

# 便携式血糖仪的规范应用及质量控制

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**【摘要】** 目的 规范本院即时检验(POCT)血糖仪的使用,确保院内血糖仪检测结果的准确性和一致性。方法 结合本院实际情况,对各临床科室的护理人员进行规范化培训,在对全院临床科室所有 POCT 血糖仪进行现状调查后,规定统一使用博士医生 TD-4279a 型血糖仪。同时在检验科指定一台博士医生 TD-4279a 型血糖仪进行校准,用厂家配送的高、低值质控品进行批内、批间精密度检测,并参加卫健委临床中心室间质评,定期将 POCT 血糖仪与全自动生化分析仪进行比对。临床各科室每天派一名经过培训的工作人员携带本科室血糖仪至检验科做室内质量控制(质控),与检验科血糖仪同步进行,由检验科工作人员把关并做好记录。结果 博士医生血糖仪达到卫健委规定的血糖仪精密度和准确性要求,但仍具有一定的局限性。如血糖明显偏高或偏低时,应抽取静脉血至检验科进行检测。血糖仪只能用于临床糖尿病患者的血糖检测,但不能代替全自动生化分析仪的血糖监测结果作为确诊实验,防止因 POCT 血糖仪测量结果的误差影响临床医生对病情的诊断。结论 为保证检验结果的准确性和一致性,规范 POCT 血糖仪的应用,应及时校准血糖仪的准确性和精密度测定,认真做好室内质控和室间质评,对操作者进行规范化培训,定期进行生化比对,从而提高 POCT 检测结果的准确性,更好地为临床和患者服务。

**【关键词】** 即时检验血糖仪; 规范应用; 质量控制; 准确性

## Standard application and quality control of portable blood glucose meter

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**【Abstract】 Objective** To standardize the use of POCT blood glucose meter to ensure the accuracy and consistency of the meter test results in this hospital. **Methods** According to the actual situation of our hospital, standardized training was conducted to cultivate the nursing members in various clinical departments, and after investigation on the current situation of all point-of-care testing (POCT) blood glucose meters in clinical departments of our whole hospital, the doctorate doctor TD-4279a type blood glucose meter was stipulated to be used uniformly. In the mean time, a doctorate doctor TD-4279a blood glucose meter was appointed to carry out calibration in the clinical laboratory. The high and low quality control products delivered by the manufacturer were used to proceed intra-batch and inter-batch precision tests, the performance of the meter tests also participated in the inter-center department quality evaluation hosted by the Health Planning Commission, and regularly the POCT blood glucose meter was compared with the full-automatic biochemical analyzer. In addition, each clinical department sent a trained nurse to bring the blood glucose meter of her own department to the clinical laboratory everyday for intra-department quality control, which was carried out simultaneously with the blood glucose meter of the clinical laboratory, and the working member in the clinical laboratory checked and kept the records. **Results** The doctorate doctor blood glucose meter has met the precision and accuracy requirements of the blood glucose meter stipulated by the Health Planning Commission, but it still had certain limitations. If blood glucose was significantly higher or lower than normal range, the venous blood should be collected to immediately send to the laboratory for testing. The blood glucose meter was only used by clinical diabetes patients to test their blood glucose levels, but it could not replace the blood glucose monitoring results of the full automatic biochemical analyzer as a definite diagnostic experiment. It was important to prevent the errors in the measurement results of POCT blood glucose meter from affecting clinicians' diagnosis of the disease. **Conclusions** The application of POCT blood glucose meter should be standardized to ensure the accuracy and consistency of the blood glucose test results. The accuracy and precision of the blood glucose meter ought to be calibrated in time, the indoor- and inter-department quality evaluation should be done seriously, the operators should be trained by standardized training, and the biochemical comparison should be carried out regularly to improve the accuracy of the POCT test results and serve the clinics and patients better.

