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Retrospective Review

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Background: The American Society of Regional Anesthesia currently recommends ceasing antithrombotic medications for all spinal epidural steroid injections, however there is a paucity of data on the true risk of spinal epidurals via various approaches versus the risk of cessation of an agent as it relates to the underlying medical condition.

Objective: This study evaluated the complication rate of caudal epidural steroid injections in patients who remain on antithrombotic medications.

Study Design: Retrospective chart review.

Setting: Physiatric Spine Clinic in Orthopedic Specialty Office and Surgical Center.

Methods: A retrospective chart review was performed identifying patients (n = 335) who received a caudal epidural steroid injection (n = 673) from June 2015 through April 2020. Patients were included if they had received the injection while taking an antithrombotic medication. Patients were excluded if they were not taking an antithrombotic. The patient's age, indication for the injection including magnetic resonance imaging or computed tomography findings, antithrombotic medication, the medical condition requiring an antithrombotic, and any complications following the injection were collected via chart review.

Results: Of the 443 injections included in the study, 51 encounters were lost to follow-up. Of the other 392 injections, there were no reported complications, regardless of the patient's imaging findings, age, the antithrombotic medication used, or the underlying medical condition for which an antithrombotic medication was indicated.

Limitations: This is a retrospective study. Therefore, a prospective study may have yielded fewer encounters lost to follow-up. Patients were not contacted directly after the procedure and chart reviews were utilized to evaluate for complications, which was limited to a patient's reporting of perceived complications without any imaging.

Conclusions: We conclude that caudal epidural steroid injections can be performed safely in patients while taking antithrombotic medications. Catastrophic events have been observed in patients who have discontinued antithrombotic agents preceding procedures. Thus, discontinuing antithrombotic medications may pose a greater risk than benefit for patients on an antithrombotic medication who have painful lumbar radiculopathy.

Key words: Epidural injection, caudal, antithrombotic, safety, steroids, anticoagulant, antiplatelet, epidural hematoma

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Painful lumbosacral radiculopathy (LSR) is estimated to affect 3-5% of the population (1). Most cases of LSR are secondary to herniated nucleus pulposus, spinal stenosis, spondylolisthesis, synovial cyst, and less commonly, a tumor or infection. Conservative treatment of benign and noninfectious LSR includes physical therapy, anti-inflammatory and analgesic medications, and membrane-stabilizing medications. If these interventions fail, epidural steroid injections (ESIs) may be considered as a tool to reduce pain to aid in the rehabilitation process. Recalcitrant pain or progressive neurologic deficit may require surgical decompression and possible stabilization.

The true incidence of epidural hematoma secondary to epidural injection/anesthesia is not known, but a literature review of obstetric epidurals estimated the risk as 1 in 168,000 (2). Kreppel et al (3) performed a meta-analysis of 613 cases of epidural hematomas and found that epidural needle/catheter placement while on anticoagulants was the fifth most common cause and tenth most common cause without these medications (3). The American Society of Regional Anesthesia and Pain Medicine (ASRA) recommends cessation of nonaspirin antithrombotics prior to ESIs to allow bleeding times to normalize (4).

It is estimated that 2.6 million people in the United States have atrial fibrillation (5). Over 795,000 strokes occur in the United States each year (6). According to an audit of the IMS Health National Disease and Therapeutic Index, approximately 4.21 million people are on oral anticoagulants in the United States (7). It is noted that cessation of warfarin may result in a temporary hypercoagulable state (8). Stopping a blood thinner may result in a catastrophic event and may not be possible in some instances.

The caudal approach is the oldest form of epidural injection and was first described by Corning with cocaine in 1885 (9). Since this time, the technique has been modified and typically performed with fluoroscopic guidance for safety and accuracy. A 22-gauge or 25-gauge spinal needle is typically placed through the sacral hiatus and not advanced beyond the S3 level so as not to pierce the thecal sac. Once the needle is through the sacral hiatus, the medicine can be delivered epidurally, regardless of how close to S3 it is placed. This is confirmed with the use of contrast medium and fluoroscopy.

