Annals of Pharmacology and Pharmaceutics

Short Communication
Published: 16 Mar, 2018

Variation between Point-of-Care and Laboratory HbA_{1c} Testing in Clinical Practice

Shawn E Fellows and Gabriela Cipriano*

Department of Pharmacy Practice, Wegmans School of Pharmacy at St. John Fisher College, USA

Abstract

Aims: The aim of this study was to identify potential disparities between Point-Of-Care Testing (POCT) and laboratory hemoglobinH bA_{1c} reporting at a Federally Qualified Health Center (FQHC).

Methods: The electronic medical record was reviewed to identify POCT HbA_{1c} done at a FQHC and centralized laboratory HbA_{1c} performed on the same day. Manual data extraction was used to identify potential variables that could account for disparities between POCT and laboratory testing.

Results: A total of 42 samples in 40 patients were identified. The median HbA_{1c} difference was 1.5mmol/mol (0.15%) and ranged from -26-52 mmol/mol (-2.4 to 4.8%). Of the patients in the study, two had underlying co morbidities that could affect the POCT HbA_{1c}.

Conclusion: Point-of-care HbA_{1c} testing should not be used in solidarity to diagnosis pre-diabetes and diabetes. When using HbA_{1c} results to guide therapy, self-monitoring of blood glucose and symptoms of both hypo- and hyperglycemia should be correlated to help determine appropriate therapy.

Introduction

HbA_{1c} is recommended for screening, diagnosis, and monitoring diabetes [1-2].Point-of-care testing in the primary care setting has increased the number of documented HbA_{1c} since the patient medical record for between allowing and providers to make preventative or therapeutic interventions[3]. However, disparities between POCT HbA_{1c} and laboratory measurements in a controlled environment have been reported to be as high as 5 mmol/mol (0.4%) [4-5]. The impact of this may result in misdiagnosis and/or overly aggressive treatment increasing the risk for medication adverse effects. The American Diabetes Association recommends that if POCT is used for diagnostic purposes, the results should be confirmed by repeat testing unless the patient is experiencing overt signs of hyperglycemia[2].Since use of POCT HbA_{1c} began at this FQHC in 2011, several providers noticed disparities between testing performed onsite and laboratory. The purpose of this paper was to identify any HbA_{1c} variances in a real world setting between POCT and laboratory testing.

Methods

Design

This is a retrospective review of the electronic medical record. Point-of-care HbA_{1c} testing with DCA™ Vantage (Siemens Healthcare Diagnostics) began in May 2011. Reagent cartridges are stored and calibrated after each new lot number is received per manufacturer specifications. Three of our nine practice sites utilize on site POCT HbA_{1c}. Each utilizes the same equipment, policies and procedures to ensure ongoing quality control. A report from May 2011 through May 2016 was created to identify patients who had both POCT and central laboratory HbA_{1c}s performed on the same day. Any patients that had a POCT HbA_{1c} performed at one of the three locations that use onsite testing were eligible for inclusion. Results were excluded if both onsite and central laboratory tests were not performed on the same day. This study was Institutional Review Board approved.

Sample

Our center is a FQHC. It provides a broad range of health services to the area's inner city communities. Approximately 15% of the 750,000 residents in our county live below the poverty level. Additionally, our practice site provides care to a large number of refugee patients from several continents.

OPEN ACCESS

Correspondence:
Shawn E Fellows, Department of Pharmacy Practice, Wegmans School of Pharmacy at St. John Fisher College, USA, Tel: 585-899-3704; E-mail: sfellows@sjfc.edu

Received Date: *10 Jan 2018*
Accepted Date: *10 Mar 2018*
Published Date: *16 Mar 2018*

Citation:
Fellows SE, Cipriano G. Variation between Point-of-Care and Laboratory HbA_{1c}Testing in Clinical Practice. Ann Pharmacol Pharm. 2018; 3(2): 1143.

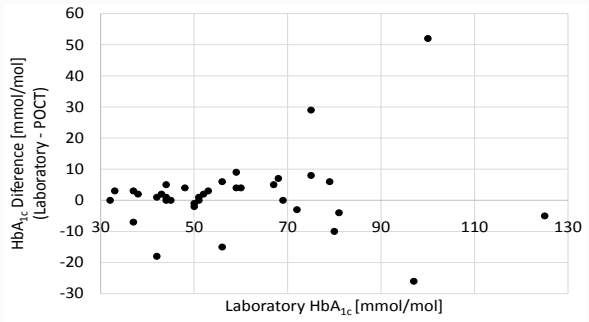

Figure 1: Fourteen samples showed a clinical significant.

