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Original Research Article

The Risks of Continuing or Discontinuing Anticoagulants for Patients Undergoing Common Interventional Pain Procedures

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Abstract

Background. Guidelines have been published that recommend discontinuing anticoagulants in patients undergoing interventional pain procedures. The safety and effectiveness of these guidelines have not been tested.

Objectives. The present study was performed to determine if continuing or discontinuing anticoagulants for pain procedures is associated with a detectable risk of complications.

Methods. An observational study was conducted in a private practice in which some partners continued anticoagulants while other partners routinely discontinued anticoagulants.

Results. No complications attributable to anticoagulants were encountered in 4,766 procedures in which anticoagulants were continued. In 2,296 procedures in which anticoagulants were discontinued according to the guidelines, nine patients suffered serious morbidity, including two deaths.

Conclusions. Lumbar transforaminal injections, lumbar medial branch blocks, trigger point injections, and sacroiliac joint blocks appear to be safe in patients who continue anticoagulants. In patients who discontinue anticoagulants, although low (0.2%) the risk of serious complications is not zero, and must be considered when deciding between continuing and discontinuing anticoagulants.

Key Words. Interventional; Anticoagulants; Guidelines; Spine; Procedures; Nerve Block; Sacroiliac Joint; Trigger Point Injections; Transforaminal Injection

Introduction

Epidural hematoma is an unforgiving entity. Recovery of neurologic function tends to be poor unless decompression is undertaken within 8–12 hours after onset of symptoms [1,2]. The cardinal causes of epidural hematoma are procedures such as epidural or intrathecal injections or catherizations, but the risk is double in patients who are anticoagulated [1].

For these reasons, several learned bodies have declared that central neuraxial blocks are contraindicated in patients taking anticoagulants, and have issued guidelines for the temporary discontinuation of anticoagulants in patients who need to undergo neuraxial blocks [3–7]. The objective of these guidelines is to reduce the incidence of epidural hematomas. Some guidelines have extended the call to discontinue anticoagulants in patients undergoing peripheral nerve blocks. The objective is to reduce complications due to blood loss and hematomas in fascial spaces and in the thoracic or abdominal cavities [3,5,6].

When issued, these guidelines caused concerns amongst physicians who practice interventional pain medicine [8]. Although the guidelines were originally written to apply to perioperative analgesia, interventional pain physicians felt obliged to comply with them, if for no other reason than to avoid medicolegal censure in the event of misadventure. In this regard, the most

Table 1 The classification of various pain procedures according to risk if performed in patients taking anticoagulants, as declared by the American Society for Regional Anesthesia [7]

Classification	Pain procedure
High risk	Spinal cord stimulation, intrathecal catheter, vertebral augmentation, epiduroscopy
Intermediate risk	Epidural injections, transforaminal injections, medial branch blocks, radiofrequency neurotomy, paravertebral blocks, sympathetic blocks, peripheral nerve stimulation, pocket replacement
Low risk	Peripheral nerve blocks, peripheral joint injections, trigger point injections, sacroiliac joint block, sacral lateral branch blocks.

recent edition of the guidelines of the American Society for Regional Anesthesia expressly includes pain procedures [7]. They list various procedures as high-risk, intermediate risk, and low risk (Table 1), and although the guidelines allow for discretion, they are cast from the perspective that discontinuation of anticoagulants should be the default position.

To no small extent the concerns of interventional pain physicians are justified. In the guidelines, data on the incidence of epidural hematomas were drawn from studies of operative procedures (e.g., orthopedics and obstetrics), in which intraspinal injections and catheterizations were performed with large gauge needles, without image-guidance, during prolonged procedures. No data were derived from studies of pain procedures in which fine-gauge needles are used under image-guidance, in procedures lasting seconds rather than hours. Therefore, it is not known if the same risks apply for pain procedures; yet the obligation to discontinue anticoagulants seems to apply.

