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Original Article
Laboratory Medicine

Effect of the Standardization of Diagnostic Tests on the Prevalence of Diabetes Mellitus and Impaired Fasting Glucose

Bora Lee,[1*] **Ji Sung Lee**,[2*] **Yong-Wha Lee**,[3] **Mi-Ae Jang**,[3] **Junghan Song**,[4] **Jeong-Ho Kim**,[5] **Wee Gyo Lee**,[6] **Won-Ki Min**,[7] **Juneyoung Lee**,[8] **and You Kyoung Lee**[3]

[1]Department of Biostatistics, Clinical Trial Center, Soonchunhyang University Bucheon Hospital, Soonchunhyang University College of Medicine, Bucheon, Korea
[2]Clinical Trial Center, University of Ulsan College of Medicine, Asan Medical Center, Seoul, Korea
[3]Department of Laboratory Medicine and Genetics, Soonchunhyang University Bucheon Hospital, Soonchunhyang University College of Medicine, Bucheon, Korea
[4]Department of Laboratory Medicine, Seoul National University Bundang Hospital, Seoul National University College of Medicine, Seongnam, Korea
[5]Department of Laboratory Medicine, Yonsei University College of Medicine, Seoul, Korea
[6]Department of Laboratory Medicine, Ajou University School of Medicine, Suwon, Korea
[7]Department of Laboratory Medicine, University of Ulsan College of Medicine, Asan Medical Center, Seoul, Korea
[8]Department of Biostatistics, Korea University College of Medicine, Seoul, Korea

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Address for Correspondence:
You Kyoung Lee, MD, PhD
Department of Laboratory Medicine and Genetics, Soonchunhyang University Bucheon Hospital, Soonchunhyang University College of Medicine, 170 Jomaru-ro, Wonmi-gu, Bucheon 14584, Republic of Korea.
E-mail: cecilia@schmc.ac.kr

*Bora Lee and Ji Sung Lee contributed equally to this work.

ORCID iDs
Bora Lee
https://orcid.org/0000-0002-6322-5712
Ji Sung Lee
https://orcid.org/0000-0001-8194-3462
Yong-Wha Lee
https://orcid.org/0000-0002-4459-6286
Mi-Ae Jang
https://orcid.org/0000-0002-6558-5236
Junghan Song
https://orcid.org/0000-0003-0576-9938
Jeong-Ho Kim
https://orcid.org/0000-0003-2479-0548

ABSTRACT

Background: Without standardization of medical laboratory's testing practices, there is an increase in false diagnoses when relying on test results. However, the effect of test standardization is difficult to assess numerically. This study's purpose is to quantify the effect of the standardization level of a laboratory on the prevalence of diabetes mellitus (DM) and impaired fasting glucose (IFG).

Methods: Laboratories were classified into three levels: 'highly-standardized laboratory,' 'basically-standardized laboratory,' and 'non-standardized laboratory.' Based on the results of Korean External Quality Assessment Scheme (KEQAS), the cutoff values for diagnosis of DM and IFG were recalculated, given false positive and false negative rates.

Results: The prevalence of DM and IFG in the population as a whole was estimated using the 2013 Korea National Health and Nutrition Examination Survey (KNHANES) database. When the prevalence of DM from KNHANES was 11.88% (95% confidence interval [CI], 10.59%–13.17%), the proportion with a systematic false error ranged from 10.91% (95% CI, 9.65%–12.17%) to 13.09% (95% CI, 11.74%–14.45%). The prevalence of IFG varied from 13.59% (95% CI, 12.25%–14.91%) to 40.49% (95% CI, 38.54%–42.43%), in contrast to 24.58% (95% CI, 22.85%–26.31%) of the reference value. The prevalence of DM and IFG tended to be over- and under-estimated more as the laboratory standardization level became lower, respectively.

Conclusion: Our study proved that standardization of clinical laboratory tests is an important factor affecting the prevalence estimation of national disease statistics based on the simulation using KNHANES data.

Keywords: Standardization of Diagnostic Tests; Korean External Quality Assessment Scheme; Variance Index Score; National Prevalence; False Positivity; False Negativity