Data analysis

Descriptive statistics were used to analyze the information gathered from the medical record. Point-of-care testing HbA_{1c} results +/-5 mmol/mol (0.5%) from centralized laboratory results are considered clinically significant differences based on previous publications.[6] Patient records for these charts were reviewed manually to identify variables that are known to influence POCT HbA_{1c} testing.[7] Evaluation of POCT technique in the pre- and post-analytic phases was not available.

Results

A total of 42 POCT HbA_{1c}s were performed on the same day (Figure. 1). Fourteen samples showed a clinical significant difference of >5 mmol/mol (0.5%) ranging from -26-52 mmol/mol (-2.4 to 4.8%) (Table 1).The median difference was 1.5 mmol/mol (0.15%). The most significant changes were observed in patients with HbA_{1c} laboratory values above 86 mmol/mol (10%). Between the three different sites, the number of clinically significant differences for Site 1 was eight. For Sites 2 and 3 the number was four and two respectively. Site 1 receives roughly the same volume of patients as Sites 2 and 3 combined. Each clinically significant difference was performed at least one month apart. A total of seven different staff members performed the onsite testing that resulted in a clinically significant difference, two of whom were connected to two differences each. Information on staff members for five draws was not able to be determined due to inadequate documentation. Two patients each had their blood drawn on the same day on two separate occasions. Neither resulted in a clinically significant difference between results. A manual chart review resulted in two patients with underlying comorbidities that may affect point-of-care testing according to the HbA_{1c} reagent cartridge package insert[7]. Both had thalassemia. One patient did not have significant difference while the other resulted in a 7 mmol/mol (0.7%) difference, 37-44 mmol/mol (5.5-6.2%) for the central laboratory and point-of-care testing respectively.

Table 1: Difference of ≥5 mmol/mol (0.5%) ranging from -26-52 mmol/mol (-2.4 to 4.8%).

HbA_{1c} Discrepancies ≥5 mmol/mol (0.5%)	POCT HbA_{1c} mmol/mol (%)	Laboratory HbA_{1c} mmol/mol (%)
-26 (-2.4)	123 (13.4)	97 (11)
-18 (-1.6)	60 (7.6)	42 (6)
-15 (-1.3)	71 (8.6)	56 (7.3)
-10 (-0.9)	90 (10.4)	80 (9.5)
-7 (-0.7)	44 (6.2)	37 (5.5)
5 (0.5)	39 (5.7)	44 (6.2)
5 (0.5)	62 (7.8)	67 (8.3)
6 (0.6)	73 (8.8)	79 (9.4)
6 (0.6)	50 (6.7)	56 (7.3)
8 (0.7)	67 (8.3)	75 (9)
7 (0.7)	61 (7.7)	68 (8.4)
9 (0.8)	50 (6.7)	59 (7.5)
29 (2.6)	46 (6.4)	75 (9)
52 (4.8)	38 (6.5)	100 (11.3)

