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FactFinders for patient safety: Delaying epidural steroid injections: Infection and safe platelet cutoff

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A B S T R A C T

This series of FactFinders presents a brief summary of the evidence and outlines recommendations to improve our understanding and management of patients with potential contraindications to epidural steroid injections.

Evidence in support of the following facts is presented. (1) *Delaying Epidural Steroid Injections During an Infection* – There is a theoretical, small increased risk of infection associated with an epidural steroid injection in a patient taking antibiotics. However, there is little empiric evidence to guide when, and for how long, to delay an epidural steroid injection in the setting of ongoing infection and antibiotic treatment. (2) *"Safe" Cut Off for Platelet Count Prior to Interlaminar Epidural Access* – An evidence-based absolute "safe" platelet count value does not exist. The decision to proceed in the setting of thrombocytopenia should be based on patient-specific factors and overall bleeding risk.

FACTFINDERS FOR PATIENT SAFETY: Delaying Epidural Steroid Injections During an Infection.

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Myth: Concurrent antibiotic use is an absolute contraindication to the performance of an epidural steroid injection (ESI).

Fact: There is a theoretical, small increased risk of infection associated with an ESI in a patient taking antibiotics. However, there is little empiric evidence to guide when, and for how long, to delay an ESI in the setting of ongoing infection and antibiotic treatment.

Epidural steroid injections (ESIs) are a safe and effective means of treating radicular pain syndromes when performed according to evidence-based guidelines [1–4]. As with all interventions, ESIs have inherent risks including but not limited to vasovagal reactions, headache, facial flushing, transient pain, numbness or tingling, and exceedingly rarely, neurologic compromise and infection [5]. Because steroid administration can suppress the immune system [6,7], anecdotally, many physicians delay ESIs in the case of an active infection requiring treatment with antibiotics. However, practices vary substantially due to a lack of published guidance regarding when, and for how long, to delay ESIs during treatment of an infection with antibiotics.

Risk of infection with ESI

Skin puncture during ESIs can introduce pathogens into the body. Furthermore, systemic corticosteroid therapy may adversely affect both the innate and the adaptive immune response. The ability of neutrophils

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to migrate to sites of infection is impaired by corticosteroids [8]. Macrophage and monocyte function may also be inhibited by corticosteroids [9,10]. The capability of plasma cells (terminally differentiated B-lymphocytes) to produce immunoglobulins IgG and IgA is reduced 10–20% by corticosteroids [11]. Large cohort studies suggest that the risk of infection is exceedingly low, though these studies did not mention whether injections were performed in patients with active or recent signs of infection. Three large cohort studies found a 0% incidence of post-injection infection: McGrath et al. reported on over 4265 injections over seven years including cervical, lumbar, and caudal ESIs [12]; Karaman et al. reviewed 1305 transforaminal lumbar ESIs [5]; El-Yahchouchi et al. reviewed 16,638 consecutive procedures of all spine segments [4]. Alternatively, a study of 52,935 ESI procedures in 22,059 patients revealed 244 adverse events with four major complications of infection (three cases of spine infection, one case of septic shock with an unknown focus – no further details provided, all after caudal or interlaminar ESIs) [13]. Furthermore, case reports of infection after ESIs exist. Hooten et al. summarized 14 reports of epidural abscesses and/or meningitis with eight patients having had underlying medical illnesses that adversely affect immune function [14]. It was not clear if any of them had active infections or were on antibiotics prior to the injection.

Risk of infection associated with steroid injection during active unrecognized remote or systemic infection

Data that supports the need to delay steroid injection in the context of active infection is sparse. It is clear that intra-articular joint injections should not be performed in the setting of septic arthritis [15]. In a review of 1528 cases of alleged treatment errors relating to injections, 278 cases of complications were identified in cases involving steroid injection. Of those, 223 cases of infection were identified following intra-articular, paravertebral, intra-muscular and other injections. The authors ultimately determined that 73 “treatment errors in corticosteroid injection leading to infection” occurred, including 24 cases of missed infection at the time of injection [16]. Unfortunately, the types of injections leading to infections, type of infections, and clinical outcomes were not reported.