Reciprocally, the guidelines pay little or no attention to the risks associated with discontinuing anticoagulants. Although some warn about discontinuing heparin, none estimate the risk of discontinuing oral anticoagulants. Interventional pain physicians are, therefore, justified in worrying if the risks of medical complications from discontinuing anticoagulants might outweigh any risks of ostensibly innocuous pain procedures.

The present study was undertaken in an effort to provide quantitative data pertinent to these concerns. Explicitly it sought to answer two questions: In patients who continue to take anticoagulants, is the performance of pain procedures associated with a detectable risk of hemorrhagic complications; and in patients who discontinue anticoagulants, is there a detectable risk of morbidity?

Methods

The present study was conducted in a private pain practice located in a sub-metropolitan city of Wisconsin that serves a population of over 100,000 people. All consecutive patients scheduled for pain procedures and who were taking anticoagulants were enrolled in the study during the period between January 1, 2005 and December 31, 2015.

All spinal procedures were performed in accordance with the Practice Guidelines of the Spine Intervention Society [9]. Peripheral procedures, such as trigger point injections or injections into bursa, were performed using conventional techniques.

The practice consisted of two senior partners and five associates. During the period of study the associates discontinued anticoagulants in accordance with the anticoagulation guidelines [3,6], for all procedures that they performed, doing so with the agreement of the prescribing physician. For patients taking warfarin, coagulation status using the INR (international normalized ratio) was checked on the morning of the procedure, or before the patient left home if they had to travel a long way. No procedure was performed unless and until coagulation had been normalized.

One of the senior partners, the senior author of the present study (Stephen Endres), elected to continue anticoagulants. The theoretical risks of doing so were explained to each patient, as well as the precautions that would be taken, and the measures for dealing with an adverse event, such as close monitoring and rapid response. Procedures were undertaken only if coagulation status was at therapeutic or sub-therapeutic levels.

Anticoagulants were routinely continued by the senior partner for all transforaminal injections, all medial branch blocks, all sacroiliac joint blocks, and all trigger point injections and peripheral procedures. For interlaminar injections, anticoagulants were continued only in those patients who were taking warfarin but whose INR was in the normal range (because their dose of warfarin happened to be sub-therapeutic). For radiofrequency neurotomies, anticoagulants were continued only in those patients in whom anticoagulants could not be discontinued on the advice of the treating cardiologist. After the first 18 months of the study, the second senior partner adopted this same protocol for continuing anticoagulants.

Data on age, gender, indications for anticoagulants, dose, and coagulation status were recorded prospectively in the patient's medical record. For the purposes of later analysis, these data were retrieved from the records by college students paid by the practice. Once collected, the data were collated and analyzed by the authors. The numbers of patients taking particular anticoagulants were tallied and cross-tabulated against the procedure performed, the anticoagulant prescribed, and whether anticoagulants were discontinued or not. For various categories, proportions and their 95% confidence intervals were calculated. Records were not kept of patients taking aspirin alone; this drug was disregarded for the present study for it has been shown that aspirin and other antiflammatory agents are safe for spinal procedures [10,11].

All patients who underwent procedures were routinely followed, by telephone at 5–10 days after the procedure if they were not returning for additional procedures, or in person at 2–3 weeks after the procedure, if they were having further procedures. Any adverse effects or complications at the time of the procedure were noted in the medical record, as were any effects that occurred during the period of follow-up. Adverse events that occurred before a scheduled procedure were identified in several ways. Patients who failed to attend for a procedure or for follow-up, were pursued to determine the reason for not attending. Otherwise, the patient, the treating doctor, or the referring doctor notified the practice of any adverse event. All telephone follow-up and pursuit of patients who failed to attend was conducted a registered nurse with a 4-year college degree, and 12 years experience in the pain practice of the senior author.

Results

During the period of study, 1,383 patients underwent or were scheduled for 7,062 pain procedures. They were 723 males and 660 females, aged between 24 and 102, with a mean age of 72 years. No patients were lost to follow-up during the 2 weeks after completing their intervention.

