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SOUTH CAROLINA COLLEGE OF PHARMACY

The Impact of Enoxaparin on INR in Patients Monitored by Point-of-Care Device

Larissa N. Hall, PharmD

PGY 1 Resident

MUSC Medical Center and College of Pharmacy Residency Program

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Point-of-Care Testing

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- Advantages:
  - Simple handling
  - Smaller sample volumes
  - Elimination of sample transport
  - Timely monitoring
  - Patient satisfaction

Thrombosis Research 2005;115;131-134

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i-STAT® PT

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- Whole blood determination of prothrombin time
- Established accuracy versus standard laboratory measurement
- No reported interaction with enoxaparin

i-STAT® PT procedure manual 2007
http://www.musc.edu/medcenter/lab_poct/

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Previous Studies

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- Conflicting results
- Utilized CoaguChek® system
- Prospective analysis
  - No apparent interaction with enoxaparin
- Retrospective study
  - Higher INR results by POC device with enoxaparin
  - Discordance in dosage adjustments
  - Premature discontinuation

Pharmacotherapy 2002;22(6):677-685
Pharmacotherapy 2005;25(10):1341-1347

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Study Objective

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- Primary outcome of interest
  - Difference in INR results obtained by the i-STAT® PT and laboratory venipuncture in patients receiving warfarin plus enoxaparin compared to the difference in the same patients receiving warfarin only

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Methods

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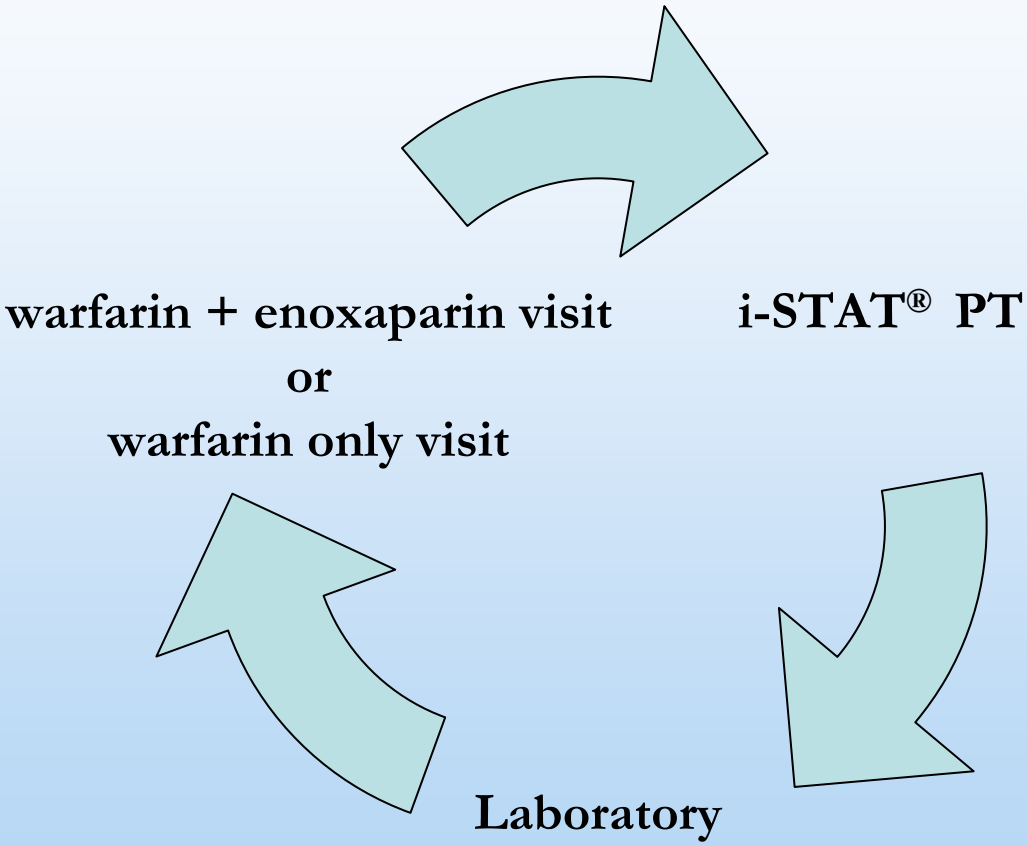
- Prospective study
- Approved by MUSC institutional review board
- Patients at least 18 years of age
  - Receiving warfarin plus enoxaparin
- Followed by clinical pharmacists at MUSC outpatient clinics
- Enrolled from October 2007 to March 2008

Methods


warfarin + enoxaparin visit
or
warfarin only visit
i-STAT® PT
Laboratory

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Methods

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- i-STAT® PT procedure
  - Fingerstick for capillary blood sample
- Laboratory procedure
  - Venipuncture for venous blood sample
  - STA-R® system

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Patient Demographics

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- 11 patients consented to study enrollment
  - All data collected for 8 patients to date
  - 1 patient excluded

- 7 patients for data reporting/analysis
  - Age: 45 ± 14 (average ± SD)
  - 4 female, 3 male
  - Indication: 4 DVT, 1 PE, 2 DVT + PE

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Results

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	Warfarin + enoxaparin		Warfarin only	
	i-STAT® PT	Laboratory	i-STAT® PT	Laboratory
INR (Average ± SD)	2.3 ± 0.7	2.0 ± 0.7	3.2 ± 0.9	2.9 ± 0.7
Difference (%)	+15%		+ 10.3%	

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Results

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	Warfarin + enoxaparin			Warfarin only		
Patient	i-STAT® PT	Laboratory	Difference (%)	i-STAT® PT	Laboratory	Difference (%)
1	2.2	1.9	**15.8**	2.0	2.0	**0**
2	2.6	2.0	**30.0**	3.6	2.8	**28.6**
3	1.9	1.7	**11.8**	4.0	3.4	**17.6**
4	**2.0**	**1.7**	**17.6**	4.0	2.9	**37.9**
5	2.6	2.6	**0**	4.0	4.1	**-2.4**
6	3.3	3.3	**0**	2.2	2.8	**-21.4**
7	1.2	1.2	**0**	2.3	2.2	**4.5**

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Considerations

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- Strengths
  - Limited evidence available
  - Use of the i-STAT® PT
  - Prospective study
  - Patients served as controls
  - i-STAT® PT training
- Limitations
  - Small sample size
  - No exclusions for coagulation disorders, other diseases/medications
  - Unable to enroll patients from 1 of 3 clinics

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Conclusions

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- Results and effects on clinical practice are inconclusive
  - Enoxaparin may not have an impact on INR results
- Use caution in decisions with therapy changes
  - Results may be falsely elevated
- Further studies are needed

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Future Research

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- Large prospective study with same comparisons
- Subgroup analyses based on patient demographics
- Consider exclusions
- Focus on clinical decisions and outcomes

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