Warfarin: Point-of-Care INR Monitoring

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Objective:

To provide an overview of point-of-care (POC) international normalized ratio (INR) monitoring.

Background:

A POC device is a small portable instrument that measures clotting time from a fingerstick blood sample. Most POC devices report the result as an INR. POC INR devices vary in their ease of use due to differences in required blood sample volume, the technique of application of the blood sample to the meter, the type of external quality control testing required (e.g. testing an external quality assessment material, comparison against an instrument that satisfactorily participates in an external quality assessment program, or testing of the POC INR against a separately collected venous sample for laboratory INR testing at defined intervals), the need for test strip refrigeration, and meter portability.

How are POC Devices Used?

For both adults and children, use of a POC INR device provides a simple and convenient way to manage warfarin anticoagulation in both the office/clinic setting and at home. The POC INR device uses a sample of blood acquired by fingerstick to produce an INR result within one minute. This enables timely warfarin dose adjustments and allows prompt attention to INR values that fall outside the target range. INR measurements can be performed at a patient's convenience and the need for laboratory visits can be reduced or eliminated. This convenience may facilitate more frequent INR testing. Furthermore, in randomized trials comparing POC testing with patient self-management to standard physician-managed laboratory-based INR monitoring, POC-based monitoring with a weekly INR improved the quality of anticoagulation control (i.e. time in the therapeutic range [TTR]). Higher TTR is associated with fewer thromboembolic and bleeding events.

There are three approaches to POC-based INR testing and warfarin management:

1. **POC INR testing within a clinic setting, pharmacy or a physician's office** where patients receive immediate INR results and instructions on drug dosage by the health professional;
2. **Patient self-management** in which the patient self-tests using the POC device and also self-adjusts the dose of the warfarin using predetermined dosing instructions, combined with their own accumulated experience;
3. **Patient self-testing** in which the patient self-tests using the POC device and then calls a clinician for advice on how to adjust the dose of the warfarin.

What is the Accuracy and Precision of POC INR Devices?

When comparisons are made between laboratory-based and POC-based INR measurements, the differences between values are generally within 15%. Such differences are similar to the variability in INR results obtained in different laboratories using anticoagulant-spiked plasmas. In addition, such differences have been shown to not result in different dosing instructions when assessed by experienced anticoagulation clinicians.

Special Considerations:

- The POC devices are less accurate when the INR is above the therapeutic range (i.e. INR > 3.5).
- INR readings in the setting of severe anemia or polycythemia (hematocrit below approximately 25% or above about 55%, respectively), co-administration of other anticoagulants in addition warfarin (e.g. low molecular-weight heparin), or antiphospholipid antibody positivity may be inaccurate on a POC device; these patients should be referred to an anticoagulation clinic or thrombosis specialist.
- Children requiring long-term anticoagulation with warfarin may particularly benefit from POC INR testing because of the convenience of home monitoring and the elimination of venipunctures. Parental education, supervision and commitment are essential.

How does one define clinically-important differences in INR between POC and laboratory-based measurements?

Although there may be numeric differences in INR results between POC- and laboratory-based INR measurements, the INR values should be within 0.5 of each other.

Checklist for Determining if Patient is Suitable to Use a POC INR Device:

Generally, patients who would like to use the portable INR device at home must satisfy **all** of the following 8 criteria:

1. Patient is aware of the commitment required to do this safely.
2. Patient has demonstrated acceptable adherence to INR test visits and daily warfarin administration.
3. Patient has no physical challenges that preclude use of the device.
4. Patient has been trained and is able to do the testing reliably (the training is generally done by certified community pharmacy distributors of the devices).
5. Patient is willing and able to do their own dosage adjustments by following appropriate pre-determined instructions for out-of-range INR values and agrees to keep a record of all INR values and warfarin doses.
6. There is back-up by a knowledgeable health professional (eg. family physician/anticoagulant clinic) for the patient with respect to instructions for treating significant out-of-range INR values and to answer questions.
7. Patients should generally be reviewed every 6-12 months in an anticoagulant clinic to do a quality check on their POC device, to review their longitudinal INR/warfarin dose records and to answer questions.
8. Patient can afford the initial cost of the POC device as well as the ongoing costs of the test strips if insurance re-imbursement is not possible.

Advantages of Patient Self-Management:

Self-management empowers the patient to participate in and manage their therapy in a manner similar to glucose self-monitoring in the management of diabetes. Self-managed care assumes that patients can be taught to accurately self-test using a POC INR device and will be able to successfully manage their warfarin therapy. In clinical trials of adults who required long-term warfarin therapy, self-management using a POC INR device was associated with cost-savings to the health care system, as well as to the patient. Self-management of anticoagulation also confers moderate improvement in the time within the therapeutic range and improvements in patients' quality of life.

Advantages of Patient Self-Testing:

Patients who can self-test, but unable to self-manage their dose of warfarin may still benefit from using a POC device, particularly when lab INR testing is difficult.

Other Relevant Thrombosis Canada Clinical Guides:

- Warfarin
- Warfarin: Management of Out-of-Range INRs

References:

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