General literature on delaying elective procedures in the setting of active infection

In studies of post-operative infections, remote site infection increased the rate of post-operative infection by a factor of 2.7–5.3 [17]. Specifically, in a study of 2349 post-operative patients, of whom 208 had a documented remote infection (mostly skin infections, urinary tract infections, pulmonary infections, abscess infections – not further clarified, and perirectal tissue abscesses), 178 developed wound infections. The wound infection rate in the 208 patients with remote infections was 14.4%, whereas it was 6.9% in the 2141 patients without known remote infections [18]. These studies highlight the consensus that active infection should be recognized and appropriately treated before procedures are pursued.

The anesthesiology literature suggests that preoperative pyrexia is one of most common reasons for cancellation of elective surgeries [19]. The presence of fever is concerning, as it can indicate a systemic infection that may hamper postprocedural recovery and cloud post-procedural management given the increased difficulties of distinguishing between surgically related complications or pre-existing infection [20]. Furthermore, an association between percutaneous regional anesthesia techniques and risk of central nervous system infection in bacteremic patients has been observed [21]. Alternatively, there is literature that epidural anesthesia may be safe in patients with ongoing infection as multiple studies have shown that spinal and epidural anesthesia may be safe even in women with active chorioamnionitis [22,23].

Risk of infection with steroid injection once antibiotics have been initiated

The literature on how long to delay steroid injection after the initiation of antibiotics is sparse. Studies have shown that after infections such as urinary tract infection, sterilization is achieved within three days of antibiotic therapy in 86% [24]. With group A streptococci pharyngitis, 91% of children treated bacteria were undetectable the next morning [25]. Intra-articular steroid injections have been trialed in animals with concurrent antibiotic administration in efforts to decrease inflammatory joint damage with no significant difference in infection-related outcomes [26]. In relation to skin flora, which may be most relevant to ESIs, it is thought that most bacteria from the dermal layers may be eradicated within the first few days of antibiotic therapy and that 5 days of antibiotic therapy is equally effective as 10 days for uncomplicated cellulitis [27]. In the Valentine study, patients with known remote infections were less likely to have developed subsequent wound infections if they had received antibiotics at least 24 hours before surgery: only 8.8% (2.1–15.5%) of the patients who developed subsequent wound infections had started antibiotics at least 24 h before surgery (68 total) compared with 24.5% (15.8–33.2%) who had only received prophylactic antibiotics within 24 h of surgery [18]. This suggests that even 24 h of antibiotic treatment may be helpful in preventing procedure site infection in the context of an active remote infection. However, similar data does not exist when the procedure is an ESI. As such, guidance based on direct evidence on how long to delay an ESIs in the context of a concurrent infection after antibiotics have been initiated is not possible.

Guidance

Data to guide practice is sparse but suggests the need to carefully weigh risks [especially given the patient’s underlying medical illness(es) that may adversely affect immune function] versus benefits when deciding to pursue an elective procedure such as an ESI:

- Systemic infections: In cases of suspected systemic infection by symptoms of fever, cough, dysuria, or elevated white blood count, workup and establishment of treatment is recommended prior to ESI.
- Localized infections at the site of planned injection
  - In the case of local infection in the region of the planned injection, but in which antibiotics have not been initiated, work up and establishment of treatment is recommended prior to ESI.
  - In the case of local infection in the region of the planned injection in which antibiotics have been initiated, it is unclear when it is safe to proceed with injection. Detailed assessment of individual comorbidities, infectious symptoms, response to antibiotic course, possible consultation of an infectious disease specialist, along with detailed discussion regarding the risks, benefits, and alternatives are possible recommendations. Given the lack of evidence, propose to err on the side of caution and await complete resolution of infection prior to proceeding.
- Localized infection at a remote site with no evidence of systemic infection
  - In the case of local infection in an area remote to the injection region and with no evidence of system infection, if antibiotics has not been initiated, it is unclear whether to proceed. Though, based on post-operative infection literature, it is best to workup the infection and initiate treatment prior to ESI.
  - In the case of a contained infection in an area remote to the injection region with no evidence of system infection, if an antibiotic has been started, it is also unclear when it is safe to proceed. A detailed assessment of individual comorbidities, infectious symptoms, response to the antibiotic course, possible consultation of an infectious disease specialist, along with detailed discussion regarding the risks, benefits, and alternatives on a case-by-case

basis are recommended. However, in the absence of unique circumstances, one should wait until antibiotic treatment has been completed and the patient is asymptomatic.