The indications for anticoagulants were diverse. They were used mainly for cardiovascular disease, but some were prescribed for unusual conditions (Table 2).

The most commonly used anticoagulants were warfarin (57%) and clopidrogel (38%). Lesser proportions of patients used aspirin with dyridamole, and other agents (Table 3). All patients were taking their prescribed medication at doses within the recommended range.

The most common procedures performed were transforaminal injections (34%) and medial branch blocks (38%); smaller proportions of patients underwent other spinal procedures such as sacroiliac joint blocks, interlaminar injections, and radiofrequency neurotomy. The remainder of patients had trigger point injections, injections into trochanteric bursae, or fluoroscopy-guided, intra-articular hip injections (Table 3). The trigger point injections were performed in cervical and peri-scapular muscles.

Anticoagulants were continued in the majority of patients who underwent transforaminal injections, zygapophysial joint blocks, sacroiliac joint blocks, trigger point injections, and miscellaneous minor procedures (Table 3). Conversely, anticoagulants were discontinued in the majority of patients who underwent interlaminar injections or radiofrequency neurotomy.

(In Table 3, procedures have not been stratified according to cervical, thoracic or lumbar segmental levels, because it would render the tables too large and sparse, with too many zero entries; but not doing so does not affect the principal results to follow. Later, where relevant, data relating to procedures at particular segmental levels are provided.)

No complications, attributable to anticoagulation, occurred in any patient who continued to take anticoagulants during their pain procedure. For most of the procedures (Table 3), the sample sizes were too small to provide meaningful confidence intervals around the observed prevalence of zero for complications, but the samples were substantial for lumbar transforaminal injections, lumbar medial branch blocks, trigger point injections, and sacroiliac joint blocks (Table 4). For those procedures, for the observed rate of complications of 0%, the upper 95% confidence limit was 0.2% for lumbar transforaminal injections and lumbar medial branch blocks, 0.8% for trigger point injections, and 1.4% for sacroiliac joint blocks (Table 4).

In contrast, of the patients who discontinued anticoagulants, as recommended by the guidelines, nine suffered morbidity (Table 5). Two patients died; five suffered strokes; one had a pulmonary embolism; and one suffered a myocardial infarction. All these patients discontinued warfarin. In all but one case, the morbidity occurred between 2 and 5 days after the procedure, after warfarin was recommenced (Table 5).

Discussion

The present study differs from a previous study of pain procedures in patients taking anticoagulants [12]. In that study the majority of patients were taking aspirin-like drugs, but anti-platelet medications have been shown not to be a significant hazard for the conduct of spinal pain procedures [10,11]. In contrast, the majority of patients in the present study were taking warfarin and clopidrogel, whose safety has not been determined.

Like the previous study, the present study was consciously undertaken as an exploratory, observational

Table 2 The numbers of patients who were taking anticoagulants for the various indications listed. Some patients had more than one indication

Cardiac		Cerebrovascular	
Atrial fibrillation	409	Stroke	62
Coronary artery disease	250	Transient ischemic attacks	21
Stent placement	208	**Venous**	
Valve replacement	40		
Myocardial infarction	31	Deep vein thrombosis	115
Coronary artery bypass	49	Pulmonary embolism	93
Pacemaker	4	Blood clots	36
Septal defect	2	**Miscellaneous**	
Cardiomegaly	1		
Vascular		Factor V	25
		Pulmonary disease	20
Hypertension	74	Lupus	3
Peripheral vascular disease	20	Knee surgery	1
Aneurysm	4	Cancer	1
Fistula stenosis	1	Hyperlipidemia	1
Aortic stenosis	1	Loeys-Dietz syndrome	1
		Shunt placement	1

study. Patients were not randomized because at the time that the study was initiated, insufficient information was available. Although the guidelines implied that discontinuation of anticoagulants should be the standard of care, those guidelines had not been tested either for safety or for effectiveness. Reciprocally, the likelihood of complications caused by many common pain procedures had not been established.