In our practice, we have offered patients with painful lumbosacral radiculopathy of various etiology while on antithrombotics, the option of a caudal ESI while only allowing the needle tip to enter the sacral hiatus. This study retrospectively looked at complications of 443 caudal epidural steroid injections performed with a 22-gauge or 25-gauge spinal needle by 2 fellowship-trained interventional physiatrists at the same institution.

Methods

The investigators performed a retrospective chart review identifying patients who received caudal ESIs from June 2015 through April 2020. Patients were included if they had received a caudal ESI and were taking an antithrombotic at the time of the injection. Patients included were taking one or more of the following: aspirin 81 mg, aspirin 325 mg, clopidogrel, ticagrelor, prasugrel, apixaban, rivaroxaban, warfarin, enoxaparin, dipyridamole, and dabigatran. Patients were excluded if they were not actively taking an antithrombotic. Each caudal procedure for any given patient was defined as a separate event. In the scenario that aspirin and clopidogrel were taken as part of a dual antiplatelet treatment, this was included in the clopidogrel category. If the patient was taking an antiplatelet agent as well as a formal anticoagulant or additional antiplatelet medication, this was categorized by the anticoagulant or brand name antiplatelet medication. This occurred in 25.51% of our patients. The patient's age, diagnosis for the injection with MRI or CT findings, antithrombotic agent(s), medical condition requiring the medication(s), and any complications following the injection were collected for each injection. No procedures were aborted. A total of 335 patients who received 443 total injections were identified and included (Fig. 1).

The procedures were performed at a single center by 2 fellowship trained interventionalists (JG and JIS). All procedures were performed under fluoroscopic guidance with a 25-gauge or 22-gauge 3.5-inch spinal needle (Halyard, Alpharetta, GA). The injectate varied by practitioner: JG utilized methylprednisolone acetate 80 mg (Teva Pharmaceuticals, Inc. North Wales, PA) and triamcinolone acetonide (Bristol-Myers Squibb Company, Princeton, NJ) 80 mg for patients with risk factors such as diabetes mellitus or osteoporosis and 120 mg for other patients; JIS utilized betamethasone sodium phosphate and sodium acetate 12 mg (American Regent Inc. Shirley, NY). A total volume of 10 mL of injectate was administered as a mixture of the corticosteroid, 1% lidocaine without epinephrine (Hospira Inc., Lake Forest, IL), and 0.9% saline (Hospira Inc., Lake Forest,

IL). One case was identified in which dexamethasone was utilized. In all injections, the needle tip was placed just beyond the sacral hiatus (Fig. 2). Live fluoroscopy with Omnipaque™ 240 nonionic contrast medium (GE Healthcare, Marlborough, MA) was used to confirm epidural flow and the absence of vascular uptake.

Determination of any postinjection complications or adverse events was completed by chart review for each procedure, and included a review of office notes, telephone encounters, and external documents after each injection. This review included encounters within the physiatry department, as well as other practitioners within the same multidisciplinary orthopedic specialty practice. A complication or adverse event was defined as documentation of postinjection bleeding, infection, or neurologic compromise. In the case that no follow-up data regarding any adverse events or complications were available, the injection was considered to be without complication.

Results

A total of 673 caudal ESIs were performed by JG and JIS from June 2015 through April 2020. There were 230 patients excluded from the analysis, as they were not taking antithrombotic medications. Thus, 335 patients who underwent a total of 443 injections were included in the analysis. The patients' ages ranged from 35-93, with a mean age of 74.5, median age of 75, and mode of 78. Of the included patients, 148 were men and 187 were women. Of the 443 procedures, 178 injections utilized methylprednisolone, 164 utilized betamethasone, 100 utilized triamcinolone, and one utilized dexamethasone (Fig. 1).