FACTFINDERS FOR PATIENT SAFETY: "Safe" Cut Off for Platelet Count Prior to Interlaminar Epidural Access.

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Myth: An absolute platelet count exists above which it is safe to proceed with interlaminar epidural access.

Fact: An evidence-based absolute "safe" platelet count value does not exist. The decision to proceed in the setting of thrombocytopenia should be based on patient-specific factors and overall bleeding risk.

Thrombocytopenia is classified as a platelet count below the lower limit of normal (*i.e.,* <150,000/microL [150 × 10^9/L] for adults). The safety of epidural access procedures in thrombocytopenic patients is unclear due to the potential for increased risk of epidural hematoma and permanent neurologic injury. There is a paucity of interventional pain literature to guide clinical decision-making including identification of thrombocytopenic patients prior to procedures. Data can be cautiously extrapolated from other thrombocytopenic populations, including parturients undergoing labor neuraxial anesthesia [28–30] and oncologic patients undergoing lumbar punctures [31]. Ultimately, absolute platelet count does not necessarily correlate with platelet function, and consultation or additional testing may be indicated to evaluate function. It also stands to reason that needle size (gauge) may affect risk with interlaminar epidural access, but limited data is available to provide insight on the relative risks of specific needle sizes. Additional caution may be warranted with spinal cord stimulation lead placement in patients with thrombocytopenia due to the larger needle size for interlaminar access and maneuvering of leads within the epidural space.

Data on "safe" platelet values for epidural access procedures are most robust in the obstetric anesthesia literature. It is important to be cognizant, however, that the etiologies of thrombocytopenia and baseline population characteristics are markedly distinct between parturients and outpatient pain patients. A mixed retrospective observational and systematic review study from the Multicenter Perioperative Outcomes Group (MPOG) database was conducted by Lee et al. to estimate the risk of epidural hematoma in parturients with platelet counts <100,000 who underwent a neuraxial procedure including epidural, spinal, and combined spinal-epidural analgesia/anesthesia [28]. Patients who had an underlying coagulopathy or who were taking an antiplatelet medication were excluded. A total of 573 patients were identified and combined with data from a systematic review of existing literature for a total of 1524 patients. Of these, 53 patients had platelet counts between 50,000 and 69,000, and 12 patients had a platelet count between 0 and 49,000. No cases of epidural hematomas requiring surgical decompression were identified.

In both the obstetric and oncologic literature, upper bounds of statistical confidence of a zero proportion are calculated with the "Rule of 3" due to a lack of identified events [34]. The "Rule of 3" states that if a specified event did not occur in a sample with n subjects, then the interval from 0 to 3/n is a 95% confidence interval (CI) for the rate of occurrences in the population. The Lee et al. study calculated a 95% CI upper bound for risk of a clinically significant epidural hematoma of 11% for platelet counts between 0 and 49,000, 3% for 50,000 to 69,000, and 0.2% for 70,000 to 100,000. As the majority of cases evaluated had platelet counts ≥70,000, the calculated CI is most robust at this level. The data are less clearly defined for counts <70,000 given the limited population evaluated. The authors' methods only identified patients who reportedly underwent decompressive laminectomies due to epidural hematomas; and, therefore, were unable to identify epidural hematomas that were non-operatively managed.

These data built on prior smaller cohort studies in comparable patient populations that yielded similar upper bounds of statistical confidence [32,33]. A multicenter retrospective cohort study of 173 parturients with thrombocytopenia (<100,000) was conducted by Goodier et al., and the data were then aggregated with 326 cases from previous studies for a final sample of 499. The estimated upper 95% CI for probability of spinal-epidural hematoma was 0.6%. A subsequent single center retrospective study was conducted by Bernstein et al. of 256 parturients with platelet counts <100,000. This was combined with 173 patients from the Goodier et al. study and the 326 prior published cases for a calculated upper 95% CI of 0.4%. Meaningful analysis was not possible for platelet counts <50,000 given the very small number of patients.

