Interventional Pain Medicine 1 (2022) 100090

Contents lists available at ScienceDirect

Interventional Pain Medicine

journal homepage: www.journals.elsevier.com/interventional-pain-medicine

FactFinders

Factfinders for patient safety: Anticoagulant and antiplatelet agents and cervical medial branch procedures

Haewon Lee [a,b,*,1], Mathew Saffarian [c,1], Vivek Babaria [d], Zachary L. McCormick [e], on behalf of the Spine Intervention Society's Patient Safety Committee

[a] University of California, San Diego, USA
[b] Department of Orthopedic Surgery, San Diego, CA, USA
[c] Michigan State University, Department of Physical Medicine and Rehabilitation, East Lansing, MI, USA
[d] Orange County Spine and Sports, PC, Interventional Physiatry, Costa Mesa, CA, USA
[e] University of Utah School of Medicine, Department of Physical Medicine & Rehabilitation, Salt Lake City, UT, USA

A B S T R A C T

This series of FactFinders presents a brief summary of the evidence and outlines recommendations regarding the safety of anticoagulant and antiplatelet agents for cervical medial branch blocks and cervical medial branch radiofrequency neurotomy.

The evidence in support of the following facts is presented: (1) In patients maintained on therapeutic anticoagulant (AC) and/or antiplatelet (AP) therapy, for whom cervical medial branch blocks (CMBBs) are being considered, there is strong evidence to guide decisions on continuing or discontinuing these AC/AP agents in preparation for the procedure. (2) Therapeutic anticoagulation (AC) and antiplatelet (APT) agents should be discontinued prior to cervical medial branch radiofrequency neurotomy (CMBRFN) due to serious hemorrhagic risks.

Anticoagulant and Antiplatelet Agents for Cervical Medial Branch Blocks

Haewon Lee[1,*]; Vivek Babaria[2]; and Zachary L. McCormick[3] on behalf of the Spine Intervention Society's Patient Safety Committee.

[1]University of California, San Diego, Department of Orthopedic Surgery, San Diego, CA, USA;

[2]Orange County Spine and Sports, PC, Interventional Physiatry, Costa Mesa, CA, USA;

[3]University of Utah School of Medicine, Department of Physical Medicine & Rehabilitation, Salt Lake City, UT, USA.

Myth: In patients maintained on therapeutic anticoagulant (AC) and/or antiplatelet (AP) therapy, for whom cervical medial branch blocks (CMBBs) are being considered, there is strong evidence to guide decisions on continuing or discontinuing these AC/AP agents in preparation for the procedure.

Fact: Severe hemorrhagic events that cause permanent neurological injury due to CMBB performed according to clinical practice guidelines have not been reported in the published literature. Alternatively, published evidence indicates that ceasing AC agents for the duration required for CMBB, specifically warfarin, carries an approximate 0.5% risk of a catastrophic thromboembolic cerebrovascular or cardiopulmonary event. Based on the nature of these thromboembolic risks, physicians should consider continuation of anticoagulation and AP therapy during CMBBs; however, more data are required to support **a definitive recommendation. In addition, the decision to withhold AC and AP therapy prior to CMBB should be made on a case-by-case basis, as the relative risk of hemorrhage versus thrombosis is different for each unique patient.**

Cervical medial branch blocks (CMBBs) are a diagnostic procedure designed to determine the presence of cervical zygapophysial joint pain. When conducted according to clinical practice guidelines, CMBBs are among the safest interventional spine procedures [1]. With proper technique, the needle tip remains dorsolateral to the articular pillars, outside of the spinal canal and intervertebral foramen, and dorsal to the vertebral artery at all times.

Vascular penetration at the target site of a properly performed CMBB is a well-documented phenomenon. The incidence of intravascular injection at the cervical spine has been reported to range from 3.9% to 20% [2–5]. This is not surprising given the vascular anatomy in close proximity to the target region for CMBB. Anterior to the intended target zone, small periforaminal arteries have been noted to be present along the lateral aspect of the cervical spine. In one study of 102 patients, 238

* Corresponding author. University of California, San Diego, USA.
E-mail address: HAL026@health.ucsd.edu (H. Lee).
[1] Denotes co-first authors.