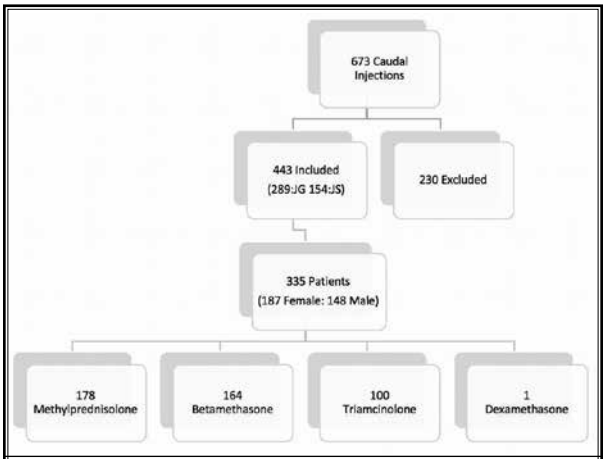

Fig. 1. *Patient demographics (age; range 35-93, mean 74.5, mode 78).*

With regards to antithrombotic profile, there were 77 patients on only aspirin 81 mg, 17 patients on aspirin 325 mg, one patient on an unlisted dose of aspirin, 105 patients on clopidogrel, 80 patients on warfarin, 82 patients on apixaban, 63 patients on rivaroxaban, 8 patients on ticagrelor, 4 patients on prasugrel, 4 patients on dabigatran, one patient on enoxaparin, and one patient on dipyridamole (Table 1).

The reasons for antithrombotic use included cardiac disease in 59.1% of patients, arrhythmia in 31.0%, poststroke or transient ischemic attack in 11.0%, pos-

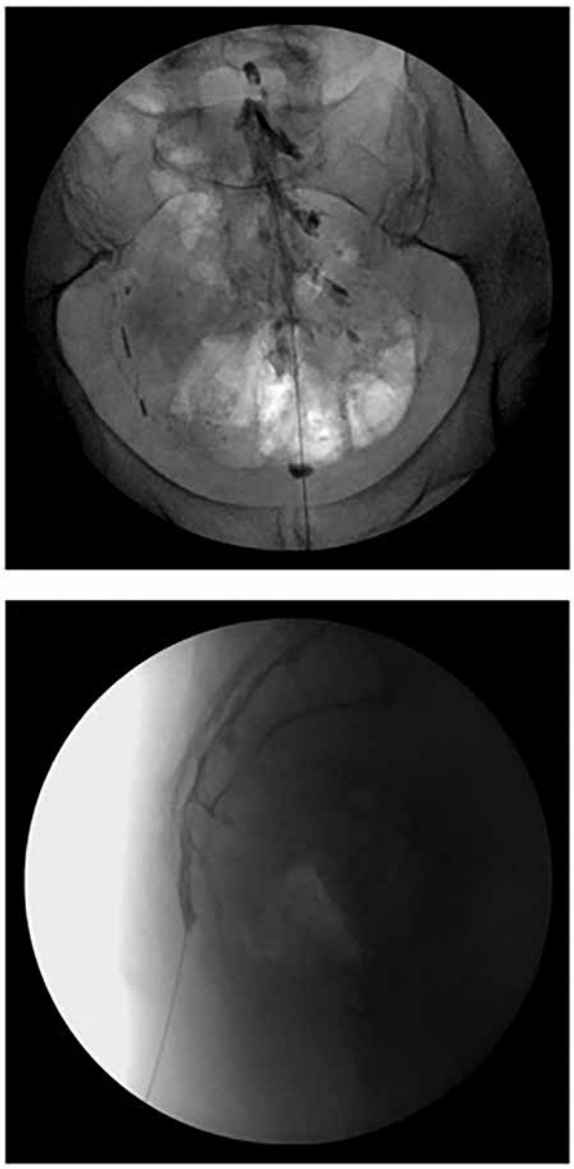

Fig. 2. *AP and Lateral Views of Caudal Epidurogram.*

Table 1. *Distribution of antithrombotics.*

Agents combined	#	% of total
Clopidogrel	105	23.7%
Apixaban	82	18.5%
Warfarin	80	18.1%
ASA 81 mg Only	77	17.4%
Rivaroxaban	63	14.2%
ASA 325 mg	17	3.8%
Ticagrelor	8	1.8%
Dabigatran	4	0.9%
Prasugrel	4	0.9%
ASA Dose ?	1	0.2%
Enoxaparin	1	0.2%
Dipryridamole	1	0.2%
TOTAL	443	100.0%

