Utility of an international normalized ratio testing device in a hospital-based dental practice

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atients with congenital or acquired coagulopathies are common in the general population. Dentists should have access to the patients' appropriate and current laboratory values to prevent bleeding complications during and after invasive dental procedures, in particular for patients receiving warfarin and those who have liver disease.

Various protocols have been proposed for the dental care of patients receiving antithrombotic medications, but the lack of a definitive standard of care suggests a lack of necessary evidence. Bleeding after a dental procedure is rare and almost always easily controlled with local measures. However, some authors recommend withholding medication,^{1,2} despite the potentially devastating consequences, which can include life-threatening thromboembolic events such as stroke¹⁻⁴ -the risk of which is three to five times greater than the risk of postoperative bleeding that is uncontrollable by local measures.⁵

Dental care of patients with liver disease requires a familiarity with the pathophysiology, signs and symptoms associated with liver damage. Liver impairment whether resulting from infectious

ABSTRACT

Objectives. The authors aimed to evaluate the utility of an in-office international normalized ratio (INR) testing device in identifying patients with INR test values considered out of the normal range for dental procedures.



Methods. This prospective cohort study involved use of an INR testing device to obtain INR test values in the dental office for patients thought to be at risk of experiencing bleeding complications after undergoing invasive dental procedures. The authors recorded demographic, social and medical history data, as well as clinical signs and symptoms of liver disease. The authors considered an INR out of range if it was greater than or equal to 1.4 for patients with potential liver disease and greater than 3.5 for patients receiving warfarin.

Results. The authors completed an in-office INR test for 66 patients receiving warfarin whose INR had not been tested within the preceding 48 hours and 34 patients suspected of having liver disease. Eleven (17 percent) patients receiving warfarin and seven (21 percent) patients suspected of having liver disease had INR values considered out of range. Dental treatment was deferred for eight of 11 patients in the warfarin group who had INR values in the range of 3.6 to 7.4, while three others had dental procedures without bleeding complications. Six of seven patients who had documented or suspected liver disease and an out-of-range INR (range 1.5-2.5) underwent their dental procedures without experiencing bleeding complications.

Conclusions. Use of an in-office INR test indicated a high incidence of elevated INR values. The results of this study point to the importance of obtaining current INR values before performing invasive dental procedures for patients receiving warfarin therapy whose INR values have not been tested recently, and for patients thought to be at risk of developing or having liver disease.

Key Words. Anticoagulation therapy; dental care for chronically ill patients; ethanol; hemorrhage; oral hemorrhage; oral surgery; risk assessment.

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disease, alcohol abuse or vascular or biliary congestion—can significantly alter a patient's ability to tolerate surgery and general anesthesia and poses a significant risk of perioperative and postoperative complications. Therefore, it is important to determine preoperatively the patient's degree of hepatic compromise; risk of experiencing oral bleeding as a result of impairment of coagulation factors synthesized in the liver; and risk of experiencing thrombocytopenia, which may develop from splenomegaly secondary to portal hypertension.⁶⁻⁹

The risk of bleeding associated with warfarin use or with coagulopathies resulting from liver disease can be assessed preoperatively with a prothrombin time reflected as an international normalized ratio (INR) laboratory test result. This laboratory value reflects the extrinsic coagulation pathway, which is affected by both liver disease and warfarin therapy.

The major purpose of this study was to evaluate the utility of an in-office INR testing device in identifying the incidence of patients who are receiving warfarin therapy or have liver disease and have INR measurements considered too high (out of range) to receive dental treatment. A secondary objective was to determine if demographics, patient-reported social and medical history and clinical signs and symptoms were associated with an elevated INR. Finally, we determined the incidence of bleeding complications after invasive dental treatment among patients who received treatment while having elevated but clinically acceptable INR values.

METHODS

In this prospective cohort study, we used the CoaguChek system (Roche Diagnostics, Indianapolis) to obtain in-office INR values for patients thought to be at risk of experiencing bleeding complications after a planned dental procedure. Patients were scheduled for dental care in the dental clinic at a large academic medical center (Carolinas Medical Center, Charlotte, N.C.). Members of the clinical staff—including dental assistants, nurses or dental hygienistsperformed the INR test if a patient had one of the following conditions: receiving warfarin without having completed an INR test in the 48 hours preceding the dental visit; history of viral hepatitis with a self-report of abnormal liver function test values; history of excessive bleeding after an invasive procedure; current or history of heavy alcohol use (more than 20 drinks per week for more than

two years)¹⁰; clinical signs of jaundice, ascites or encephalopathy; or experiencing significant bleeding after undergoing an invasive dental procedure. We collected demographic data, social and medical history, information on concomitantly used medications reported to interfere with coagulation (such as aspirin, clopidogrel, cilostazol, nonsteroidal anti-inflammatory medications and selective serotonin reuptake inhibitors), and clinical signs and/or symptoms of liver disease. This study was approved by the medical center's institutional review board.

We considered an INR out of range if it was 1.4 or higher for patients with potential liver disease, and higher than 3.5 for patients receiving warfarin.¹¹⁻¹³ For patients receiving warfarin, we considered minor oral surgical procedures safe at an INR up to $3.5.^{13}$

Bleeding complications follow-up. We evaluated bleeding complications after invasive dental treatment in all patients. We did so by reviewing whether patients returned to our dental clinic or emergency department (ED) with a complaint of bleeding. We conducted an electronic search for ED patient visits that occurred within two weeks of the dental procedure. We reviewed the medical records of patients who returned to the ED to determine the reason for their visits.

Statistical analysis. We determined descriptive statistics, including mean, standard deviation, number of patients and percentages. We used *t* test or the Wilcoxon rank sum test for continuous variables and χ^2 or the Fisher exact test for dichotomous variables. We made comparisons between out-of-range (that is, higher than 3.5 for warfarin and 1.4 or higher for liver disease) versus within-range INR values. We considered significance to be P < .05. We completed analyses by using statistical software (SAS, Version 9.1, SAS, Cary, N.C.).

RESULTS

We completed an in-office INR test for 100 consecutive patients who met the inclusion criteria from June 2004 to October 2005. These included

ABBREVIATION KEY. CLIA: Clinical Laboratory Improvement Amendment. **ED:** Emergency department. **FDA:** U.S. Food and Drug Administration. **INR:** International normalized ratio. **POC:** Point of care.

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