Under those conditions, patients rely on the experience and insights of their treating physician. The physician determines the possible hazards of a particular procedure and estimates the likelihood of adverse events, but also puts into place contingency plans to respond promptly to any adverse complaints.

In this regard, the data of the present study conspicuously reflects the intuition of the participating physicians. The senior partners saw little risk in continuing anticoagulants for procedures such as medial branch blocks, sacroiliac joint blocks, and trigger point injections. On balance they saw relatively little risk for the conduct of transforaminal injections.

In contrast, they were wary about interlaminar injections and radiofrequency neurotomy. Interlaminar injections risk injuring epidural veins; and radiofrequency neurotomy involves stab incisions and the use of large-gauge electrodes in multiple positions. As a result, anticoagulants were not routinely continued for these procedures; they were continued only when they could not be discontinued, or when coagulation status was normal. Consequently, the numbers of patients continuing to take anticoagulants for these procedures are small and artificial, and no conclusions are drawn about the safety of these procedures in anticoagulated patients. Likewise, conclusions cannot be drawn for cervical procedures, which only relatively small numbers of patients underwent.

Firm conclusions, however, can be drawn for lumbar transforaminal injections and lumbar medial branch blocks, which patients were willing to undergo and physicians willing to perform while maintaining anticoagulant therapy. A zero prevalence in 1,600 or 1,800 procedures suggests that these procedures are safe, but this sample size does not exclude a possible of prevalence of complications less than two in 1,000.

Interestingly, however, previous studies that declared that epidural injections and epidural or spinal anesthesia were safe in patients taking anti-platelet drugs did so on the basis of a zero percent prevalence of complications in substantially fewer than 1,600 patients (386 [10] and 383 [11]). In those studies the upper confidence limits of 0% were reported as 1.1% [10] and 0.96% [11], which are some five times greater than some of those encountered in the present study (0.2%). Applying the same standard to the present study means that transforaminal injections, zygapophysial joint blocks, and trigger point injections can be regarded as safe in anti-coagulated patients. Sacroiliac joint blocks approach that threshold for safety.

For greater confidence in safety, prohibitively large studies would be required. For example, a zero prevalence, even in 10,000 patients, does not exclude a prevalence less than 4 in 10,000. It is unlikely that studies of this magnitude would ever be conducted in order to produce strong evidence of safety for every pain procedure.

The alarming observation of the present study was the number of patients who suffered morbidity after discontinuing anticoagulants, as recommended by the guidelines. Although small, the prevalence of morbidity [0.4%; 95%CI: 0.2–0.7%] was non-zero. There is, therefore, a finite risk of complications from discontinuing anticoagulants. This has implications both for authors of anticoagulation guidelines and for individual physicians.

Defenders of anticoagulation guidelines might argue that these patients should not have discontinued anticoagulants, that they should have been identified as high-risk candidates for pain procedures, and that their physicians should have exercised greater insight. However, in this regard the guidelines are silent or inexplicit. They advise that the risks of discontinuing anticoagulants

Table 3 The numbers of patients taking various anticoagulants, and the procedures that they underwent, according to if they continued or discontinued anticoagulants for the conduct of that procedure

