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ORIGINAL ARTICLE

Establishing Mean Normal Prothrombin Time Bias Benchmarks for PT/INR Accuracy: a Patient-Based Simulation Study

Kyu Won Cho [1], Min Young Lee [1, 2]

[1] *Department of Laboratory Medicine, Kyung Hee University Hospital at Gangdong, Seoul, South Korea*
[2] *Department of Laboratory Medicine, Kyung Hee University College of Medicine, Seoul, South Korea*

ABSTRACT

Background: **Accurate assessment of prothrombin time (PT)/International Normalized Ratio (INR) is essential for warfarin monitoring. Mean normal prothrombin time (MNPT) is the critical denominator in the INR formula. However, laboratories often adopt manufacturer-assigned MNPTs, tolerating up to 10% deviation from the locally established mean. This study quantitatively evaluated the clinical impact of this variation on dosing reclassification to establish a stringent evidence-based analytical tolerance threshold.**
Methods: **INR variations were simulated using patient data from 120 individuals receiving warfarin (target INR 2.0 - 3.0) at a single institution. The MNPT baseline was defined by the locally derived geometric mean MNPTs following the Clinical and Laboratory Standards Institute H47-A2 guidelines. Analytical biases ranging from ± 2.5 to ± 10.0% were applied to the baseline to calculate the reclassification rates across critical therapeutic boundaries (under-anticoagulation < 2.0, therapeutic 2.0 - 3.0, and over-anticoagulation > 3.0). The simulated results were interpreted alongside current international analytical performance specifications.**
Results: **Applying a ± 10.0% MNPT bias resulted in a clinical reclassification rate of 14.2 to 19.2%. Restricting MNPT bias to ± 2.5% reduced reclassification to 3.3%, with no patients showing an absolute INR difference ≥ 0.2 units relative to baseline.**
Conclusions: **Larger MNPT biases may result in clinically meaningful changes in INR interpretation and therapeutic classification. Patient-based simulation findings support the use of ± 2.5% MNPT verification target as a practical analytical goal that can be interpreted alongside existing international analytical performance specifications.**
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Correspondence:
Min Young Lee, MD, PhD
Department of Laboratory Medicine
Kyung Hee University College of Medicine and
Kyung Hee University Hospital at Gangdong
892, Dongnam-ro
Gangdong-gu, Seoul
South Korea
Phone: + 82 4407196
Fax: + 82 440 7195
Email: petite215@naver.com

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Supplementary Data

Table S2.

PT 시약 Lot 변경에 의한 MNPT 검증

Setting MNPT Due to PT Reagent Lot Change

Reagent Name	PT Rec	검증일자	2024.07.24
Lot Number	763823	ISI	0.954
Expiration date	2025.10.31	MnPT	9.78

cobas t 711			
Sample ID:	Gender	Age	PT sec
1	F	32	9.09
2	F	34	9.03
3	F	35	8.85
4	F	38	8.89
5	F	42	8.94
6	F	42	9.91
7	F	48	8.66
8	F	50	8.86
9	F	53	8.82
10	F	53	8.80
11	M	26	9.47
12	M	34	8.90
13	M	39	8.89
14	M	41	9.29
15	M	42	9.22
16	M	45	9.94
17	M	51	8.60
18	M	57	9.34
19	M	60	8.88
20	M	60	8.74
N		20	
기하 평균 Geometric mean		9.05	
산술 평균 Arithmetic mean		9.1	
SD		0.37	
CV%		4.12	
MnPT (%) difference		-7.48	

※ Geomean $GM_{\bar{y}} = \sqrt[n]{y_1 y_2 y_3 \cdots y_n}$

※ 허용범위 : 차이가 10%이내인 경우 제조사에서 제공하는 MnPT값 사용

Medical technologist 담 당 자 [redacted]

Physician in charge 전 문 의