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ORIGINAL ARTICLE

Survey Result of the Counting Efficiency of Gamma Counter by Certified Reference Materials

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Abstract

Purpose In radioimmunoassay (RIA), the gamma counter is the important instrument for the accurate measurement. To manage quality assurance of RIA, the counting efficiency of gamma counter is one of the important parameters. The aim of this study was to evaluate the counting efficiency of gamma counters in multiple institutes on the base of traceability by using the certified reference materials (CRMs).

Methods Twenty-three institutes that perform RIA were enrolled in this study. I-125 CRMs that were certified by National Institute of Standards and Technology (NIST) were used. Each institute was asked to count the activity of I-125 CRMs at most twice on all gamma counters in use. The counting efficiency of each well of counter was calculated on the base of NIST-certified information, corrected for I-125 decay for date of testing.

Results From 23 institutes, 44 gamma counters were evaluated. The average counting efficiency of all wells was 85.9% and the standard deviation was 13.5%. As a mean value of each gamma counter, three gamma counters showed poor counting efficiency (less than 70%). The poorest counting efficiency was 7%. The counting efficiency of seven gamma counters was between 70 and 75%. Eight counters had the counting efficiency between 75 and 90%. More than half of counter (26 gamma counters) showed excellent counting efficiency (more than 90%). The standard deviation variation range of inter-well efficiency was from 0 to 11.2.

Conclusion The first survey on the counting efficiency of gamma counter was performed in South Korea. Most of the RIA laboratories have well managed the quality assurance of gamma counter.

Keywords Radioimmunoassay · Immunoradiometric assay · Efficiency · Quality control

Introduction

Since Yalow and Berson developed the radioimmunoassay (RIA) for quantitative measurement of insulin in human serum, RIA has been known as a diagnostic technique with precision, specificity, and sensitivity for measuring diverse biomarkers in human sample [1]. Sensitivity of RIA originates from the radioactivity of radioisotopes and the sensitivity of antibody [2]. Therefore, gamma counter is the main instrument for the measurement in RIA. Among several factors for management of quality control (QC) in RIA, counting efficiency is one of the important parameters. RIA often uses batch or random assay technique, using the standard curves of a reference source in same gamma counter as patient samples, which could reduce the quantification error through relative quantification of count rate for measurement [3, 4]. However, comprehensive QC including the counting efficiency is a fundamental procedure for maintaining the highly reliable and accurate RIA laboratory.

QC could be categorized as internal quality control (IQC) and external quality control (EQC). The Korean

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Society of Nuclear Medicine (KSNM) established and has managed the EQC program for RIA since 1989. The nationwide QC has been done successfully for EQC survey all across the laboratories. Main purpose of this nationwide QC includes assessment of different RIA kits for each test and performance of RIA technique among different laboratories. However, counting efficiency has never been surveyed before as a part of QC in RIA. Therefore, this study aims to investigate the state of counting efficiency among RIA laboratories by using international certified reference materials (CRMs).

Materials and Methods

Materials

For the accurate measurement of the counting efficiency, we applied 20 I-125 CRMs for measuring the counting efficiency. Those CRMs were produced to have same radioactivity and certified by National Institute of Standards and Technology (NIST). NIST is reference laboratory of USA. The radioactivity of CRMs was 36,852 Bq (2,221,120 dpm, match tolerance 0.5% at January 9, 2017). All the CRMs had same activity and were certified. Therefore, we could have traceability of all gamma counters that used CRMs for the evaluation of counter efficiency.

Counting Efficiency Evaluation

Twenty-three institutions that perform RIA were enrolled in this study between January 2017 and August 2017. All institutions were required to count I-125 CRMs at most twice on all gamma counters in use and record the testing date. The counting efficiency of each well of counters was calculated on the base of NIST-certified information, corrected for I-125 decay for date of testing. To keep the accuracy and security of the survey, the detailed information of the CRMs was not released to each center. Only the central team had the accurate information of the CRMs. The counting efficiency was calculated as the equation below.

$$\text{Counting efficiency} = \frac{\text{CPM (count per minute)}}{\text{DPM (decay per minute)}} * 100(\%)$$

Results

Institutions and Gamma Counters

From 23 institutions, 44 gamma counters were evaluated. The gamma counters were the products from three different companies. Twenty of the counters used were Dream gamma counters, 16 were Packard Cobra gamma counters, and 8 were Wallac Wizard gamma counters.

