Preinjury warfarin does not impact outcome in trauma patients.

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Preinjury Warfarin Does Not Impact Outcome in Trauma Patients

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Objective: **The objective of this study was to determine whether the preinjury condition of anticoagulation had an adverse impact on patients sustaining injury.**

Methods: **A retrospective analysis was performed for prospectively collected registry data from 1995–2000 from all accredited trauma centers in Pennsylvania. The registry was queried for all trauma patients who had anticoagulation therapy as a preinjury condition (PIC). This group served as our experimental cohort. A control cohort (not having warfarin therapy as a PIC) was developed using case-matching techniques for age, sex, Glasgow Coma Scale (GCS), Injury Severity Score (ISS), A Severity Characterization of Trauma (ASCOT) score, and in the head injured patients, *International Classification of Diseases, Ninth Revision, Clinical Modification* (ICD-9-CM) diagnoses. Head and non-head injured patients were evaluated separately. The cohorts were examined for 28-day mortality, intensive care unit length of stay (ICU-LOS), hospital length of stay (HOS-LOS), PICs, occurrences, discharge destinations, and functional status at discharge. χ^2 and Student's t test were used to evaluate the data; p values < 0.05 were considered significant.**

Results: **Two thousand nine hundred forty-two patients were available for analysis. The prevalence of PICs was significantly greater in the warfarin group for both the head and non-head injured populations ($p < 0.003$ and $p < 0.0001$, respectively). The incidence of occurrences in the non-head injured population was statistically higher for the warfarin patients ($p < 0.001$), but showed no difference in the head injured group regardless of warfarin use ($p = 0.15$). Functional status at discharge demonstrated no clinically significant difference between the warfarin and non-warfarin groups in both head and non-head injured populations. There was no difference in discharge destination in the head injured population; however, in the non-head injured population a greater percentage of non-warfarin patients was discharged to home when compared with the warfarin patients.**

Conclusion: **Our data suggest that the PIC of anticoagulation with warfarin does not adversely impact mortality or LOS outcomes in both head and non-head injured patients. In non-head injured patients, however, the occurrence rates and discharge destination were different. More research needs to be done to determine whether this is related to anticoagulation or other reasons (i.e., number of PICs). These data should be used when weighing risk/benefit ratios of prescribing chronic anticoagulation.**

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Chronic oral anticoagulation with warfarin is used in the management of many clinical conditions, including atrial fibrillation, mechanical heart valves, and venous thromboembolism.[1] The current literature has clearly demonstrated a reduction in thromboembolic events for patients receiving long-term warfarin treatment.[2,3] As the population ages and the use of chronic oral anticoagulation increases, we anticipate a significant number of trauma patients will be injured while on chronic anticoagulation therapy.[4] The decision to anticoagulate a patient requires a fundamental understanding of the risk/benefit ratio. In most patients this ratio balances the benefits of thromboembolic prevention against the risk of bleeding. Many physicians assume that the combination of warfarin therapy and trauma leads to an excessively high risk of morbidity and mortality and choose not to prescribe anticoagulation therapy to patients who are at increased risk for trauma. It is not clear from the current literature whether warfarin therapy has a significant impact on outcome in the trauma patient. Data from our own institution indicates prehospital use of warfarin does not have an adverse impact on outcome in the elderly trauma patient; however, those data were limited by the small numbers of patients and no injury stratification.[5] We sought to analyze a large statewide database to determine whether the use of prehospital warfarin had an impact on outcomes in patients sustaining trauma.

