

COMPARISON OF FINGERSTICK INR VALUES WITH LABORATORY VENIPUNCTURE VALUES: STATISTICAL AND CLINICAL ANALYSIS

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INR by lab or fingerstick?

- Franciscan Health System (FHS) is comprised of 3 hospitals and multiple ambulatory care clinics.
- At the time of this study, pharmacist-managed anticoagulation therapy existed in 2 clinics and was expanding to a clinic without an on-site laboratory.
- Both patients & pharmacists were expressing frustration with waiting for laboratory results.
- Study published in August 1999 AJHP found significantly higher INR's with fingerstick meter.

Objectives

- Compare reliability of a fingerstick INR meter to laboratory INR analyzer.
- Estimate clinical impact and assess feasibility of using fingerstick INR meter in clinics.

Methods – Obtaining INR's

- Recruited 40 anticoagulant patients and 10 controls.
- Obtained a capillary blood sample via fingerstick & venipuncture lab sample.
 - Finger stick meter:
 - International Technidyne Corporation's ProTime Microcoagulation System (ITC)
 - Laboratory:
 - Organon Technika MDA (MDA)
 - Organon Technika Coag-A-Mate (MTX)

Methods – Analysis of Data

- Statistical analysis:
 - Linear regression to test correlation between INR's from ITC meter vs. the two laboratory analyzers.
 - Predictability statistics to test accuracy & bias.
- Clinical assessment
 - Two anticoagulation pharmacists assessed INR's in blinded fashion.
 - Number of times clinical decision would have differed between laboratory analyzers and ITC meter.

Results

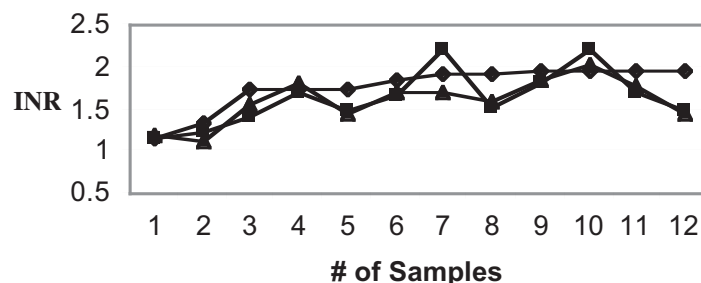
- Linear Regression
 - MDA vs. MTX
 r (correlation coefficient) = 0.97
 - MDA vs. ITC
 r (correlation coefficient) = 0.90
 - MTX vs. ITC
 r (correlation coefficient) = 0.92
- Acceptable level of correlation between the 3 INR analyzers

INR Results

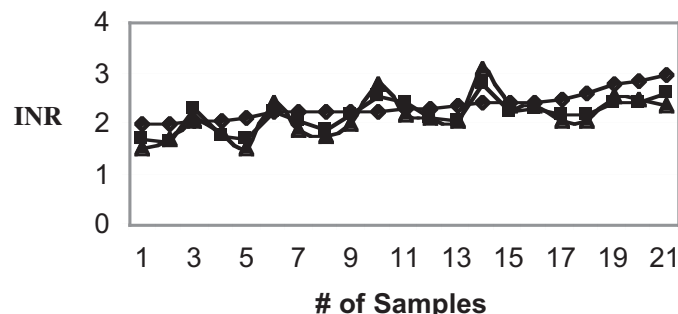
Key:

ITC ◆ MDA ■ MTX ▲

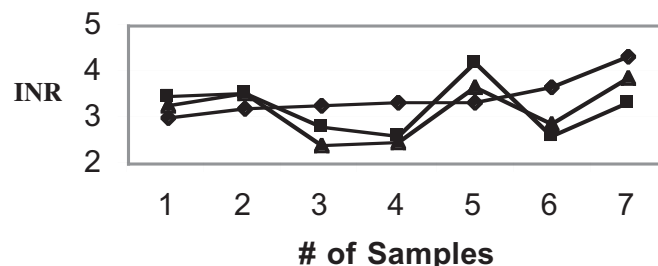
INR < 2



INR 2-3



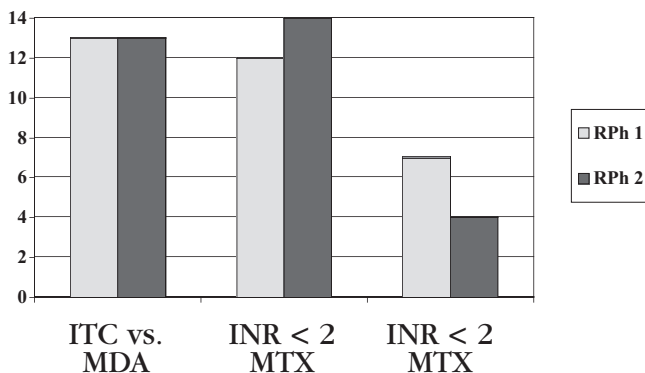
INR > 3



Results - Predictability Statistics

- **Accuracy:** MDA = $\geq 97.5\%$ (gold standard)
Compared to MDA:
ITC ~ 85.7% MTX ~ 96.3%
- **Bias:** MTX vs. MDA = 0.027
ITC vs. Labs: overall bias = 0.174
 - a. INR < 2 ~ 0.2
 - b. INR 2-3 ~ 0.2
 - c. INR > 3 = NA (too few samples)
- ITC statistically less accurate than lab analyzers.
- ITC ~ 0.2 INR higher in INR range < 2 - 3

Clinical Analysis: # Times Dosing Decision Differed



Most of the discrepancies were in ITC INR range of 1.85-2.25. The second largest category was INR >3.2

Compared

- Number of times the dosing decision differed using the ITC meter compared to each lab analyzer
- Number of times the dosing decision differed when comparing the two lab analyzers
- Difference not statistically significant (Chi square test, $p=0.11$, $p=0.07$).
- ITC clinically as accurate as lab analyzers.

Conclusions

- Acceptable correlation between ITC meter and 2 lab analyzers.
- Pharmacists' dosing decisions using the ITC meter vs. the lab analyzers were not statistically different than pharmacists exposed to two different lab analyzers.
- Decided to use ITC machine in anticoagulation clinics.
 - Subjective assessment of patient acceptance
 - Timely results provided



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