The Counting Efficiency of Each Institution

The counting efficiencies of each institution were plotted on Fig. 1. The average counting efficiency of all wells was 85.9%

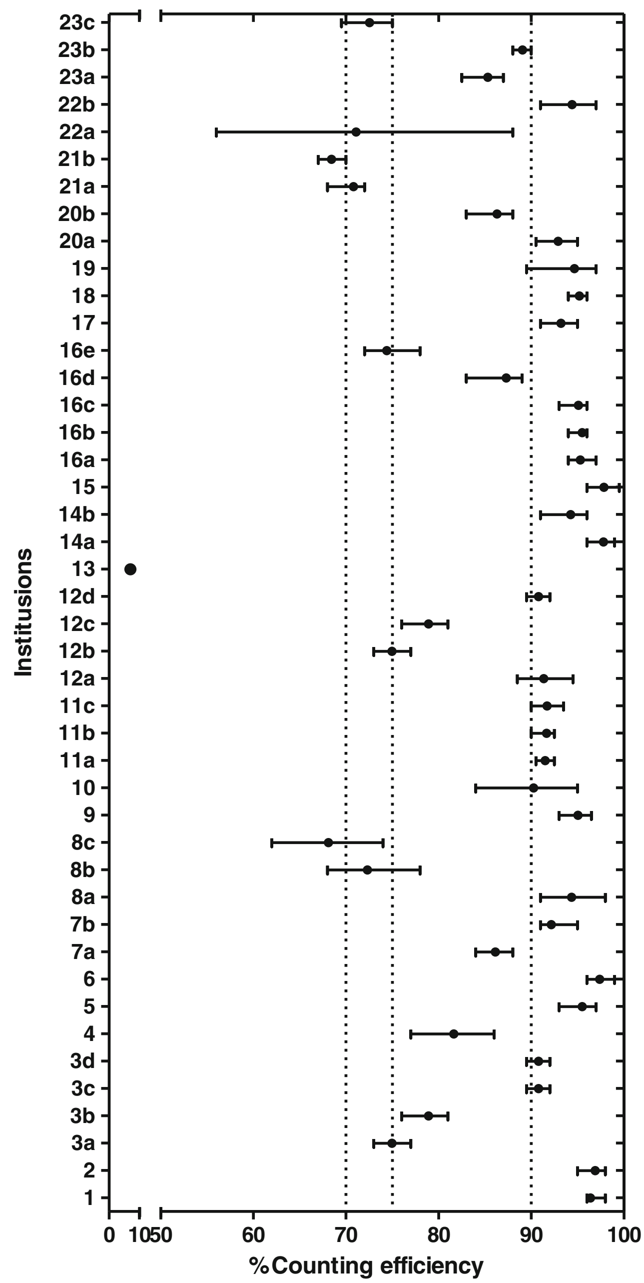

Fig. 1 The counting efficiency of 44 gamma counters from 23 institutions. The counting efficiency of 44 gamma counters from 23 institutions was demonstrated as graph. The mean (circle) and range (bar) of percent counting efficiency were shown for each gamma camera from each institution

and the standard deviation was 13.5%. Three gamma counters showed poor counting efficiency (less than 70% as a mean value of each gamma counter). The poorest counting efficiency was 7%. The counting efficiency of seven gamma counters as a mean value of each gamma counter was between 70 and 75%. Eight counters had the counting efficiency between 75 and 90% as a mean value of each gamma counter. More than half of counters (26 gamma counters) showed excellent counting efficiency (more than 90% as a mean value of each gamma counter).

For each well, the counting efficiency less than 70% was 7 gamma counters; between 70 and 75%, 3 gamma counters; between 75 and 90%, 14 gamma counters; and more than 90%, 20 gamma counters.