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MATERIALS AND METHODS

A retrospective review of prospectively collected data from the Pennsylvania Trauma Outcome Study (PTOS) database was conducted. The registry, described elsewhere,[6] contains data from all accredited trauma centers in the state of

Table 1 Head Injured Patients' ICD-9-CM Diagnoses

800—fractures of the vault of the skull
801—fractures of the base of the skull
803—other and unqualified skull fractures
804—multiple fractures involving skull or face with other fractures
850—concussion
851—cerebral laceration and contusion
852—subarachnoid, subdural, and extradural hemorrhage
853—other and unspecified intracranial hemorrhage following injury
854—intracranial injury of other and unspecified nature

Pennsylvania and includes all patients with the diagnosis of trauma (i.e., *International Classification of Diseases, Ninth Revision, Clinical Modification* [ICD-9-CM] codes 800–959).

A case-control study was performed from January 1995 through November 2000. Patients with injuries were stratified by the presence or absence of head injury. In both populations experimental and control cohorts were selected. The experimental cohorts consisted of all trauma patients admitted with the preinjury condition (PIC) of anticoagulation, while the control cohorts did not have the PIC of anticoagulation. Case-matching methodology was applied to the cohorts with patients being matched for age (±2 years), sex, GCS, ISS, ASCOT (±0.025), and in the head injured patient ICD-9-CM diagnoses 800, 801, 803, 804, and 850–854 (Table 1). All PICS were evaluated, but patients were not matched with respect to this variable.

Outcomes analyzed were 28-day mortality, intensive care unit length of stay (ICU-LOS), overall hospital length of stay (HOS-LOS), occurrences, discharge destinations, and functional independence measurement scores (FIMS). Occurrences were defined as an unexpected event directly affecting patient care as per the Pennsylvania Trauma Systems Foundation definition. All occurrences must be documented in the patient record by a physician and confirmed by the definition of the specific occurrence. Forty-four separate occurrences are listed in the registry. Functional status at discharge as computed by FIMS evaluated the following criteria separately: feeding, locomotion, expression, transfer mobility, and social interaction. Each individual criteria received a score of 1 (complete dependence), 2 (modified dependence), 3 (independence with device), or 4 (complete independence) (Table 2).

Outcome data that were dichotomously coded compared the warfarin and non-warfarin groups using the Pearson χ^2 test. Continuous outcome data were compared using group t test. Any observed p value less than 0.05 were considered significant for this analysis.

RESULTS

The database identified 1,916 patients as having the PIC of anticoagulation with warfarin for the study period. Eight hundred six patients were stratified to the head injury group, and 1,110 were stratified to the non-head injury group. Four hundred sixteen (51.6%) head injured and 1,054 (94.9%) non-head injured patients were matched as per the stipulated criteria (Table 3).

There were no statistically significant differences in the criteria between warfarin and non-warfarin cohorts in both the head injured and non-head injured populations. All patients were evaluated for the number of preinjury conditions present on admission to the trauma center. After excluding anticoagulation therapy in both the head and non-head injured patients, the prevalence of preinjury conditions was significantly greater in the warfarin cohort for both the head and non-head injured populations ($p < 0.003$ and $p < 0.0001$, respectively).

Table 2 Functional Status at Discharge

	Feeding	Locomotion	Expression	Transfer Mobility	Social Interaction
Head injured patients					
Warfarin	3.6 (0.8)	3.1 (1.1)	3.7 (0.7)	3.2 (1.0)	3.7 (0.7)
Non-warfarin	3.7 (0.7)	3.3 (0.9)	3.8 (0.6)	3.3 (0.9)	3.8 (0.6)
p value	0.04	0.006	0.15	0.06	0.26
Non-head injured patients					
Warfarin	3.5 (0.8)	2.8 (1.0)	3.8 (0.6)	2.9 (1.0)	3.8 (0.6)
Non-warfarin	3.6 (0.8)	2.9 (1.0)	3.8 (0.6)	3.0 (1.0)	3.8 (0.6)
p value	0.16	0.01	0.08	0.01	0.54

