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Retrospective Comparison of Laboratory Based Versus Point-of-Care Haemoglobin A1c Testing

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Abstract

Aim

The aim of this study was to look at the precision and accuracy of Point of Care glycosylated haemoglobin (POC-HbA1c) compared with laboratory-measured HbA1c (Lab-HbA1c).

Methods

Retrospective analysis of the charts of patients attended paediatric diabetes outpatient clinics during January 2018 to July 2019 in University Hospital Limerick (UHL) was conducted.

Results

In total, 163 patients' charts were analysed, including 79 females (48.5%) and 84 males (51.5%). Lab-HbA1c data were skewed positively, with a median of 67mmol/mol (IQR (60 to 76). POC- HbA1c data were also positively skewed, median of 61mmol/mol (IQR (55 to 68). The differences between POC-HbA1c and Lab-HbA1c was skewed negatively, median of -6mmol/mol (IQR (-9, -2). Gender, age and month of testing did not affect results.POC-HbA1c was more reliable and accurate when tested within 14 days of Lab-HbA1c.

Conclusion

POC-HbA1c was comparatively lowered as compared with Lab- HbA1c. The results for POC- HbA1c is most reliable compared with Lab-HbA1c if tested within14 days.

Introduction

HbA1c is a key indicator of glycaemic control in patients with type 1 diabetes(T1D). Point of care HbA1c(POC-HbA1c) is commonly used as it is cost effective and results are immediately available in clinic. In this study, we sought to determine the precision and accuracy of POC-HbA1c compared with Lab-HbA1c in children with T1D attending a dedicated paediatric diabetes outpatients' clinic (PDOPC).

Methods

This is a single centre retrospective observational study done, using data from a dedicated paediatric diabetic outpatients clinic in University hospital Limerick(UHL).The Primary outcome of the study was to compare POC-HbA1c with Lab HbA1c and evaluate any reasons for differences between the two measures. All the patients less than 18 years old who attended PDOPC between January 2018 to July 2019 who had Lab-HbA1c and POC-HbA1c measured within 4 weeks and with diabetes duration longer than 6 months were eligible for study inclusion. Demographic data including age, gender, duration of diabetes and HBA1c were collected. Prospectively collected data in patient charts and on electronic databases were supplemented with retrospective data collection, when indicated. Patients who had their Lab- HbA1c done within 4 weeks of POC- HbA1c were enrolled because usually HBA1c gives you a reflection of diabetic control in last 4 weeks. Capillary blood HbA1c taken by a finger-prick blood sample was analysed on a DCA Vantage Analyzer (Siemens/Bayer, Germany) in the clinic at the time of outpatient visit. Venous whole blood samples were collected in containers with EDTA either on the same day or within 4 weeks either before or after the clinic attendance and were analyzed on Tosoh G8 HPLC analyzer. Patients who had only one reading of HbA1c were excluded from the study.

Results

This report summarises the details of findings we found over 18 months in our hospital. We found point of care testing is equivalent to laboratory testing if they are done within certain time period. In total, 240 eligible patients attended PDOPC during the time frame; of which 163 patients were meeting the inclusion criteria (who had Lab-HbA1c and POC-HbA1c within 4 weeks' time frame). Seventy-seven patients were excluded due to only one HbA1c recorded. Lab-HbA1c data was skewed positively, with a median of 67mmol/mol (IQR (60 to 76). POC-HbA1c data was also positively skewed with a median of 61mmol/mol (IQR (55 to 68). Nonparametric Wilcoxon signed rank test was significant at $p<0.001$ with a downwards trend.

Analysis of demographics showed, 79 females (48.5%) and 84 males (51.5%). Only males demonstrated reduced Lab- HbA1c compared with POC-HbA1c ($p<0.001$). Median Lab-HbA1c 68.5mmol/mol, IQR (63, 76.8) vs. median POC-HbA1c 62.5mmol/mol, IQR (56.3, 68.8) ($p<0.001$). Females only also showed a significant drop Lab-HbA1c compared with POC-HbA1c, median Lab-HbA1c 65mmol/mol, IQR (59, 76) vs. median POC-HbA1c 59mmol/mol, IQR (54, 68) ($p<0.001$).

The differences in readings had a negative skew with a median of -6 IQR (-9, -2). These differences were significantly different between the groups <14 days and >14 days between measures. Median <14 days -5mmol/mol IQR (-7, -2) vs. >14 days -8.5mmol/mol, IQR (-13.3, -2, $p=0.001$). Therefore, there were significantly greater differences (drops) in the >14 days group.

When the differences were plotted against the child's age in years. There was no statistically significant relationship was identified when the differences between Lab-HbA1C and POC-HbA1c were plotted against child's age or gender.

The drop in the measures was not significant when adjusted for gender and the time differences, using exploratory ANOVA to account for skewed distribution. Only the time by difference in measure interaction was significant $p<0.001$ with those having measures taken >14 days having a bigger difference between measures. Females tended to have lower average values when second measure taken >14 days and males tended to have higher values when the second measure taken >14 days. As all results of differences between measures were significant using the Wilcoxon signed rank test for time < 14 days and larger time spans and so the measures were not equivalent. In fact, for all tests there was a significant drop between the lab measurements and the POC measurements.

Discussion

This study clearly shows that in a population of paediatric patients with type 1 diabetes POC-HbA1c results are more reliable if they are done within 14 days of lab-HbA1c testing. To our knowledge, this is the first time that a comparison between POC-HbA1c and Lab-HbA1c has been studied in Irish population. The important finding in this study is that POC-HbA1c results are somewhat lower than Lab-HbA1c, but that the highest correlation between the two measurements was when the samples were drawn within 14 days of each other. There was no effect of gender, age and timing of testing during the whole year. There are several limitations of this study. It is a single centre study with relatively small sample size. This is a retrospective study as well. Ideally it should be prospective study and all patients should be undergoing both tests on the same day by a trained phlebotomist who is performing both tests consecutively. When we looked retrospectively, we found that many patients had not done both POC testing and laboratory testing limiting our sample size. In conclusion POC testing should be interpreted cautiously in clinical decision making and need more multicentre studies with large sample size with contemporaneous sampling and analysis using point of care and laboratory measures to draw definitive conclusion.

Declaration of Conflicts of Interest:

The authors confirm that there are no conflicts of interest regarding the article.

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