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A Review on the Clinical Impact of Point of Care Capillary Blood Glucose Measurement in Diabetes Patients in Public Primary Care Clinics in Hong Kong

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Abstract

Background: Point of Care (POC) capillary blood glucose measurement in diabetes patients in the primary care setting has been used in out-patient settings for many years; however, there were no published studies on the clinical impact of this practice.

Aim: To evaluate the clinical impact of Point of Care (POC) capillary blood glucose measurement in diabetes patients and to evaluate the risk factors in patients with abnormal POC capillary blood glucose readings.

Method: A retrospective review study was conducted in two public primary care clinics in Hong Kong. 784 diabetic patients were included in the study after randomisation. The POC capillary blood glucose readings during follow up would be documented and analysed. Factors that might be associated with abnormal POC capillary blood glucose readings were evaluated.

Results: Among the 2573 consultations, 1.6% was found to have hypoglycaemia readings (capillary blood glucose level<4 mmol/L) while clinically significant hyperglycaemia (capillary blood glucose level ≥ 14 mmol/L) was detected in 4.5% consultations. Further analysis of the results identified male patients, patients on more number of oral anti-diabetics drugs, patients on insulin, patients without practice of self-monitoring of blood glucose and patients with suboptimal latest HbA1c were more likely to have abnormal POC capillary blood glucose readings.

Conclusions: POC capillary blood glucose levels might provide additional clinical information about the current diabetic control. However, if resources were limited, it could be selectively performed in patients with the risk factors for abnormal POC capillary blood glucose readings.

Keywords: Primary health care; Hong Kong; Diabetes mellitus; Point-of-care systems; Blood glucose; Risk factors

Introduction

Diabetes mellitus is a prevalent disease worldwide and is a major cause of morbidity and mortality. A study conducted in 1995 showed that in Hong Kong the age-adjusted prevalence rate of diabetes mellitus was 7.3% [1]. A study in the older population showed that the prevalence of non-insulin dependent diabetes mellitus was 15% among the 60-80 year-old age group and 17% in those older than 80 years [2]. According to the Hospital Authority primary care service portfolio 2013/2014, diabetes mellitus also ranked the third most common chronic disease in public primary care clinics in Hong Kong [3].

The American Diabetes Association (ADA) recommended regular use of Self-Monitoring of Blood Glucose (SMBG) to assess the whole day glycaemic variability or hypoglycaemia in patients on multiple-dose insulin or insulin pump therapy. For patients using less frequent insulin injections or non-insulin therapies, the ADA suggested that the SMBG results might be helpful to guide treatment decisions and/or patient self-management [4]. The United Kingdom National Institute of Clinical Excellence (NICE) guideline also recommended SMBG to patients on insulin treatment or oral glucose-lowering medications in order to provide information on hypoglycaemia, assess and monitor changes in glucose control and during intercurrent illness and to ensure safety during activities, including driving [5].

However, diabetic patients may not perform SMBG due to various psychological, practical or financial reasons [6-8] Even for those patients with SMBG, there might be problems of accuracy and reliability of the reported SMBG readings with under-reporting, omission, over-reporting or addition of phantom values [9-11]. A study found that three fourths of the patients had reported lower than actual mean blood glucose values [12]. The accuracy of SMBG is also instrument and user dependent [13]. It was recommended by the NICE guideline that patients should be assessed at least annually in a structured way about the skills in SMBG [5]. However; this was not commonly performed in public primary care clinics in Hong Kong due to the large patient load.

Although measurement of glycated haemoglobin (HbA1c) is the recommended method for monitoring of recent diabetic control of diabetic patients, Point-Of-Care (POC) capillary blood glucose measurement may also be useful in providing additional clinical information about the current diabetic control of the patients. A review article on the accuracy of POC glucose measurements concluded that currently available POC glucose monitors were generally accurate within the range of physiological glucose levels [14].

In the public primary care clinics in Hong Kong, almost all diabetic patients would have routine POC capillary blood glucose measured with a validated glucometer by trained health care assistants during follow up before doctor consultations. These POC capillary blood glucose tests would be done at any time irrespective of the time of their last oral intake. Therefore, under some situations, e.g. a patient with high POC capillary blood glucose shortly after a meal, the POC capillary blood glucose results might have little clinical implication. On the other hand, the POC capillary blood glucose results might reveal instant hyper- or hypo-glycaemic state of patients so that prompt management could be provided.