Single Agent	#	% of total
Apixaban	68	15.3%
ASA81	77	17.4%
Warfarin	73	16.5%
Rivaroxaban	51	11.5%
Clopidogrel	35	7.9%
Dabigatran	4	0.90%
Enoxaparin	1	0.23%
Prasugrel	1	0.23%
ASA Dose ?	1	0.23%
ASA325	17	3.84%
Ticagrelor	2	0.46%
TOTAL	330	74.49%

Dual Agent	#	% of total
Apixaban/Clopidogrel	2	0.46%
ASA/Dipyridamole	1	0.23%
ASA325/Clopidogrel	1	0.23%
ASA81/Apixaban	12	2.71%
ASA81/Clopidogrel	69	15.6%
ASA81/Prasugrel	3	0.69%
ASA81/Rivaroxaban	11	2.48%
ASA81/ticagrelor	1	0.23%
ASA81/Ticagrelor	5	1.13%
ASA81/Warfarin	7	1.58%
Rivaroxaban/Ticagrelor	1	0.23%
TOTAL	113	25.51%

tinterventional cardiac procedure in 12.8%, deep vein thrombosis or pulmonary embolism in 13.7%, vascular or circulatory conditions in 3.3%, and postmyocardial infarction or heart failure in 10.4% (Table 2). With regards to the analysis of imaging reports, 255 patients had an MRI or CT scan with a primary finding of central lumbar or neuroforaminal stenosis; 52 had findings consistent with postsurgical changes from a lumbar or lumbosacral laminectomy, fusion, kyphoplasty, or vertebroplasty; and 28 had findings consistent with lumbar spondylosis or degenerative changes without significant stenosis (Table 3). There were no reported complications or adverse events, as previously defined, following any of the procedures (Table 4).

Discussion

Caudal ESIs are generally well tolerated, and the majority of adverse events are uncommon and limited. Our retrospective review of 443 injections revealed no complications or adverse events in 392 caudal ESIs in patients taking antithrombotic agent(s). The other 51 encounters were lost to follow-up. ASRA recognizes that complications of neuraxial injections, such as spinal hematoma, are multifactorial, yet their guidelines are particularly specific and focus on medications. Contrarily, their recommendations regarding the type of procedure are more generalized and they make broad categorization of procedures based on 3 risk categories of high, intermediate, and low-risk procedures. An interlaminar sacral ESI, which we assume to include caudal ESI, is considered an intermediate-risk procedure. Specifically, they recommend cessation of all nonaspirin antiplatelet and/or anticoagulant medications prior to any intermediate risk procedures, such as interlaminar epidural injections (cervical, thoracic, lumbar, and sacral) (4).

For intermediate risk procedures, cessation of each individual medication is detailed. They recommend stopping clopidogrel for 7 days prior to a procedure; this recommendation stems from the CURE trial that recommended discontinuing clopidogrel 5 days prior to a procedure (10). Their increased time table of 7 days is attributed to their consideration that neuraxial injections are elective procedures. On the other hand, they cite no reports of epidural hematoma and state stopping clopidogrel 5 days prior to the procedure is "probably acceptable." For the newer anticoagulants—apixaban, rivaroxaban, and dabigatran—ASRA's recommendation is to stop the medication 5 half-life intervals prior to the procedure. They cite 10 case reports of spinal hematomas, 7 for rivaroxaban, 2 for dabigatran, and one for

apixaban. However, 8 out of 10 of the hematomas were spontaneous and none were related to caudal ESIs. We continued these medications without complication in 82, 63, and 4 patients respectively. In regards to warfarin, they feel in both high and intermediate risk procedures, the medication should be stopped 5 days prior to the procedure and that the International Normalized Ratio (INR) should be less than 1.2. Their regional anesthesia guidelines state no procedure should take place with an INR greater than 1.4 for patients not on medication. Overall, it appears these guidelines heavily weigh the medication profile with little risk to the actual risk related to the procedure.

