, *wound drain*, *suction drain*, *surgical* AND *hematoma*, *epidural hematoma*, *spinal hematoma*, *postoperative complication*, *cauda equina syndrome*, *spinal cord compression*, *morbidity and mortality*, *surgical mortality*, *hospital mortality*. To illustrate, the full search strategy for the Ovid MEDLINE database is included in Appendix A.

4. Inclusion and exclusion criteria

Articles considered for full review met the following inclusion criteria: (i) examined outcomes of LDS specifically, or had data for LDS patients that could be separated from patients undergoing spinal fusion surgery; (ii) included participants receiving post-operative wound drains, and identified which participants had or had not received a drain; (iii) detailed adverse outcomes including symptomatic epidural hematomas or wound infection; and (iv) were published in English in peer-reviewed journals. Exclusion criteria included: (i) patients undergoing spinal fusion surgery; (ii) cases where the pathology was neoplastic or traumatic; and (iii) studies in which no patient received a wound drain. Both prospective randomized studies and retrospective cohort series were eligible for inclusion in the current review, as randomized control trial designs can be impractical for accumulating sufficient sample sizes in rare conditions, and less rigorous retrospective research designs may still provide an initial demonstration of the efficacy, safety, and tolerability of alternative treatments.

5. Identification of relevant studies and data extraction

The eligibility assessment was performed independently in a standardized manner by one of the authors (CD). After deleting duplicate papers, the title and abstract of all articles were screened to assess suitability for inclusion. Those considered potentially eligible were read in full. Articles meeting the specified inclusion criteria were included in the review. Data on patient characteristics (e.g. age, neurological signs and symptoms), surgical characteristics (e.g. type of surgical intervention, type of wound drain), and primary and secondary surgical outcomes were then extracted by two of the authors (CD and JR). Only non-fusion participants were included in the final analysis. The primary outcome was the occurrence of a symptomatic epidural hematoma requiring surgical decompression. Secondary outcomes included any additional post-surgical morbidity, such as wound infection rate. As per previous work [15], when post-operative adverse outcomes were described in the Methods section, but the occurrence of complications was not reported in the Results section, it was assumed they did not occur. Disagreements between reviewers were resolved by consensus, with the senior author (AD) as arbitrator. The last database search was completed 17 November 2017. Hand-searching of the reference lists of relevant reviews and articles was also used to identify potentially relevant publications. The last hand-search was performed 28 November 2017, yielding no additional relevant articles.

6. Quality assessment

Methodological quality of the included studies was independently assessed by two of the authors (CD and JR), using the criteria for prognosis studies recommended by Hayden and colleagues [20,21]. For each of the following domains, the risk of bias was categorized as *high*, *moderate*, or *low*: study participation, study attrition, prognostic factor measurement, outcome measurement, confounding measurement, and statistical analysis. Each individual study was also assigned an overall risk of bias rating of *high*, *moderate*, or *low*, indicating the extent to which the study design and analysis controlled for the influence of selection bias, misclassification, and confounding. Disagreements between reviewers were resolved by consensus, arbitrated by the senior author (AD).

7. Data analysis and statistical methods

Incidence rates of primary and secondary post-operative outcomes were entered into Comprehensive Meta-Analysis version 3.3.070 (CMA; Biostat, Englewood, NJ). All calculations were based on data in the published manuscripts. Pooled Mantel-Haenszel (M-H) Risk Differences (RDs) were calculated by aggregating the mean RDs weighted by each study's sample size, calculation of 95% confidence intervals (CIs), and computation of *z*-scores based on the total difference in the number of events. M-H Risk differences are recommended to obtain unbiased estimates of variance when sample sizes are unbalanced [22]. RDs were calculated so that outcomes favoring wound draining had a value less than zero and effects favoring no wound drainage had a value greater than zero. As heterogeneity was expected in the way included studies were sampled, all analyses were conducted using the more conservative random effects model. Heterogeneity was formally assessed with the I^2 statistic, where a value of 0% indicates no observed heterogeneity, 25% *low*, 50% *moderate*, and 75% *high* heterogeneity [23]. Finally, given the small number of included studies, risk of publication bias was assessed using Egger's regression test (two-tailed *p*-value).

8. Results

8.1. Literature search

The search strategy identified 435 potentially relevant articles. Following the selection process depicted in Fig. 1, eight articles were retained for this review, including three OCEBM Level 1b [24] prospective randomized studies [18,25,26] and five Level 2b

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