Although the routine practice of POC capillary blood glucose measurement had been used in our out-patient settings for many years, there was no recommendation by international guideline about the clinical application of the test. With the aging population and increasing prevalence of diabetic patients, the increasing workload of POC capillary blood glucose measurement has become a stress to our public primary care service. Therefore question has been raised about whether it is evidence-based and clinically indicated to continue our usual practice of POC capillary blood glucose measurement for every diabetic patient in the primary care out-patient clinic setting. This study was therefore designed to answer the research question of "Is there any clinical implication to continue our usual practice of POC capillary blood glucose measurement in out-patient diabetic patients?" with the objectives stated below.

Objectives

To evaluate the clinical impact on the use of POC capillary blood glucose measurement in terms of the proportion of patients with hypo or hyper-glycaemic readings and to evaluate the risk factors for those patients with abnormal POC capillary blood glucose readings.

Methodology

Study design

This is a retrospective review study to investigate the clinical impact of POC capillary blood glucose measurement in diabetic patients in two of the public primary care clinics in a local district in Hong Kong. The two participated clinics served approximately 6000 diabetes patients in 2014. Bayer glucometers were used in the clinics and the accuracy of the glucometer was validated by trained health care assistant daily by control solution in both hyperglycaemic and hypoglycaemic ranges.

A list of patients coded for diabetes mellitus by International Classification of Primary Care (ICPC) (T89: Diabetes insulin dependent, T90: Diabetes non-insulin dependent) who had been seen in the clinics between 1 May 2014 to 31 August 2014 was generated from the Hong Kong Hospital Authority Clinical Data Analysis and Reporting System (CDARS). All patients attended for regular follow-up for diabetes during the above period in the participating clinics would be included. The 4 month period would be able to include all the diabetic patients as the longest follow up duration was 16 weeks. The patients' information and the clinical consultation notes in the past 1 year would be reviewed in the computerised Clinical Management System and the relevant data would be retrieved for further data analysis.

Procedure

Demographic and biochemical data including age, sex, duration of diabetes and latest HbA1c level were documented. Other factors that might be associated with abnormal POC capillary blood glucose readings would be evaluated and these included reported hypoglycaemic episodes within past one year, number of oral anti-diabetic drugs taking, use of sulphonylurea and use of insulin. The practice of SMBG with its readings was also evaluated. The POC capillary blood glucose readings during follow up would be reviewed. The readings would be further categorized into at fasting, less than 2 hours post-prandial and 2 hours or more post-prandial for analysis.

Optimal diabetes control was defined as latest HbA1c level within the range of 6 to 7% [4]. Hypoglycaemic range of capillary blood glucose level was defined as value less than 4 mmol/L while hyperglycaemia with risk of Diabetic Ketoacidosis (DKA) or Hyperosmolar Hyperglycaemic State (HHS) was defined as capillary blood glucose level greater than or equal to 14 mmol/L since the diagnosis of diabetic ketoacidosis requires the patient's plasma glucose concentration to be above 13.9 mmol/L. Abnormal POC capillary blood glucose readings were defined as either hypoglycaemic or hyperglycaemic readings with risk of DKA or HHS as stated above, or capillary blood glucose levels greater than 6 mmol/L at fasting or greater than 8 mmol/L at 2 hours or more post-prandial.

Sample size calculation

There were approximately 220,000 patients with diabetes mellitus being followed up in all public primary care clinics in Hong Kong during the study period. A sample size of 784 patients would be able to achieve 95% confidence interval, 80% power with 5% margin of error [15].

Sampling method

Simple random sampling of all diabetes patients with follow-up attendances at the two participating clinics during the study period was used.

Outcomes

Primary outcome was the proportion of patients with hypo- or hyper-glycaemic POC capillary blood glucose readings and the secondary outcome was to evaluate the risk factors for patients with abnormal readings.

Statistical analysis

All statistical analyses were conducted with IBM SPSS version 21.0. Proportions were presented by percentages. Continuous data with normal distribution were presented by mean with standard deviations. Differences were considered statistically significant when $p<0.05$. Risk factors for patients with abnormal clinic capillary blood glucose readings were evaluated by logistic regression.

Results

Study population

A list of 5962 diabetes patients was retrieved during the study period with 784 patients included after randomisation. A total number of 2741 consultations were conducted during the study period. The

mean number of consultations per patient per year was 3.5. The demographic and clinical characteristics of the patients were summarised in Tables 1 and 2.