Further consideration should be taken to regard caudal ESI a lower risk procedure than other intermediate risk procedures. Prior authors, including those of medical education textbooks, claim that caudal epidural injections pose a decreased bleeding risk compared to more cephalad epidural injections, and thus, are reasonable treatment options for patients on antithrombotic agents (11-13). This is based on one study of 37 anticoagulated patients and 19 thrombocytopenic patients who underwent caudal procedures (14). A total of 336 blocks were performed using either 25-gauge, 1.5 cm needles or 25-gauge, 3.8 cm needles, depending on body habitus. Once the needles were thought to have advanced through the sacrococcygeal ligament, medication was injected, and the needles were then removed. No hematoma or neurological complications were reported. However, details regarding specific antithrombotic agents were not provided, and fluoroscopic guidance to confirm epidural placement was not utilized. Furthermore, a large systematic review of more than 2,400 articles of which 120 were relevant to patients continuing anticoagulant medication while undergoing image-guided procedures, concluded that hemorrhagic complications were exclusively reported during interlaminar injections and spinal cord stimulator placement and removal. Complications were seen at the cervical, thoracic, and lumbar levels, but none were reported at the caudal level. They found no complications in any segmental level transforaminal injection, sacral lateral branch blocks, zygapophysial or sacroiliac joint or medial branch block, or radiofrequency neurotomy (15). This was consistent with 2 large studies that looked at rates of epidural hematomas in spine procedures in patients regardless of antiplatelet or anticoagulant medication that showed epidural hematoma in only 2 out approximately 69,000 patients between the 2 studies (16). Although it appears there is low risk with these procedures, we recommend further prospective studies before these procedures can be deemed safe while continuing antiplatelet and anticoagulant medications.

Risk factors for epidural hematoma include female gender, advanced age, antithrombotic medications, traumatic needle and/or catheter placement, and spinal stenosis (17). Fluoroscopic-guided caudal epidural injections have been associated with intravascular injection in 3%-14% of cases (18). Based on our experience under live fluoroscopy, we observed the incidence of intravascular injection on the lower end of this re-

Table 2. *Charted primary diagnoses for anti-coagulant use.*

	Entries	Exclusions*	Total	Percent of Total
Arrythmia/Atrial Fibrillation	143	39	104	31.0%
CVA or TIA	56	19	37	11.0%
Cardiac Disease	248	50	198	59.1%
Cardiac Stent, Valve, Bypass, or Implantable Device	65	22	43	12.8%
Pulmonary Embolism or Deep Vein Thrombosis	60	14	46	13.7%
Vascular or Circulation	13	2	11	3.3%
Heart Failure or Post Myocardial Infarction	38	3	35	10.4%
Unknown	3	0	3	0.9%

*Exclusions are entries for the same patient but separate procedural event

Table 3. *Primary impressions on imaging studies.*

	Entries	Exclusions*	Total	Percent of total
Post-Surgical: Lamenectomies, Fusions, Kyphoplasty, or Vertebroplasty	72	20	52	15.5%
Central or Foraminal Stenosis without prior surgery	331	76	255	76.1%
Spondylosis and Degenerative changes without significant stenosis	40	12	28	8.4%

*Exclusions are entries for the same patient but separate procedural event

Table 4. *Complication rate.*

	Total	Percent of Total
Complication rate for all procedures	0	0.0%
No Follow Up	51	

ported range when the needle tip lies just cephalad to the sacrococcygeal ligament. The sacral canal has fewer veins than the lumbar canal (19). Unfortunately, specifics regarding vascular anatomy at the sacral hiatus are not well defined (20). Consideration for vascular injury can be extrapolated based on previous studies of intravascular injection of lumbar transforaminal ESIs; to our knowledge, there have been no studies at the caudal level. Based on previous studies and our data, we feel there is likely no difference in risk between 25- or 22-gauge or long versus short beveled needles (21,22). Based on Özcan's (23) study of 185 patients, ablunt needle may pose less risk than a beveled needle.