Table 3 Case-Matching Criteria

	Age	ISS	ASCOT	GCS
Head injured patients				
Warfarin (n = 416)	71.9 (13.0)	11.64 (8.7)	0.90 (0.19)	14.13 (2.8)
Non-warfarin (n = 416)	71.8 (13.1)	11.64 (8.7)	0.90 (0.19)	14.13 (2.8)
Non-head injured patients				
Warfarin (n = 1,054)	73.9 (12.7)	7.18 (5.3)	0.95 (0.06)	14.8 (1.1)
Non-warfarin (n = 1,054)	73.8 (12.8)	7.18 (5.3)	0.95 (0.07)	14.8 (1.1)

Table 4 Outcome Results

	28-Day Mortality (%)	ICU-LOS	HOS-LOS
Head injured patients			
Warfarin (n = 416)	31 (7.5)	1.8 (5.1)	6.9 (7.6)
Non-warfarin (n = 416)	34 (8.2)	1.8 (3.5)	7.0 (7.6)
p value	0.70	0.98	0.87
Non-head injured patients			
Warfarin (n = 1,054)	46 (4.4)	1.4 (5.1)	7.8 (8.1)
Non-warfarin (n = 1,054)	44 (4.2)	1.3 (6.4)	9.0 (11.4)
p value	0.83	0.85	<0.01

Twenty-eight day mortality, ICU-LOS, and HOS-LOS for the warfarin and non-warfarin cohorts in both the head and non-head injured populations are shown in Table 4. The only statistically significant difference in these outcomes was a shorter HOS-LOS for the warfarin cohort in the non-head injured population.

Mortality was further evaluated by stratifying GCS and ISS. The ISS for the warfarin and non-warfarin cohorts were stratified to ISS > 15. In the patients with ISS > 15 there was no difference in mortality in the head inured ($p = 0.765$) and non-head injured ($p = 0.793$) populations based on warfarin status. Glasgow Coma Scale score was stratified into three groups: GCS 3–8, GCS 9–13, and GCS 13–15. Again, there was no difference in mortality between warfarin and non-warfarin cohorts in both the head injured ($p = 0.57$, 1.00, 1.00) and non-head injured ($p = 1.00$, 1.00, 0.71) populations when stratified to GCS 3–8, GCS 9–13, and GCS 13–15, respectively.

In the head injured patients there was no significant difference in the incidence of in-hospital occurrences between the warfarin and non-warfarin cohorts ($p = 0.15$). In the non-head injured population the incidence of occurrences was statistically higher in the warfarin cohorts ($p < 0.001$).

The functional independence measurement scores for feeding and locomotion in the head injured population and locomotion and transfer mobility in the non-head injured population were statistically different between the warfarin and non-warfarin cohorts (Table 2). Discharge destinations are shown in Figure 1. The head injured population demonstrated no significant difference ($p = 0.27$) in discharge destination based on anticoagulation status. In the non-head injured population there was a significant difference ($p < 0.001$) in discharge destination between the warfarin and non-warfarin groups. A greater percentage of non-warfarin patients were discharged to home (62% vs. 49%), whereas a greater percentage of warfarin patients were discharged to skilled nursing facilities (30% vs. 20%).

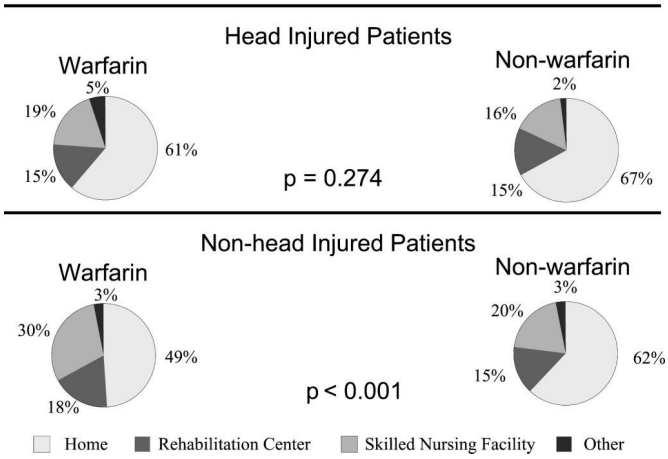

Fig. 1. *Discharge destination.*

DISCUSSION

Chronic anticoagulation with warfarin therapy has clearly demonstrated a reduction in the risk of thromboembolism for specific conditions.[2,3] Anticoagulation therapy has been effective in reducing the risk of recurrent venous thromboembolism by about 80%.[7–11] Patients with nonvalvular atrial fibrillation and mechanical heart valves have been shown to have a reduction in the risk of embolism by about 66% and 75%, respectively.[12–15]