	Transforaminal injection	Medial branch blocks	Sacroiliac joint blocks	Radiofrequency neurotomy	Interlaminar injection	Trigger point injection	Trochanteric bursa injection	Hip joint injection	Total
Warfarin									
Discontinued	482	443	39	289	169	24	3	38	1,487
Continued	880	1,090	171	29	25	227	40	87	2,549
Clopidrogel									
Discontinued	225	174	6	187	69	10	6	19	696
Continued	639	890	81	22	15	214	50	52	1,963
Aspirin/dipyridanole									
Discontinued	24	4	0	8	1	0	0	0	37
Continued	18	31	3	0	0	1	7	0	60
Rivaroxaban									
Discontinued	2	0	0	12	0	0	0	0	14
Continued	32	25	2	0	0	10	1	0	70
Dabigatran									
Discontinued	21	12	2	6	11	0	1	0	53
Continued	13	12	0	0	0	0	1	0	26
Cilostazol									
Discontinued	0	0	0	0	0	0	0	0	0
Continued	15	7	2	0	1	4	0	0	29
Apixaban									
Discontinued	0	0	0	0	0	0	0	0	0
Continued	26	13	1	6	0	0	0	0	46
Enoxaparin									
Discontinued	1	3	0	2	0	0	0	0	6
Continued	4	2	0	0	1	0	0	3	10
Ticagrelor									
Discontinued	1	0	0	0	2	0	0	0	3
Continued	5	4	0	0	0	0	2	0	11
Prasugrel									
Discontinued	0	0	0	0	0	0	0	0	0
Continued	1	0	1	0	0	0	0	0	2
Total									
Discontinued	756	636	47	504	252	34	10	57	2,296
Continued	1,633	2,074	261	57	42	456	101	142	4.766

should be discussed with the prescribing physician, but they offer no critical operational criteria for assessment. In the absence of criteria, decisions cannot be objective, and cannot be distinguished from optimism, conservatism, or a lucky guess. In the present study, the nine patients who suffered morbidity exhibited no features with respect to history, pathology, or current clinical features that distinguished them as higher risk than like patients who suffered no ill effects.

The implication for proponents of anticoagulation guidelines is that they should not advocate discontinuing anticoagulants as if doing so is without hazard. Authors of anticoagulation guidelines should estimate the risk of discontinuing anticoagulants, and balance these against the purported risks of pain procedures in patients who continue anticoagulants. Unfortunately the comparison cannot be adjudicated statistically. To prove that a risk of, say, one in 1,000 is significantly less than, say, three in 1,000 would require sample sizes in excess of 7,000 per group. Such data are unlikely to be forthcoming.

Practicing physicians face a dilemma: For every patient they need to choose between discontinuing and continuing anticoagulants. Either action has hazards; the risks for each are low, but too low to be weighed statistically in a valid manner. What remains as a

Table 4 The number of patients who continued to take anticoagulants during the procedures listed; and the number of complications encountered, their prevalence, and the 95% confidence intervals of that prevalence

Procedure	Number	Complications		
		Number	Prevalence	95% CI
Lumbar transforaminal injections	1,601	0	0%	0.0–0.2%
Lumbar medial branch blocks	1,836	0	0%	0.0–0.2%
Trigger point injections	456	0	0%	0.0–0.8%
Sacroiliac joint blocks	261	0	0%	0.0–1.5%

CI = confidence intervals.

Table 5 The morbidities suffered by patients who discontinued anticoagulants, the indication for anticoagulants, and when the morbidity occurred in relation to the procedure that they were scheduled to undergo

Morbidity	Anticoagulant	Indication	When	Procedure
Fatal myocardial infarction	Warfarin	IHD	7 days after	Cervical epidural
Fatal stroke	Warfarin	AF	Morning of	Lumbar RFN
Non-fatal stroke	Warfarin	AF	2 days after	Cervical MBB
Non-fatal stroke	Warfarin	AF	5 days after	Cervical epidural
Non-fatal stroke	Warfarin	AF	3 days after	Lumbar TFI
Non-fatal stroke	Warfarin	AF	4 days after	Lumbar interlaminar
Non-fatal stroke	Warfarin	AF	3 days after	Lumbar interlaminar
Pulmonary embolism	Warfarin	PE	2 days after	Lumbar intrathecal injection
Myocardial infarction	Warfarin	IHD/AF	5 days after	Cervical epidural

IHD = ischemic heart disease; AF = atrial fibrillation; PE = pulmonary embolism; RFN = radiofrequency neurotomy; MBB = medial branch block; TFI = transforaminal injection.

basis for decision is a qualitative judgment. Are the possible complications of discontinuing anticoagulants more serious, or less manageable, than the possible complications of performing a pain procedure while continuing anticoagulants? Effectively this means comparing stroke or heart attack with hematoma or blood loss.

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