	Mean (SD)	Number (%)
Age (years)	65.5 (11.8)	
Sex		
Male		373 (47.6)
Female		411 (52.4)
Duration of diabetes (years)	7.4 (5.9)	
Latest HbA1c level (%)	6.8 (1.0)	
Practice of SMBG		
Yes		287 (36.6)
No		497 (63.4)

Table 1: Demographic data and clinical characteristics of patients (N=784)

Reported hypoglycaemic episodes in past 1 year	
Yes	166 (6.1)
No	2575 (93.9)
No. of oral anti-diabetic drugs taking	
0	632(23.1)
1	1101 (40.2)
2	905 (33.0)
3	103 (3.8)
Use of sulphonylurea	
Yes	1165 (42.5)
No	1576 (57.5)
Use on insulin	
Yes	93 (3.4)
No	2648 (96.6)
SMBG = Self-Monitoring of Blood Glucose	

Table 2: Demographic data and clinical characteristics of consultations (N=2741)

Evaluation of practice of SMBG

The evaluation of practice of SMBG was summarised in Table 3 and 4. Among those 287 (36.6%) patients who had reported to have SMBG in at least one of the consultations during the study period, the results were available in 854 (31.2%) consultations. Discordant POC capillary blood glucose readings were found in 24.1% patients who reported optimal home capillary blood glucose levels.

	Number (%)
Consultations with reported home capillary blood glucose results to target	349 (40.9)
Discordant clinic capillary blood glucose readings	84 (24.1)
Concordant clinic capillary blood glucose readings	152 (43.6)
Clinic H'stix less than 2 hours post-prandial	105 (30.1)
Missing time of clinic H'stix	8 (2.3)
Consultations with reported home capillary blood glucose results not to target	505 (59.1)
Discordant clinic capillary blood glucose readings	164 (32.5)
Concordant clinic capillary blood glucose readings	177 (35.0)
Clinic H'stix less than 2 hours post-prandial	148(29.3)
Missing time of clinic H'stix	16(3.2)

Table 3: Evaluation of practice of self-monitoring of blood glucose (N=854)

POC capillary blood glucose readings (mmol/L)	Mean (SD)	Number (%)
At fasting (n=278)	6.82 (1.84)	
≤3.9*		4 (1.4)
4-6		90 (32.4)
6.1-13.9*		181 (65.1)
≥14*		3 (1.1)
At less than 2 hours post-prandial (n=878)	9.36 (3.31)	
≤3.9*		7 (0.8)
4-13.9		808 (92.0)
≥14*		63 (7.2)
At 2 hours or more post-prandial (n=1417)	7.71 (2.99)	
≤3.9*		31 (2.2)
4-8		885 (62.4)
8.1-13.9*		450 (31.8)
≥14*		51 (3.6)
* Ranges defined as abnormal POC capillary blood glucose readings		

Table 4: Distribution of POC capillary blood glucose readings (N=2573)

Distribution of POC capillary blood glucose readings

The distribution of POC capillary blood glucose readings was shown in Table 4. 168 out of the total 2741 consultations were excluded due to missing data on POC capillary blood glucose readings.

Abnormal POC capillary blood glucose readings were detected in 790 (30.7%) consultations with 42 (1.6%) hypoglycaemia, 117 (4.5%) hyperglycaemia with risk of DKA or HHS, 181 (22.9%) suboptimal capillary blood glucose level at fasting and 450 (57.0%) suboptimal capillary blood glucose level at 2 hours or more post-prandial.

Factors associated with an abnormal POC capillary blood glucose readings

Multivariate analysis was used to study the factors associated with abnormal POC capillary blood glucose readings. 1743 consultations were included in the model after exclusion of 809 consultations with POC capillary blood glucose readings in the range from 4 mmol/L to 13.9 mmol/L at less than 2 hours post-prandial since it was not able to define whether the readings were normal or abnormal. 167 consultations with missing number of post-prandial hours and 22 consultations with missing HbA1c were also excluded.

All variables were fitted into a logistic regression model and the results were shown in Table 5. The final model was achieved by backward selection of variables according to Wald statistics until all the p values were less than 0.1 and the results were shown in Table 6.

Associated factors	Adjusted odd ratio	95% confidence interval		p value
		Lower	Upper	
Age	1.01	1	1.01	0.3
Male sex vs. female sex	1.35	1.11	1.65	0.003
Duration of diabetes	0.98	0.96	1	0.056
Suboptimal latest HbA1c control	1.53	1.25	1.88	<0.001
Reported hypoglycemic episodes in past 1 year	1.2	0.81	1.78	0.364
No. of oral anti-diabetic drugs taking				
1 vs. 0	2.31	1.74	3.07	<0.001
2 vs. 0	2.9	1.74	4.82	<0.001
3 vs. 0	3.53	1.74	7.14	<0.001
Use of sulphonylurea	1.07	0.71	1.62	0.738
Use of insulin	2.23	1.27	3.95	0.006
No practice of SMBG	1.38	1.1	1.74	0.006
SMBG=Self-Monitoring of Blood Glucose				

Table 5: Initial model of multivariate analysis of factors associated with an abnormal POC capillary blood glucose readings (N=1743)

The results showed that abnormal POC capillary blood glucose readings were more likely to be found in male patients (odd ratio 1.34), patients with suboptimal latest HbA1c (odd ratio 1.53), patients currently on more oral anti-diabetic drugs (odd ratio 2.33 if on one oral anti-diabetic drug, odd ratio 3.06 if on two oral anti-diabetic drugs and odd ratio 3.70 if on three oral anti-diabetic drugs), patients currently on insulin (odd ratio 2.28) and patients without practice of SMBG (odd ratio 1.39).