https://doi.org/10.1016/j.inpm.2022.100090
Received 2 March 2022; Accepted 1 April 2022

arteries out of 363 small innominate vessels were identified under ultrasound [6]. The arteries were noted to have a mean diameter of 1.25±0.45 mm and were located in the C5-7 posterior foramina and at the articular pillars of C6 and C7. Injury of these structures could potentially lead to extra-axial bleeding, particularly in patients who are maintained on AC/AP agents. Accidental injury to such small periforaminal arteries would be unlikely to lead to hemorrhagic compression of an exiting nerve root significant enough to cause irreversible injury to the exiting nerve root. Additionally, such extra-axial bleeding is incapable of causing compression of neural elements within the spinal canal. Notably, there are no reported cases of neurological injury due to CMBB in the published literature. Similarly, bleeding from a branch of the deep cervical artery overlying the articular pillar would likely be contained within the soft tissue and result in an inconsequential paraspinal hematoma. There is a theoretical risk of puncture of the vertebral artery (VA) at more superior cervical levels. The VA has known anatomical variants in which it travels over the superior articular process (SAP) of the C3 vertebral body 0.4% of the time [7]. This anatomic variant can be particularly important for procedures targeting the third occipital nerve (TON) more so than those targeting the C3 medial branch. While VA injury due to needle trauma is a theoretical possibility, local hemorrhage is highly unlikely, as vasospasm of the artery would be expected to curtail any significant bleeding. Review of axial imaging prior to the performance of upper CMBB assists in procedure planning for avoidance of needle trespass through anatomical variations of the VA.

Despite the presence of vascular structures in the vicinity of the CMBB target region, there have been no published reports of serious hemorrhagic complications following CMBB, even in patients who continued taking AC/AP agents. In one study of 2,074 patients who underwent medial branch blocks at various spinal regions (cervical, thoracic, lumbar), there were no hemorrhagic complications reported [8]. However, there was one incident of a non-fatal stroke sustained two days following CMBB in a patient for whom warfarin was held according to guidelines [8]. In another study, 40 (85%) patients continued AC/AP agents for CMBB with no hemorrhagic complications reported [9]. Agents continued in this study included aspirin, clopidogrel, ticagrelor, warfarin, and dabigatran. In another retrospective study that included 74 patients undergoing CMBB, AC/AP agents were held for 15 while AC/AP agents were continued in 59, and no hemorrhagic or thrombotic events were reported [10]. In the entire study, AC/AP agents were continued in 4,099 cases and discontinued in 2,124 cases for cervical, thoracic, and lumbar level injections. A total of 30 ischemic complications occurred: 14 in the AC/AP discontinuation group (0.66%, 95% CI: 0.3–1.0%) and 16 in the AC/AP continuation group (0.39%, 95% CI: 0.2–0.58%). No hemorrhagic complications occurred in either group, including those who underwent CMBB [11].

A single case of a large cervical epidural hematoma 1 h following a CMBB in a patient with no history of coagulopathy and no history of taking either AC/AP agents has been reported [12]. Surgical decompression was required. No procedural images were included in the publication, and it is not clear if the injection was performed according to clinical practice guidelines [13].

Multiple studies have reported no hemorrhagic complications associated with CMBB in patients maintained or not maintained on therapeutic AC/AP agents [4,8,9,14–17]. Indeed, in a systematic review examining the risks of continuing or ceasing AC/AP agents prior to image-guided spine procedures performed according to clinical practice guidelines [13], there were no reports of hemorrhagic complications associated with CMBB, although the authors note that there were no compelling data specifically addressing the safety of this procedure in patients who continue AC agents [18].

Alternatively, there is evolving evidence that ceasing AC therapy for the duration required prior to an interventional pain procedure carries significant risk of a catastrophic thromboembolic neurovascular or cardiopulmonary event. Recent studies have demonstrated a significant increase in the risk of thromboembolic events when warfarin [8,19] was discontinued prior to common spinal interventions [8–10,19,20]. These events include myocardial infarction, stroke, pulmonary embolism, and death. The rate of serious cerebrovascular or cardiovascular complications associated with stopping warfarin for interventional pain procedures has been found to be approximately 0.5% [19]. There is also one reported case of a fatal myocardial infarction after clopidogrel was held in advance of a neuraxial procedure [9]. However, given the absence of other known cases, as previously reported [21], the risk of thrombotic complications due to withholding AP agents prior to spinal interventions has not been clearly established. Also as previously reported [21], a Cochrane Review concluded that while continuation or discontinuation of AP agents prior to surgery had little or no effect on outcomes, there is an absolute effect of 17 fewer participants per 1,000 with an ischemic event in the continuation group [22].

It is important to acknowledge that previous guidelines classified CMBB as carrying an "intermediate risk" of bleeding complications [23]. The authors acknowledged that these recommendations represented expert consensus "based on limited clinical and animal data." Since those guidelines were published in 2018, the evidence demonstrating tangible risk of a catastrophic thromboembolic cerebrovascular or cardiopulmonary event when AC/AP is discontinued has grown. For this reason, physicians should consider continuation of AC/AP agents during CMBBs, though more data are needed to improve the confidence of a zero-incidence estimate associated with the risk of a serious hemorrhagic event when a CMBB is performed according to clinical practice guidelines when AC/AP is continued.