**【Key words】** POCT blood glucose meter; Standardized application; Quality control; Accuracy

近年来,随着医学检验技术的迅速发展,便携式血糖仪因体积小、使用简便、检测迅速及携带方便等特点,作为检验领域的一种检验手段被广泛应用于临床。但在使用过程中,血糖仪的管理及质量控制(质控)方面仍存在许多需要改进的问题<sup>[1-3]</sup>,因此对即时检验(point-of-care testing, POCT)血糖仪进行全面、有效的质量管理至关重要<sup>[4]</sup>。为保证检验结果的准确性和一致性,提高医疗质量和保障医疗安全,现对本院临床科室 POCT 血糖仪的使用情况及检测结果的准确性进行调查,并对其进行原因分析及规范应用,制定改进措施。为改变目前上述状况,认真执行卫健委下发的《医疗机构便携式血糖检测仪管理和临床操作规范》<sup>[5]</sup>,结合本院实际情况,对血糖仪使用过程中存在的问题提出改进措施,进一步规范 POCT 血糖仪的使用,现报告如下。

## 1 血糖仪使用情况调查

### 1.1 品牌、型号各异

经调查,本院血糖仪分析仪分布在各个临床科室,几乎所有临床科室均备有 POCT 血糖仪,甚至有些科室存在同时使用多个品牌血糖仪的现象。POCT 血糖仪不同型号之间原理也不一样,且易受外界因素干扰及测定范围的限制,血糖值过高或过低均不能准确测定,从而产生偏差。

### 1.2 操作人员未进行规范化培训

目前各个临床科室的血糖仪均由临床医生、护士等非检验专业人员进行操作,他们未曾接受检验相关知识的培训,对仪器的测定原理、影响因素及质控方面了解甚少。

### 1.3 未建立 POCT 血糖仪的质控体系

所有临床科室的 POCT 血糖仪均未做室内质控,也未进行生化比对及精密度测定。质控意识淡薄,质量管理松散。

## 2 完善和改进措施

### 2.1 统一血糖仪的品牌和型号

全院临床科室统一规定使用博士医生 TD-4279a 型号 POCT 血糖仪,避免不同品牌和型号的血糖仪检测时造成的偏差。

### 2.2 对操作者进行规范化培训和考核

血糖仪操作虽然简单,但操作不规范也会影响检测结果的准确性。因此,应定期对操作人员进行使用及管理知识、操作规程、质量要求等内容的培训和考核,以规范操作,增强质控意识,使操作人员对相关知识的知晓率和操作正确率均达到 100%。

### 2.3 完善和建立 POCT 血糖仪的质控体系

#### 2.3.1 精密度、准确度和生化比对

卫办医政发[2010]209号文件对精密度要求质控液葡萄糖浓度 $<5.5$  mmol/L时,标准差(SD) $\leq 0.42$  mmol/L;质

控液葡萄糖浓度 $>5.5$  mmol/L时,变异系数(CV) $\leq 7.5\%$ 。生化比对时,要求血糖浓度 $<4.2$  mmol/L时,至少 95% 的检测结果误差在 $\pm 0.83$  mmol/L 的范围内;血糖浓度 $\geq 4.2$  mmol/L时,至少 95% 的检测结果的偏倚应在 $\pm 20\%$  范围内。只有当结果达到上述要求的范围时,方可用于临床标本检测。根据这一要求,检验科购置一台博士医生血糖仪,先对其进行校准,然后用厂家配送的高、低值质控品进行批内、批间精密度检测和生化比对,并参加卫健委临检中心室间质评。

#### 2.3.2 实施室内质控

临床科室必须与检验科配合做好室内质控。规定配有 POCT 血糖仪的科室每天派一名经过培训的人员携带血糖仪至检验科,与检验科血糖仪同步进行室内质控,由检验科工作人员把关,并填写室内质控记录表,只有当检测结果在控,才能用于临床测定患者样本。

## 3 讨论

为保证检验结果的准确性和一致性,规范临床 POCT 血糖仪的检测行为,提高医疗质量和保障医疗安全,加强血糖仪的质控和监管十分重要<sup>[6-7]</sup>。只有建立和完善 POCT 血糖仪的质控体系,对操作者进行规范培训,做好室内质控和室间质评,定期进行生化比对,才能保证 POCT 血糖仪测定结果准确可靠,适应检验质量的要求<sup>[8]</sup>,从而更好地服务于临床。

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