Discussion

HbA_{1c} testing in patients with diabetes is recommended quarterly for uncontrolled patients and at least annually for patients who are currently meeting their glycemic goals.[1-8]When POCT HbA_{1c} testing is used for diagnostic purposes confirmation should be performed at a laboratory that is NGSP certified with standardized DCCT assays due to the potential for errors with POCT. In our study POCT and laboratory testing occurred on the same day 42 times. The decision to perform both tests is not readily available as data was collected retrospectively. A majority of the patients already had confirmed diabetes and did not have a blood dyscrasia thus confirmatory testing was not indicated per guidelines and DCA Vantage specifications. Laboratory errors are well documented in the literature and have the potential to result in significant patient harm. [9] A majority of errors occur in the pre- and post-analytical phase. [10]Point-of-care-testing may be particularly prone to errors relative to central laboratory testing due to less stringent performance criteria allowed for POCT. At our center each site delegates quality assurance procedures to a licensed practical nurse who ensures consistency with policies, procedures, and manufacturer specifications. The LPN checks to make sure the equipment is in working order, HbA_{1c} cartridges are in date, and appropriately calibrated for specific lot numbers. Quality assurance log books were reviewed to identify potential temporal relationship between machine maintenance, cartridge lot calibration, or any other issues that may have cause disparate results. None were identified. All LPNs as part of their on boarding process receive initial training on DCA™ Vantage (Siemens Healthcare Diagnostics) POCT HbA_{1c} machines and required to undergo an annual competency to maintain proficiency. The DCA™ Vantage (Siemens Healthcare Diagnostics) POCT HbA_{1c} machines accurately measure ranges between 4-130 mmol/mol (2.5-14%).[7]It does this by measuring total HbA_{1c} concentrations in addition to total hemoglobin concentrations (%A1C = [A1C] / [Hgb] x 100). Factors that influence the lifespan of red blood cells (hemolytic anemia, thalassemia) can result in lower than expected HbA_{1c} results while those that elevate it may falsely elevate values.[11-12] Two patients had thalassemia. Only one had clinical significant differences between results. The POCT test was 0.7% higher and cannot be explained by the underlying pathology as with a shorter red blood cell life span theHbA_{1c} result should have been falsely low. There were several limitations to our study. First, collection and processing technique of samples for HbA_{1c} POCT was not available. This is significant as laboratory errors most often occur in the pre- and post-analytic phases with POCT. We reviewed the electronic medical record to identify staff performing tests who may be routinely associated with discrepancies. However this data was incomplete preventing adequate analysis. Furthermore numerous central laboratory sites were used as a comparator potentially influencing the variability in results. In

addition the impact on patient safety is unknown. Escalation or de-escalation of glycemic therapy and the direct impact on patients' blood glucose could not be correlated due to the retrospective nature of our study.

Conclusion

This study highlights the potential misleading POCT HbA_{1c} results in the primary care setting. Several patient specific factors are known to influence testing but could not fully explain our discordant results. In a controlled setting the DCA™ Vantage (Siemens Healthcare Diagnostics) displays a high degree of accuracy. The standard deviation between POCT and control groups ranged from 0.9-1.2 mmol/mol (0.18-0.39%) in validation studies thus onsite testing procedure may be the most likely reason for the different results noted in our study. Providers should correlate POCT HbA_{1c} with clinical findings and home blood glucose testing when diagnosing and adjusting therapies for diabetes.

References

1. Handelsman Y, Bloomgarden ZT, Grunberger G, Umpierrez G, Zimmerman RS, Bailey TS, et al. American association of clinical endocrinologists and american college of endocrinology - clinical practice guidelines for developing a diabetes mellitus comprehensive care plan - 2015. Endocr pract. 2015; 21: 1:1-87.
2. Classification and Diagnosis of Diabetes. Diabetes care. 2017; 40(Suppl 1): S11-24.
3. Egbunike V, Gerard S. The impact of point-of-care A1C testing on provider compliance and A1C levels in a primary setting. The Diabetes Educ. 2013; 39(1): 66-73.
4. Paknikar S, Sarmah R, Sivaganeshan L, Welke A, Rizzo A, Larson K, et al. Long-Term Performance of Point-of-Care Hemoglobin A1c Assays. Journal of diabetes science and technology. 2016.
5. Wan Mohd Zin RM, Ahmad Kamil ZI, Tuan Soh TR, Embong M, Wan Mohamud WN. Haemoglobin A1c: comparing performance of two point of care devices with laboratory analyser. BMC research notes. 2013; 6: 540.
6. Little RR, Rohlfing CL, Sacks DB. Status of hemoglobin A1c measurement and goals for improvement: from chaos to order for improving diabetes care. Clinical chemistry. 2011; 57(2).
7. DCATM Systems Hemoglobin A1C Reagents Kit [package insert]. Siemens Healthcare Diagnostics, Inc, Tarrytown, NY; 2015.
8. Glycemic Targets. Diabetes care. 2017; 40(Supplement 1): S48-56.
9. Miligy DA. Laboratory errors and patient safety. Int J Health care Qual Assur. 2015; 28(1): 2-10.
10. Chiozza ML, Ponzetti C. FMEA: a model for reducing medical errors. Clin Chim Acta. 2009; 404(1): 75-8.
11. Radin MS. Pitfalls in hemoglobin A1c measurement: when results may be misleading. J Gen Intern Med. 2014; 29(2): 388-94.
12. Rhea JM, Molinaro R. Pathology consultation on HbA(1c) methods and interferences. Am J Pathol. 2014; 141(1): 5-16.