1. Conclusion

While continuation of AC/AP agents may potentially increase the risk of common minor bleeding events, such as injection site bleeding and superficial hematoma formation, no clinically significant or catastrophic hemorrhagic complications have been reported in the published literature in association with CMBB performed according to clinical practice guidelines. Alternatively, the risk of catastrophic cerebrovascular and cardiovascular events related to holding AC agent(s), specifically warfarin (and potentially clopidogrel), have been documented and likely outweigh the minor risks associated with local extra-axial bleeding. Based on the nature of these thromboembolic risks, physicians should consider continuation of anticoagulation and AP therapy during CMBBs; however, more data are required to support a definitive recommendation. In addition, the decision to withhold AC and AP therapy prior to CMBB should be made on a case-by-case basis, as the relative risk of hemorrhage versus thrombosis is different for each unique patient.

2. Key points and recommendations

- Complications related to CMBB can arise if the procedure is not performed according to clinical practice guidelines.
- During appropriately performed CMBB, while hematoma is possible, it is likely to remain outside of the spinal canal and unlikely to result in neurological injury.
- Advanced axial imaging should be reviewed prior to CMBB in order to assess the local anatomy, which may include anatomic variants, so as to avoid inadvertent vertebral artery trespass.
- There is growing evidence that ceasing anticoagulation therapy, specifically warfarin, carries a risk of catastrophic cerebrovascular and cardiovascular events. There is one reported case of a fatal myocardial infarction associated with ceasing clopidogrel in advance of a lumbar epidural injection.
- Based on the nature of these thromboembolic risks, physicians should consider continuation of anticoagulation and AP therapy during CMBBs; however, more data are required to support a definitive recommendation.
- The decision to withhold AC and AP therapy prior to CMBB should be made on a case-by-case basis, as the relative risk of hemorrhage versus thrombosis is different for each unique patient.

- The interventional physician should always consider that not performing a procedure is a relevant option when weighing the risks of thromboembolic and hemorrhagic complications in each individual patient.

Anticoagulant and Antiplatelet Agents for Cervical Medial Branch Radiofrequency Neurotomy

Mathew Saffarian[1]; Haewon Lee[2]; and Zachary L. McCormick[3] on behalf of the Spine Intervention Society's Patient Safety Committee.

[1]Michigan State University, Department of Physical Medicine and Rehabilitation, East Lansing, MI, USA;

[2]University of California, San Diego, Department of Orthopedic Surgery, San Diego, CA, USA;

[3]University of Utah School of Medicine, Department of Physical Medicine & Rehabilitation, Salt Lake City, UT, USA.

Myth: Therapeutic anticoagulation (AC) and antiplatelet (APT) agents should be discontinued prior to cervical medial branch radiofrequency neurotomy (CMBRFN) due to serious hemorrhagic risks.

Fact: No clinically significant hemorrhagic complication has been reported in the medical literature in association with a CMBRFN procedure. Studies comparing serious risks of continuing versus discontinuing AC and APT agents for CMBRFN procedures are underpowered, but suggest that discontinuation, specifically of warfarin, may carry greater risk of permanent neurologic compromise. The decision to withhold antiplatelet therapy prior to a CMBRFN procedure should be made on a case-by-case basis, weighing the relative risks of hemorrhage versus the risk of thrombosis for each patient.

Cervical medial branch radiofrequency neurotomy (CMBRFN) is a procedure used to treat cervical zygapophysial joint pain. Studies demonstrate an excellent safety profile of CMBRFN when performed according to clinical practice guidelines [1–3]. During proper technique a needle or cannula and electrode are advanced along the path of the targeted medial branch to the "target zone" adjacent to the cervical articular pillar. The electrode remains outside of the spinal canal and the neuroforamen, and dorsal to the vertebral artery.

In the case of rare anatomic variants in which the vertebral artery traverses the cervical lateral pillar, CMBRFN should not be performed at the relevant level(s) [4]. Cases of periforaminal arteries have also been documented that could lead to vascular complications [5]. However, in most circumstances, bleeding complications would be expected to be limited to cervical paraspinal hematoma and bleeding at the needle puncture site.

Previous guidelines classified spinal medial branch RFN as carrying an "intermediate risk" of bleeding complications regardless of segmental level [6]. A subsequent update re-classified thoracic and lumbar medial branch RFN as "low risk" for bleeding complications but maintained CMBRFN as "intermediate risk" [7]. The guideline authors acknowledged that these recommendations represented expert consensus "based on limited clinical and animal data." Alternatively, recent studies have investigated the risk of serious neurologic complications while stopping AC and APT medications compared to serious hemorrhagic risks during interventional spine procedures, thus aiding evidence-based clinical decision making [8–11].