Further data on "safe" platelet values for neuraxial techniques are available in the oncologic population undergoing lumbar punctures. Again, extrapolation to a general pain population is applied cautiously. A systematic review of the MEDLINE database was conducted by Ho et al. in which eight case series were identified where a total of 13,975 lumbar punctures were performed with varying degrees of thrombocytopenia. Despite a number of "bloody taps'', no cases of clinically apparent spinal hematoma were reported. Thus, Ho et al. calculated an upper CI limit of 0.17% based on 1747 patients who underwent lumbar punctures with a platelet count range between 51 and 100 K (× 10^9/L).

In contrast to the obstetric and oncologic literature, which used the "Rule of 3" due to lack of identified events, a systematic review published in 2020 identified 33 reported cases of spinal epidural hematoma from an aggregated 7509 thrombocytopenic patients (less than 100,000 × 10^6/L) who underwent lumbar neuraxial procedures [30]. The authors searched multiple databases for patients who received a neuraxial procedure with platelet count less than 100,000 × 106/L. Neuraxial procedures included lumbar puncture, spinal or epidural or combined spinal-epidural (CSE) analgesia/anesthesia, and epidural catheter removal. Of the 33 cases identified, 25/33 (75.8%) were lumbar punctures; 6/33 (18.2%) spinal analgesia/anesthesia; 1/33 (3%) an epidural; and 1/33 (3%) an epidural catheter removal. Within the platelet count ranges of 1000–25,000; 26,000–50,000; 51,000–75,000; and 76,000–99,000, there were 14, 6, 9, and 4 spinal epidural hematomas, respectively. The authors identified an inflection point and narrow CIs near a platelet count of 75,000 or above. Between a platelet count of 75,000–99,999, the estimated event rate was 0.097% [95% CI: 0.002%–0.19%)]. On the basis of this review, the Society for Obstetric Anesthesia and Perinatology released a consensus statement suggesting that if the platelet count is ≥ 70,000 × 10^6/L, there is likely to be a low risk of spinal epidural hematoma (class IIa and level C-LD) [35]. This guidance applies to obstetric patients with thrombocytopenia secondary to gestational thrombocytopenia, immune thrombocytopenia (ITP), and hypertensive disorders of pregnancy in the absence of other risk factors. It is important to again acknowledge that the etiology of thrombocytopenia in parturients is physiologically distinct from outpatient pain patients.

Literature is also limited with respect to the utility of platelet transfusions for thrombocytopenia prior to neuraxial interventions such as lumbar punctures or epidural anesthesia. A 2018 Cochrane review identified only three retrospective cohort studies that contained participants who did and did not receive platelet transfusions prior to lumbar punctures; only two of which reported outcomes separately for participants who did and did not receive platelet transfusion [36]. Both studies had methodological limitations including retrospective design, small sample size, and non-standardized reporting of results. No evidence was found on which to base an assessment of the appropriate

platelet transfusion threshold before insertion of a lumbar puncture needle or epidural catheter.

The utility of platelet transfusions for thrombocytopenia has also been called into question in the interventional radiology literature [37]. A 2017 retrospective cohort study identified 2060 patients with thrombocytopenia ($\leq 100 \times 10^9$/L) undergoing invasive image-guided interventions with 203 patients receiving preprocedural platelet transfusion. No significant difference was observed in bleeding complications in terms of postprocedural red blood cell transfusion requirements. Incidence of epidural hematoma was not specifically evaluated in this study and may not have been captured if transfusion was not necessary.

Conclusions and recommendations

- Coagulation and the coagulation cascade are complex processes, and a multitude of factors and organ systems may affect bleeding risk outside of platelet counts alone.
  - o It is important to consider patients' medical histories to ensure appropriateness prior to recommending an epidural access procedure.
- The decision to proceed with interlaminar epidural access in a patient with thrombocytopenia should be based on consideration of risks and benefits including patient-specific factors, procedural factors, and overall bleeding risk.
  - o Consultation with a hematologist may be beneficial to guide work-up and pre-procedural management of thrombocytopenia.
- Limited evidence is available to guide the safety of interlaminar epidural access with thrombocytopenia in terms of an absolute platelet count cut-off.
  - o Data cautiously extrapolated from alternative patient populations suggest that interlaminar epidural access with platelet counts of at least 70,000 are associated with low risk of epidural hematoma in the absence of coagulopathy and drugs that are capable of inducing platelet dysfunction.
- There is no current evidence that preprocedural transfusion of platelets reduces the risk of epidural hematoma in patients with thrombocytopenia. Routine use is not indicated.

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