It is not entirely clear why there is only one reported case of epidural hematoma following a caudal ESI (24). Waldman et al (14) did not elaborate as to why their 336 caudal epidural injections in patients on antithrombotics resulted in no adverse neurological events. We speculate that the safety of caudal ESIs at least in part stems from the lack of nearby central canal stenosis. It is intuitive that a space-occupying lesion, such as an epidural hematoma, would be more likely to cause neurological complications in a location that is already compromised at baseline compared to one that is not. Stenosis is exceedingly rare in the sacral spine (25). There is also increased epidural fat with caudad progression in the spine (26). Moderate and severe central canal stenosis at the L5/S1 level is relatively uncommon compared to at the L2/L3, L3/4, and L4/5 levels (27). While there have been cases of symptomatic epidural hematomas at sites remote from the location of the procedure needle, this is not a common phenomenon (24,28-30). Thus, while epidural hematomas may or may not be unusual in the setting of caudal ESIs, we hypothesize that when they do develop, they are less likely to be clinically relevant than those in the lumbar spine where ESIs are typically performed at or very close to sites of significant neural compression. We feel this is a likely scenario as a theoretically larger vertebral canal would provide space for the propagation of hematoma and blood runoff without creating neural compression. Consistent with this notion, a prospective study of 89 patients who underwent lumbar laminotomy demonstrated that in patients with MRI-confirmed epidural hematomas 24 hours after surgery, only 2 out of 13 decompressed patients were in fact symptomatic for any period of time (31).

A review of the literature identified only 2 cases of epidural hematoma associated with caudal procedures. In both cases, the patients were taking antithrombotic agents. The first case described an 83-year-old woman taking cilostazol, a phosphodiesterase type- 3 inhibitor, in whom a caudal ESI was performed (24). The procedural needle was a 22-gauge, 3.5-inch spinal needle. Specifics regarding the cephalad placement of the needle were not provided, and it is difficult to interpret needle location based on the pictures provided in the case report. The authors concluded that "the cause of lumbar epidural hematoma following caudal steroid injection in this case was not clear. Possibilities included cilostazol, the underlying spinal stenosis, interventional violence, or a combination of all" (24). The second case described a 75-year-old woman taking warfarin, in whom a caudal epidural "pulsed radiofrequency procedure" was performed (28). The procedural needle was a 22-gauge cannula, which was advanced to the S3 level. Pulsed radiofrequency ablation was administered for 10 minutes. Blood work after the complication found the patient's INR to be highly supratherapeutic at 6.1. To the best of our knowledge, this procedure is not commonly performed and is not backed by high quality evidence. Additionally, the needle type and duration of the procedure are not consistent with those of a typical caudal ESI. These facts make it difficult to draw any useful conclusions regarding the safety of continued anticoagulation in the context of caudal ESIs, and thus, we do not feel that this case provides sufficient evidence to warrant routinely checking INRs prior to caudal ESIs in patients on warfarin.

Manchikanti et al (32) performed a prospective study reviewing patients who either continued or discontinued antiplatelet and/or anticoagulant medications prior to spinal procedures. Of the patients who underwent caudal ESIs, 8 patients were continued on warfarin, 44 patients were continued on clopidogrel, and 50 patients were continued on a combination of aspirin and warfarin or clopidogrel. Specific procedural details (needle type and precise placement) were not provided. Regardless, none of these patients experienced significant hemorrhagic events requiring intervention. Our study is consistent with these findings.