No clinically significant hemorrhagic complications have been documented in the literature associated with CMBRFN when performed with the appropriate technique [12], even when performed for patients who continue AC and APT medications [2,8–11,13–15]. Studies by Endres et al. evaluated the risks of continuing or discontinuing AC and APT medications during common interventional pain procedures [8,9]. During cervical CMBRFN, AC medications were continued for patients who could not be discontinued from their medications, or when their coagulation status was normal. Although the total number of patients undergoing CMBRFN studied was small (n = 168), no hemorrhagic events were noted among the 10 patients that continued AC (95% CI: 0.0% to 28%) [9].

Additional studies have shown similar results with zero prevalence of hemorrhagic complications, although the number of patients undergoing CMBRFN were small in patients who remained on AC/APT agents [Goodman et al. (n = 3) and Ehsanian et al. (n = 7)] [11,15]. Bernstein et al. performed CMBRFN on 40 patients from September 2009 through June 2017 [14]. Of those, 15 patients ceased AC/APT medications while the remaining 25 patients continued AC/APT. There were no hemorrhagic complications, regardless of whether patients continued or discontinued AC/APT medications (95% CI: 0.0% to 8.8%). Larger studies are needed to establish a more accurate incidence rate of serious hemorrhagic complications when AC/APT agents are continued during CMBRFN.

Conversely, patients who cease AC medications for the duration required to complete an interventional pain procedure demonstrate measurable risk of morbid or mortal thromboembolic events [9,14,16]. Endres et al. observed nine serious thromboembolic events in association with 2672 procedures for which AC was discontinued [9]. Among the complications suffered were two deaths (fatal stroke, fatal myocardial infarction), one myocardial infarction, five strokes, and one pulmonary embolism. Of note, these complications ***only*** occurred in patients who ceased warfarin; however, warfarin was the most prevalent AC, composing 1646 of the 2672 AC that were discontinued. The prevalence of cardiovascular and cerebrovascular complications in patients who ceased warfarin was found to be 0.48% (95% CI: 0.2% to 0.9%). Bernstein et al. found a similar rate of 0.2% (95% CI 0.1% to 0.4%) in those that ceased AC [14].

Risk of thrombotic complications due to withholding APT prior to spinal interventions has yet to be established. Clinical decisions regarding the cessation of APT agents needs to be balanced with the risk of serious cerebrovascular and cardiovascular hemorrhagic complications. A recent Cochrane Review concluded that continuation or discontinuation of APT prior to non-cardiac surgery had little or no effect on adverse ischemic events or blood loss [17]. However, an absolute effect of 17 fewer participants per 1,000 with an ischemic event in the continuation group was noted.

In summary, while there is no clear evidence that CMBRFN is associated with serious hemorrhagic risk when performed according to the clinical practice guidelines [12], the current literature consistently demonstrates a significant and consistent risk ranging from 0.2 to 0.9% incidence of serious thromboembolic events when AC, specifically warfarin, is discontinued for interventional pain procedures.

3. Recommendations

1. Axial cross-sectional imaging, via either MRI or CT angiogram, should be reviewed prior to CMBRFN in order to ensure the absence of rare arterial anatomic variants, such as a vertebral artery that traverses the cervical lateral pillar. If this variant is present, CMBRFN should not be performed at the relevant level(s).
2. Although larger studies are needed to provide a confident estimate of zero risk of continuing AC or APT prior to CMBRFN, there is currently no evidence that continuing AC or APT prior to this procedure carries risk of clinically significant hemorrhagic complications when performed according to the Spine Intervention Society guidelines.
3. The rate of serious cardiovascular or cerebrovascular complications associated with stopping AC, specifically warfarin, for interventional spine procedures has been found to be approximately 0.5%. It should be noted that complications were ***only*** found with warfarin while also noting that warfarin was the most commonly used AC.
4. The decision to stop or continue AC or APT should be made through a shared decision-making process with the patient, the spine interventionalist, and the prescribing provider to account for the relative risks of serious thromboembolic versus hemorrhagic complications.
5. The interventional physician should always consider that not performing a procedure is a relevant option when weighing the risks of

thromboembolic and hemorrhagic complications in each individual patient.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Consultant: Saol Therapeutics, Stryker, FUSMobile; Research support: Avanos Medical, Boston Scientific, Relievant Medsystems, SPR Therapeutics – ZM. Meals/entertainment: Boston Scientific; Tenex Health – MS.

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