HbA1c stability – is posting samples reliable?

N.DAVEY[1], K.WRIGHT[1] and A.NATARAJAN[2]
1. Point of Care Testing, Pathology, Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust.
2. Paediatric Diabetes Service, Doncaster and Bassetlaw Teaching Hospitals NHS Foundation Trust.

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INTRODUCTION

- NPDA in 2018/19, indicated that **28,597** children and young people with type 1 diabetes and **790** with type 2 diabetes were being managed within Paediatric Diabetes Units in England and Wales[1] .
- HbA1c is recommended every 3 months as per Best Practice Tariff (BPT) requirements.
- HbA1c target levels of ≤48mmol/mol are ideal to minimise the risk of long term complications[2].
- During the COVID pandemic a postal HbA1c service was proposed.
- The laboratory method (TOSOH manufacture) quotes that samples are stable for 24 hours at ambient temperature.
- WHO quotes EDTA whole blood stability of 3 days.

AIM

- The aim of this study was to assess paediatric capillary whole blood stability collected into the Sarstedt Microvette 300 EDTA tubes with a view of implementing a postal service for patients to take their own blood samples at home and send these via the post for laboratory analysis.

METHOD

- Paediatric patients had capillary blood taken from a finger prick and collected into the Microvette tube.
- The samples were delivered to the laboratory and analysed on receipt (D0) using the TOSOH G11 analyser.
- Samples were stored within the laboratory at room temperature (between 19.6-22.3°C), and re-analysed on the TOSOH G11 analyser at 1 (D1) , 2 (D2) ,3 (D3), 4 (D4),5 (D5) and 6 (D6) days after collection.
- Acceptable stability was defined as a maximum difference of ≤ ±4 mmol/mol compared to the initial (D0) TOSOH HbA1c result. This was based on the IFCC model for quality targets for HbA1c when used for monitoring purposes of ±5mmol/L[4] and the desired total allowable error for the TOSOH G11 HbA1c at DBTH based on Ricos biological variations of 3 mmol/L at 87 mmol/mol.

CONCLUSIONS

- All results, where a numerical value was obtained, were within ±4mmol/mol of the D0 result. If using a postal service a valid result with acceptable stability could be expected in 82% of samples received within 3 days of collection and 50% of samples received within 4 days of collection.
- This is the only study in the paediatric population where capillary EDTA whole blood samples have been serially analysed for 4 days to assess the stability of samples if they were to be sent in the post, validating this method for use in the under 19 years age group. Historically, centres have been using this method with no formal validation of the reliability of the results in a systematic manner published to our knowledge.
- We conclude that postage to the laboratory of samples taken by patients could be used to ensure that HbA1C can be monitored in patients shielding during the COVID pandemic and in the future for those patients who are unable to attend for other reasons providing flexibility to patients and improving patient care.

RESULTS

- D0 analysis was attempted on 52 samples.
- D1: 33 samples analysed, of which 29 (88%) samples produced a valid result (max +2mmol/mol deviation).
- D2: 25 samples analysed , of which 23 (92%) produced valid results (max deviation ±3mmol/mol).
- D3: 33 samples analysed, of which 27 (82%) produced valid results, (maximum difference ±2mmol/L).
- D4: 16 samples analysed, of which 8 (50%) produced a valid result (maximum ± 2mmol/L).
- Only a small number of samples were analysed on Day 5 and Day 6 so data has not been included
- A valid result with acceptable stability could be expected in 82% of samples received within 3 days of collection and 50% of samples received within 4 days of collection.

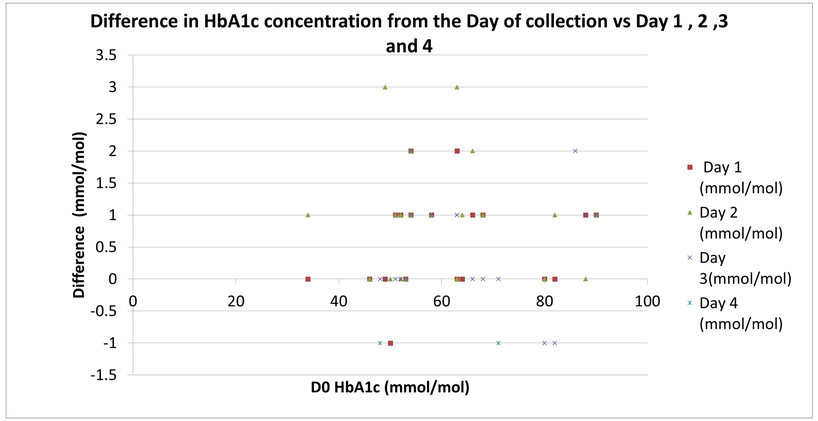

Figure 1: Difference in the HbA1c concentration from the day the sample was collected (D0) in comparison to Day 1, 2, 3 and 4 post collection. All results are within ± 4 mmol/mol from the D0 result.

Figure 2: Starstedt Microvette 300 EDTA tube with collected capillary blood inside a Pathology specimen bag.

Figure 3: Example packaging given to the patient to collect and post the sample back to the laboratory.

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CONTACT INFORMATION

- Nicola Davey: Nicola.davey8@nhs.net
- Katherine Wright: Katherine.wright2@nhs.net
- Anuja Natarajan: anujua.natarajan1@nhs.net