To date, there have been no large studies that have addressed the impact preinjury anticoagulation has had on outcome in patients sustaining trauma. Kennedy et al.[5] examined the effect of preinjury warfarin in 61 elderly trauma patients and concluded that elderly trauma patients receiving anticoagulation before injury do not have increased morbidity and mortality compared with elderly trauma patients not on warfarin. Stein et al.[16] reviewed fall-related injuries in anticoagulated stroke patients during inpatient rehabilitation and concluded that the risk for minor injury secondary to fall is no different between anticoagulated and nonanticoagulated patients. This group also found a very low risk for hemorrhagic injuries in stroke patients falling while receiving anticoagulation therapy. Garra et al.,[17] in a retrospective review of 65 patients suffering minor head trauma while anticoagulated, reported that the incidence of clinically significant intracranial injury was extremely low.

On the other hand, Mathiesen et al.[18] found a 77% mortality rate associated with warfarin therapy in 26 traumatic and 41 nontraumatic patients with intracranial hematomas. Saab et al.[19] reported on two patients receiving anticoagulation therapy that sustained minor head trauma and concluded that these patients have a 10-fold increase in the likelihood of developing intracranial hematomas than patients not on anticoagulation therapy. Ferrera and Bartfield,[20] in a retrospective review of 35 trauma patients admitted on warfarin therapy, concluded that patients receiving anticoagulation therapy with warfarin were at high risk for potentially life-threatening hemorrhages.

Unfortunately, based on the existing literature, there is no consensus whether anticoagulated trauma patients are susceptible to an increased risk of morbidity and mortality. Therefore, many physicians withhold anticoagulation therapy for patients who are at risk for falls and trauma to protect the

patient from the possibility of complications. Our study sought to answer the question: Does the preinjury condition of anticoagulation adversely impact outcomes in head and non-head injured patients sustaining trauma?

After stratifying for injury (head injured and non-head injured), case matching methodology was applied to warfarin and non-warfarin cohorts. Criteria selected were age, sex, ISS, ASCOT, GCS, and in the head injured population ICD-9-CM diagnoses. Our data showed patients admitted to trauma centers on warfarin have a greater number of preinjury conditions than their non-warfarin counterparts. This suggests that warfarin use is reflective of other illnesses. In the head injured patients warfarin did not increase morbidity as measured by outcome rates; however, there was an increase in the number of occurrences in the warfarin cohort of non-head injured patients. Whether this is related to warfarin use or other factors, such as preinjury conditions, requires further study. Despite this, warfarin use did not increase 28-day mortality, ICU-LOS, or HOS-LOS in either the head or non-head injured populations. In the non-head injured patients the non-warfarin cohorts had a longer HOS-LOS than their warfarin counterparts.

In the head injured population anticoagulation status did not impact discharge destination; however, in the non-head injured population a significantly greater number of patients were discharged to home in the non-warfarin group, whereas a greater number of patients were discharged to skilled nursing facilities in the warfarin group. Functional status at discharge was statistically different between the cohorts in both head and non-head injured populations; however, further analysis revealed no clinically significant difference.

The study population demonstrated relatively low ISS and high GCS values. To ensure that the results were similar for the more severely injured trauma patients, separate analyses were performed. Patients were stratified to an ISS $>$ 15 as well as GCS $<$ 8 and there was no difference in mortality between warfarin and non-warfarin cohorts for both the head and non-head injured populations.