Associated factors	Adjusted odd ratio	95% confidence interval		p value
		Lower	Upper	
Male sex vs. female sex	1.34	1.1	1.64	0.003
Duration of diabetes	0.98	0.97	1	0.097
Suboptimal latest HbA1c control	1.53	1.25	1.88	<0.001
No. of oral anti-diabetic drugs taking				
1 vs. 0	2.33	1.77	3.07	<0.001
2 vs. 0	3.06	2.24	4.19	<0.001
3 vs. 0	3.7	2.06	6.63	<0.001
Use of insulin	2.28	1.3	4.02	0.004
No practice of SMBG	1.39	1.11	1.73	0.004

Table 6: Final model of multivariate analysis of factors associated with an abnormal POC capillary blood glucose readings (N=1743)

Discussion

The results showed that POC capillary blood glucose measurement could detect a significant proportion of patients with clinically significant hypoglycaemia or hyperglycaemia. Moreover, it was shown that just about one-third of the studied patients were performing SMBG and discordance of reported home and clinic capillary blood glucose readings was found in some patients.

As a result, POC capillary blood glucose measurement might provide useful supplementary clinical information in addition to HbA1c in our primary care setting.

Although most patients might not have change of treatment plan just based on a single POC capillary blood glucose reading, the detection of exceptionally out of range POC capillary blood glucose levels might have significant impact on the management plan and allow more timely treatment and better patient care.

The observed clinical impacts on use of POC capillary blood glucose measurement in primary care out-patient setting can be summarised as follows:

Provides additional clinical information on current diabetes control

POC capillary blood glucose levels may provide additional clinical information about the current diabetic control especially in patients without SMBG and recent HbA1c level. High POC capillary blood glucose level may imply patients having poor diet control or poor drug compliance, and may indicate for more intensive dietary or drug compliance counselling respectively.

At the same time, very high POC capillary blood glucose level may guide for more frequent titration of anti-diabetic drug(s) without waiting for the subsequent HbA1c which can only be performed every 3 months.

Detects discrepancy between POC capillary blood glucose levels and SMBG/ HbA1c results

POC capillary blood glucose levels can be used to compare with SMBG readings to detect inaccurate SMBG readings if there are discordant results. A persistently high POC capillary blood glucose level in contrast with an optimal HbA1c result may also provide evidence of inaccuracy of HbA1c level. Clinical conditions that may affect the erythrocyte turnover such as haemolysis, blood loss, etc. would then need to be considered [4].

Detects hypo- or hyperglycaemic ranges

Very high POC capillary blood glucose levels may detect patients at risk of acute hyperglycaemic complications such as DKA or HHS. POC capillary blood glucose levels in hypoglycaemic range in asymptomatic especially elderly patients would prompt the physicians on further enquires about the underlying reasons of hypoglycaemia and adjustment of anti-diabetic drugs if indicated.

Male patients, patients on more oral anti-diabetic drugs, patients on insulin, patients without practice of SMBG and patients with suboptimal latest HbA1c level were more likely to have abnormal POC capillary blood glucose readings according to our study. If resources are not allowed, POC capillary blood glucose measurement could be selectively performed in these diabetes patients with associated risk factors.

Limitations

We acknowledge some limitations in our study. Firstly, some consultations were excluded due to missing data on POC capillary blood glucose readings. Secondly, some information obtained from patients such as the SMBG results and time of meals taken might not be accurate due to recall bias. Thirdly, the subjects in this study were recruited from two public primary care clinics in a local district which limits the generalisability of our results to the whole local population.

Conclusion

POC capillary blood glucose measurement is a simple clinic test that can provide physicians with an important clinical parameter in addition to the HbA1c level for a more timely diabetes management. With the increasing load of diabetes patients, it might not be feasible or practical to perform POC capillary blood glucose measurement in all diabetic patients on follow up. However, it should still be performed in selected patients with the risk factors for abnormal POC capillary blood glucose readings.

Declaration

Ethical approval

Approved by the Research Ethics Committee for Hong Kong Hospital Authority Kowloon Central and Kowloon East Clusters (KC/KE-14-0203/ER-3).

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Conflict of interest

None.

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