Vanga et al (33) found that of 431 patients admitted for acute ischemic stroke, 2.6% presented within 120 days of oral anticoagulation cessation. Even more troubling, these patients tended to have higher morbidity and mortality compared to those patients who had strokes but had not recently discontinued anticoagulation. Broderick et al (34) found that 5.2% of 2,197 strokes occurred within 60 days of antithrombotic medication discontinuation. Nearly half of the patients had medications discontinued for procedures, and over half of these patients' strokes occurred within one week of discontinuation.

To the best of our knowledge, the present study is the first retrospective review of adverse events of patients undergoing caudal ESIs while taking non-aspirin antiplatelet and/or anticoagulant medications. None of the individuals in our review of 335 patients who underwent a total of 443 caudal ESIs experienced any significant adverse events. This finding was true regardless of whether a 22-gauge or 25-gauge spinal needle was used for the procedure. Unfortunately, 51 encounters were lost to follow-up.

This study benefits from a large sample size over a number of years and evaluates multiple different antithrombotic agents. Limitations include that this is a retrospective study. Patients were not contacted directly after the procedure and chart reviews were utilized to evaluate for complications. However, the majority of patients in our study were followed on a long-term basis, and any serious complications most likely would have been documented. This study also looked at perceived complications or those reported by the patient as additional imaging was not utilized after the procedure to evaluate for asymptomatic bleeding events. An additional limitation is that 11.5% of the 443 injection encounters did not have postinjection follow-up documented. Some of these may be explained by the recency of the injections when the review was performed; however, it cannot definitively be stated that these patients did not experience complications.

Current data suggest high rates of use of antithrombotic medications in the United States. A review of the Medical Expenditure Panel Survey has shown clopidogrel to be the most commonly prescribed antithrombotic medication, with approximately 22 million prescriptions in 2019. This is followed closely by aspirin and warfarin, respectively (35,36). This corroborates a 2017 National Health Interview Survey published in the Annals of Internal Medicine that stated 29 million Americans take aspirin daily for prevention of cardiovascular disease. Interestingly, they estimated 6.6 million people take aspirin without the recommendation of a physician (37). These data are consistent with ours, as we found clopidogrel and aspirin to be the most commonly encountered antithrombotics, followed by apixaban, warfarin, and rivaroxaban at similar frequencies. Our study had a significant number of injections for these antithrombotic medications; however, it was underpowered for ticagrelor, prasugrel, enoxaparin, dipyridamole, and dabigatran. It should be noted, though, that no complications were observed in individuals taking these medications.

Conclusion

Based on our data, there is a low risk of complication when performing caudal ESIs in the setting of aspirin 81 mg, warfarin, combination therapy of aspirin and clopidogrel, apixaban, and rivaroxaban. Notably, aspirin, warfarin, and clopidogrel are the 3 most commonly prescribed agents in the United States, and as a result, our findings are particularly compelling. Our data were underpowered for the remainder of the antithrombotics; however, we believe it is unlikely that these medications pose a significant risk when performing caudal ESIs with the needle tip just cephalad to the sacral hiatus, given the following: 1) none of our patients experienced complications or adverse events, 2) there has only been one case of symptomatic epidural hematoma reported in the literature following a caudal ESI on antithrombotics of any type, and 3) there is a significant distance from the sacral hiatus to regions of the spine that are likely to be stenotic, making symptomatic epidural hematomas unlikely. Meanwhile, catastrophic events when antithrombotic agents are discontinued have been observed in numerous patients. Thus, discontinuing antithrombotic medications for caudal ESIs is not justified, and caudal ESIs should be considered a viable option for patients on antithrombotic therapy with painful LSR. We currently agree with the ASRA recommendation of informed decision making and shared assessment and between the procedural physician, prescribing medical physician, and patient (4). Accordingly, we hope for the future revision of guidelines for patients on antithrombotic therapy who undergo neuroaxial procedures.

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