A limitation of this study is that trauma patients may not have been adequately anticoagulated on their warfarin therapy on admission. Unfortunately the database does not contain admission international normalized ratios (INR) or Coumadin dosage. Therefore, these variables could not be evaluated across institutions. However, examination of the patients from our institution (n = 210) showed that on admission the mean INR was 2.36 (SD = 1.5), indicating that on average patients admitted to our trauma service on warfarin were therapeutically anticoagulated. Another variable we were not able to evaluate was the requirement of blood products. Unfortunately, these data were not a feature of the registry during our study dates.

CONCLUSION

Our data have shown that the PIC of anticoagulation does not adversely impact 28-day mortality, ICU-LOS, HOS-LOS, and functional status at discharge in both the head and non-head injured populations. More research needs to be done to evaluate the difference in occurrence rate and discharge destination in the non-head injured population to determine whether anticoagulation contributes to this outcome. We are hopeful that this data will be helpful to physicians when weighing the risks and benefits of anticoagulation therapy.

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DISCUSSION

Dr. Wendy L. Wahl (Ann Arbor, Michigan): First, I would like to thank Randy for sending the paper on time and I think that he really should be congratulated for this effort. I think this is particularly impressive, since he is a third year resident who has had no specific time off to do research and I think this is a compliment to him as well as to his surgical mentors.

I think, as our population in general increases in age, the number of people who will be treated with warfarin anticoagulation is also going to increase and this will become a major impact for those who are taking care of these traumatically injured patients. There are very few data out there in the literature about the effects of warfarin on injured patients. This paper is an extension of work done by the same group and recently published in *The Journal of Trauma*, which looks at the impact of anticoagulation on elderly trauma patients.

This is a much larger study than what has been previously published and over 1,900 patients were identified through the Pennsylvania Trauma Outcomes Registry as having been on warfarin anticoagulation during this 6 year study period. The patients were well stratified based on the presence or absence of head injury and case matched with patients with similar injuries, age, and ISS. The authors conclude that there is no difference, both in functional outcome or mortality in these patients or in hospital length of stay.

While these findings are based on a fairly large patient population, using case match controls, it is a retrospective analysis with findings which certainly are counterintuitive to what many of us would believe from our own clinical practices. While the authors show no difference in outcomes for the anticoagulation group, I have some concerns about why they may not see a difference. Of the over 1,900 patients admitted on anticoagulation, the authors report average INR values for only 210 of these patients and there is a large SD in this subset.

While many patients may have been prescribed warfarin, we do not know if they were indeed therapeutic on the drug. The conclusions may be better summarized that warfarin use, rather than anticoagulation, does not adversely impact outcomes.

Do the authors have any other data concerning the degree of anticoagulation for the warfarin group? While the warfarin and no warfarin groups were case matched for ISS, if the majority of patients had relatively minor injuries and in the paper the average ISS is 11, we may not expect to see a difference related to anticoagulation. Do you have any information about patients with higher ISS scores and whether there was a difference in outcome?

Only half of the head injured patients in this study were case matched in the warfarin group, so over 49% were thrown out and we did not see the outcomes for this group. Do you have any data on those patients?

Finally, of those who died in the warfarin group, how many died of bleeding or bleeding complications, and was there a transfusion difference between the two groups and could it be that we are concerned about these patients since they are on anticoagulation and perhaps we actually give them better care. Do we have any evidence that monitoring was different or information to that extent? I would like to thank the EAST for the privilege of discussing this very interesting and timely paper.

Dr. Dennis Wang (Washington, D.C.): I have a couple of questions. You do not look at prehospital deaths specifically because those will make it not a complete population study. Would you please comment on what may be the final result?

Also, clearly traumatic bleed is a subset of possible bleeding complications of anticoagulation. CNS bleed, spontaneous GI bleed, and other things increase morbidity and mortality for anticoagulatory patients, especially in the elderly patients.