The Inter-Well Variation of Counting Efficiency in Gamma Counter

Each gamma counter has multiple wells. The inter-well variation of counting efficiency was evaluated. The standard deviation (SD) variation range of inter-well efficiency was from 0 to 11.2. The overall counting efficiency ranged from 0 to 32%. The range of counting efficiency between 0 and 5% was dominated by more than half of gamma counters (32 counters). The rest of range of counting efficiency was between 5 and 10% for eight gamma counters and more than 10% for four gamma counters. Coefficient of variation (CV) of each gamma counter was less than 10 except one gamma counter (CV value as 15.8).

Discussion

QC is a process reviewing the quality of all factors related to the production or result. QC could be categorized as IQC and EQC. Main purpose of IQC is to monitor the day-to-day precision and accuracy of results for improving the quality of results for uniformity within laboratories [5]. The purpose of EQC is to improve the quality of results and uniformity between laboratories by comparing and contrasting different methods and also providing educational information [5]. The KSNM has managed external quality assessment (EQA) program since professor Chang Soon Kho set the EQA program in 1989. The EQA program started for the T3, T4, TSH, and 28 institutes applied to EQA. Nowadays, the test items of EQA have been increased to 35 items, and every institute that is performing RIA is enrolled in the program. The EQA program of KSNM is very unique and intensive. It is complete enumeration and one round of program is managed every 3 months. Furthermore, the EQA and certification program of KSNM has been close to international standard by importing the criteria of ISO 15189. However, there was no survey for the counting efficiency of gamma counter based on traceability.

Considering the process of RAI or immunoradiometric assay (IRMA), there are several factors affecting the accuracy and the precision. In part of instruments, the pipette and gamma counter are important. The counting efficiency of the gamma counter could affect the accuracy and precision of the results. The counting efficiency is the ratio between the number of photons counted with a radiation counter and the number of photons of the same type and energy emitted by the radiation source [6]. If a gamma counter with low counting efficiency is used for RIA, the slope of standard curved should be low. The low gradient of the standard curve means the lower sensitivity of the curve and larger uncertainty of the result. The counting efficiency of a gamma counter especially for I-125 in RIA can be achieved over 50% [7]. Generally, over 70% counting efficiency is recommended for quality assurance. Loss of counting efficiency leads to greater counting errors in exchange for longer counting times [8]. Also, lower counts of radioactivity result in higher random error. Not only the low counting efficiency but also the variation of counting efficiency among each well or among gamma counters in same laboratory could lead to inter-between-assay precision. For acceptable inter-between-assay from a gamma counter considering the uncertainty of RIA, inter-assay CV should be less than 10% and therefore, the range of counting efficiency among wells or gamma counters should be as low as possible. Counting efficiency should be monitored and gamma counter should be calibrated regularly to keep better sensitivity and precise inter-between-assay.

This was the first survey on the counting efficiency of gamma counter on the base of international CRMs as a part of nationwide QC program in South Korea. The reason of usage of the international CRMs is to have traceability of the survey result. The measurement traceability refers to an unbroken chain of comparison relating an instrument's measurement to a known standard [9]. Calibration to a traceable standard can be used to determine an instrument's precision and accuracy. Therefore, the result of this survey had reliability and confidence. In addition, this survey result could be used to have uniformity and harmonization of the RIA between institutes. Most of the RIA laboratories have maintained the excellent counting efficiency of gamma counter. However, three gamma counters showed poor counting efficiency (less than 70%). After the report was transferred to each laboratory, they performed or planned to correct the gamma counter. The SD of counting efficiency of most of gamma counter was less than 3.5 (41 gamma counters). However, one gamma counter had SD value of 11.2%. Beginning with this study, regular QC for gamma counting efficiency should be an official integral part of the quality assurance in RIA.

Conclusion

The first survey on the counting efficiency of gamma counter was performed in South Korea. Most of the RIA laboratories have well managed the quality control of gamma counter. Furthermore, this survey could contribute to improve the accuracy and reproducibility of radioimmunoassay in Korea.

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Compliance with Ethical Standards

Conflict of Interest Ho-Young Lee, Ji-In Bang, Geyoung Woon Noh, Jeong Mi Park, and June Kee Yoon declare that they have no conflict of interest.

Ethical Approval All procedures performed in study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed Consent All procedures performed in study involved the medical device, and the requirement to obtain informed consent was waived.

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