Critical Review Form
Prognosis

PGY-3

HYPERLINK "http://pmid.us/34130854"Mourad M, Senay A, Kharbutli B. The utility of a second head CT scan after a negative initial CT scan in head trauma patients on new direct oral anticoagulants (DOACs). Injury. 2021 Sep;52(9):2571-2575.

Objectives: **"to assess the utility of repeat imaging in this growing patient population, we undertook a retrospective review of all consecutive head traumas patients on DOAC [direct oral anticoagulant] therapy presenting to our institution." (p. 2572)**

Methods: **This retrospective chart review was conducted at Henry Ford Wyandotte Hospital, a Level III trauma center in Wyandotte, MI, between August 2013 and October 2019. All adults aged 18 years or older with confirmed or suspected blunt head trauma who were taking a DOAC (Apixaban, Rivaroxaban, or Dabigatran) and who received at least one CT scan were included. Patients who were transferred outside of the healthcare system were excluded.**

Per hospital protocol, patients taking a DOAC who suffered blunt head trauma within the previous 12 hours were admitted for observation and underwent a repeat CT scan 12 hours after the initial CT scan. The primary outcome of this study was the frequency of new or delayed acute intracranial hemorrhage found on the second CT scan.

A total of 498 encounters among 400 patients were included in this analysis. The mean age was 76 years and 55.6% were female. Fall was the mechanism of injury in 96.9% of encounters. The initial CT scan was negative in 479 (96.2%) encounters.

Guide		Comments
I.	**Are the results valid?**	
A.	**Was the sample of patients representative?** *In other words, how were subjects selected and did they pass through some sort of "filtering" system which could bias your results based on a non-representative sample. Also, were objective criteria used to diagnose the patients with the disorder?*	No. This study was conducted at a relatively small level III hospital and the mechanism of injury in almost all cases was ground level fall. These are hence patients with a low energy mechanism of injury and these results may not apply to patients suffering more serious injury (external validity). The "disorder" of interest (head trauma) is not entirely objective and it is possible that patients without direct head injury may have been included.
B.	**Were the patients sufficiently homogeneous with respect to prognostic risk?** *In other words, did all patients share a similar risk from during the study*	Yes. This does appear to be a relatively homogenous patient population, almost all of whom presented after a ground level fall. While there may have been outliers with more significant mechanism (such as MVC), given

	period or was one group expected to begin with a higher morbidity or mortality risk?	that this was a level III trauma center it seems unlikely that many of the patients suffered from a high-risk mechanism.
C.	**Was follow-up sufficiently complete?** *In other words, were the investigators able to follow-up on subjects as planned or were a significant number lost to follow-up?*	No. A repeat head CT was not obtained in 12.3% of patient encounters (loss to follow-up).
D.	**Were objective and unbiased outcome criteria used?** Investigators should clearly specify and define their target outcomes before the study and whenever possible they should base their criteria on objective measures.	Yes. The primary outcome was "new or delayed acute intracranial hemorrhage found on a second CT of the head" after an initial negative CT. This is a fairly objective outcome. The authors did not assess need for neurosurgical intervention or discontinuation of anticoagulation.
II.	**What are the results?**	

A.	**How likely are the outcomes over time?** *For the defined follow-up period, how likely were subjects to have the outcome of interest.*	• An initial positive CT scan was associated with higher injury severity score (ISS) ($p < 0.0001$). Type of DOAC, initial GCS, and trauma mechanism did not have a significant impact on the likelihood of a positive initial CT scan.
		• A positive second CT scan after an initial negative scan was seen in 2 cases (0.5%, 95% CI 0.06-1.7%).
		  ○ These 2 patients had a higher median ISS than those with a negative 2nd CT scam (11.5 vs. 1.0, $p = 0.022$).
		  ○ These 2 patients also had lower median GCS than those with a negative second CT scan (12.5 vs. 15, $p = 0.0033$).
		  ○ Neither patient required a neurosurgical intervention.

B.	**How precise are the estimates of likelihood?** *In other words, what are the confidence intervals for the given outcome likelihoods?*	See above. This was not a very large study with a very low incidence of the primary outcome. As a result, the 95% CI is rather wide and conclusions regarding associations with risk factors are difficult to make.
III.	**How can I apply the results to patient care?**	
A.	**Were the study patients and their management similar to those in my practice?**	No. This study was conducted at a level III trauma center with patient suffering primarily ground level falls. These results do not necessarily apply to patients with more significant mechanisms of injury (external

		validity). Additionally, the authors provide no information regarding race or medical comorbidities.
B.	**Was the follow-up sufficiently long?**	Uncertain. Per protocol, patients were observed and had repeat CT scans 12 hours after the initial scan. Prior protocols for patients receiving warfarin recommended 24-hour observation and repeat CT scan, and it is possible that more cases of delayed hemorrhage would have been seen in this study with a longer interval. The optimal duration of observation (if any) is at this time unknown.
C.	**Can I use the results in the management of patients in my practice?**	Yes. For patients taking DOACs with minor head injury from a low-risk mechanism, the risk of delayed hemorrhage appears to be very low, and neither of the patients in this study required neurosurgical intervention. There does not appear to be significant benefits to warrant the costs associated with observation and routine CT scanning in this patient population.

Limitations:

1. **This study was conducted at a relatively small level III hospital and the mechanism of injury in almost all cases was ground level fall. These are hence patients with a low energy mechanism of injury and these results may not apply to patients suffering more serious injury (external validity).**
2. **A repeat head CT was not obtained in 12.3% of patient encounters (loss to follow-up).**
3. **This was a rather small study with a low incidence of the primary outcome. As a result, the confidence intervals are rather wide and it is difficult to make any conclusions with regard to association with risk factors.**
4. **This was a retrospective chart review relying on documentation in the medical record, which is often incomplete.**

Bottom Line

This retrospective study from a level III trauma center found that in patients taking DOACs suffering minor head trauma, the risk of delayed hemorrhage after routine observation and repeat CT scanning 12 hours after an initial negative CT is very low (0.47%, 95% CI 0.06-1.7%). Neither of the patients with delayed hemorrhage detected required any neurosurgical intervention and both were discharged home.