Your concern, and I will try to alleviate the concerns of other people, starting anticoagulation may be only limited on trauma patients and not for the rest of the possible complications.

Would you currently, based on just the trauma data, recommend people use anticoagulation on an elderly patient of, let's say, 80 years old based on your data? Thank you.

Dr. Mark A. Healey (Burlington, Vermont): I think that this paper fails to focus on one of my primary concerns with the traumatized, coumadinized patient and that is not how they will do once they have an intracranial bleed, but how trivial was the insult that caused the intracranial bleeding?

We are looking at patients that have been matched after the problem, whereas I find the big difficulty is a fairly small motor vehicle collision will cause a significant intracranial hemorrhage and this paper fails to look at that. Did you have any data that looked at the mechanism of injury or the severity of injury and the resultant ISS? Thank you.

Dr. Blaine L. Enderson (Knoxville, Tennessee): I, too, was concerned about your findings in your head injured patients. You eliminated half of the head injured patients, didn't match them, and I was wondering if you could tell us why that was.

I may have missed that in your presentation, but like Dr. Healey, I think the problem with your design is that you are matching the injuries after they have occurred and really, what we are concerned about in the warfarin patients is what was the initial trauma that resulted in that injury?

I think by matching the patients that it is not surprising that your outcomes are exactly the same, but I think you have

to go back before that and really see the impact of warfarin in these patients. Thank you.

Dr. Randolph Wojcik (closing): I would like to thank Dr. Wahl for her informative critique as well as the discussants for their interest in my paper. We, too, agree that there are some concerns and we have learned a lot from this study.

All the comments were very insightful. To address them specifically, we were also concerned about INR. We are actively looking at the other institutions and trying to get those data to see if indeed they were anticoagulated at the other institutions.

As you could tell from the abstract that is in the program, we have done this match three times. Previous matches all reported no differences. We did have higher ISSs and actually, these were statistically significant, so we did not have true, well matched population groups. That is why we needed to tighten our match criteria and that is why we only had 52% match in the head injured and then 95% match in the non-head injured.

Unfortunately, the registry does not contain cause-of-death information. It does have occurrences, of which I gave the definition in my talk. There are 46 occurrences listed, two of which are related to hemorrhagic complications.

One is GI bleed and two are postoperative hemorrhage. Although the numbers were small, there was no statistical difference between the warfarin and non-warfarin patients.

Dr. Wang, I agree with you that we are not making a universal recommendation here. We just feel that our data could be used in a risk/benefit ratio for patients when considering anticoagulation in patients who could possibly be deemed at risk of falls or trauma.

Dr. Healey, we did not look at mechanism of injury, so I cannot answer on that question, and Dr. Enderson, I think I addressed the question about our previous matches. Again, I would like to thank you for the floor and I would like to thank the Association for the opportunity to be here today.

EDITORIAL COMMENT

The article by Wojcik et al. provides an interesting retrospective analysis of data from the Pennsylvania trauma registry. The authors have shown that warfarin use has no impact on the outcome of trauma patients with head trauma when compared with those without head trauma. They do indicate a difference in outcome in those who have no head trauma; those on warfarin do worse than those without.

This article is a retrospective study and there is no indication of the warfarin dose or the INR of each registry patient. Therefore, the level of anticoagulation is unknown in these patients. This may have important implications. The authors have reviewed their own experience previously and shown that the INR was 2.8; however, in a statewide retrospective study, the same level of anticoagulation cannot be assumed.

A Swedish study,[1] which the authors cite, indicates an increased incidence of major CNS complications secondary to hemorrhage in a group of patients on warfarin with an average INR of 2.8 for the group. Thus based on the lack of defining data in the present study and the results from the Swedish study, the present paper needs to be viewed with caution. Warfarin therapy is still necessary for specific indications, and the risks and benefits need to be weighed carefully for each individual patient. More data are needed and a large prospective study needs to be undertaken to confirm or deny the findings of the present paper.

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