



CLINICAL ARTICLE

Capillary glucose concentration during oral glucose tolerance test for the diagnosis of gestational diabetes

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Keywords

Capillary glucose concentration; Gestational diabetes; Oral glucose tolerance test; Point-of-care testing

Synopsis

Point-of-care testing, which showed a moderate-good agreement with the laboratory reference method, can improve the care of pregnant women during oral glucose tolerance tests.

ABSTRACT

Objective: To assess concordance between two point-of-care testing (POCT) devices and the standard laboratory method in screening for gestational diabetes mellitus (GDM) in Huesca.

Methods: Pregnant women who met criteria for an oral glucose tolerance test (OGTT) and attended the laboratory between October 2017 and November 2018 were recruited in this prospective observational study. Glucose was measured in venous (laboratory)

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and capillary blood (Accu-Chek or Contour Next glucometers). GDM was diagnosed attending to NDDG criteria for venous samples or capillary-specific cut-off. Linear regression, Passing–Bablok, Bland–Altman, and the kappa coefficient were used to study concordance between POCT and laboratory method.

Results: Data from 109 women were analyzed (57 for Accu-Chek, 52 for Contour Next). Statistical analyses showed good agreement between both POCT and laboratory method. There were no statistical differences in fasting glucose measurements between capillary and venous samples and both POCT devices meet the ISO 15197 standard. Accu-Chek showed good agreement ($k=0.629$) regarding the laboratory method in classifying GDM, with an acceptable inter-evaluator bias of 3.5% ($P<0.001$).

Conclusion: POCT can be used to obtain fasting values and reduce overall waiting times for patients. Additionally, Accu-Chek can be used to diagnose GDM in remote areas applying specific cut-off values.

1 INTRODUCTION

Gestational diabetes mellitus (GDM) is one of the most common medical conditions women encounter during pregnancy. GDM is associated with adverse pregnancy and neonatal outcomes such as macrosomia, delivery complications, neonatal hypoglycemia, and polycythemia [1]. International clinical practice guidelines recommend universal testing of this condition during pregnancy [1, 2]. In Huesca, Spain, screening for GDM screening is based on the “two-step” strategy following consensus of the National Institutes of Health (NIH). Pregnant women, who do not meet the risk criteria, have a 1-hour 50-g glucose load test (in a non-fasting state) during the second trimester (at 24–28 weeks of pregnancy). If the glucose level measured after 1 hour is equal to or greater than 7.8 mmol/L (≥ 140 mg/dL), patients must continue to the second stage, which consists of a fasting 3-hour 100-g oral glucose tolerance test (OGTT). The diagnosis of GDM is made when at least two of the four plasma glucose levels after the OGTT meet or exceed the criteria proposed by the National Diabetes Data Group [3].

In addition, high-risk patients, such as those with a higher body mass index (BMI, calculated as weight in kilograms divided by the square of height in meters; >30), previous GDM, impaired glucose tolerance, or previous neonatal macrosomia, should also be screened for diabetes mellitus during the first trimester [3].

Although the diagnosis of GDM should ideally be based on laboratory results of venous serum or plasma samples, the International Federation of Gynecology and Obstetrics (FIGO) considers the use of plasma-calibrated handheld glucometers to be acceptable for diagnosing glucose intolerance in pregnancy in remote locations where laboratory support is unavailable [1]. Moreover, WHO guidelines for the diagnosis and management of diabetes recommends glucose measurement on venous samples although recognizes the usefulness of point-of-care testing (POCT) devices in the daily management of patients. WHO also confirms that fasting glucose values are interchangeable between POCT devices and other laboratory methods [4].

As seen, the use of glucometers for monitoring and managing diabetes mellitus has been extensively studied and is generally accepted as a part of care of a diabetic patient, despite variations in the performance of POCT devices compared to the gold-standard laboratory test. To minimize these variations, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) strongly recommends glucometer manufacturers refer to measurements from their devices as plasma samples and not whole-blood samples to harmonize results, facilitate the classification and care of patients and less therapeutic misjudgment [5]. Nowadays, all devices sold must follow these recommendations. Although there is no international consensus on the analytical quality requirements for glucometers, the Sociedad Española de Diabetes (SED) suggests minimum compliance with ISO 15197:2013 [6, 7]. The Sociedad Española de Medicina del Laboratorio (SEQC) also published a document, "*Recommendations on the evaluation of the analytical performance of a glucometer,*" which reviewed different methods to check a glucometer's accuracy and precision [8].

There are several studies on the relationship of glucose concentrations in capillary and venous samples and in POCT and reference laboratory methods with varied results [9–11]. In general, all of them report there being no difference in fasting glucose values between methods, but capillary samples present higher glucose values than in venous samples after feeding [12, 13]. Based on this, WHO suggests increasing cut-off by 1.1

mmol/L (20 mg/dL) when using POCT in glucose overload testing (in the adult non-pregnant population) [4]. Some authors propose that use of POCT in glucose overload test for diabetes screening in low-income countries has found a good correlation between the capillary and venous samples for both fasting and 2-hour post-glucose [13, 14]. Although WHO does not refer to the use of POCT in screening for GDM in pregnant women, some authors have also studied the relationships between capillary and venous glucose concentrations in this population [15–20]. Some of them even propose a fasting capillary glucose cut-off for screening for GDM, as a previous stage to OGTT [21, 22]. An OGTT with 100 g glucose requires the patient to fast and wait a long time (more than 3 hours) at the laboratory. Before glucose overload, a fasting glucose measurement must be made because values above 7.0 mmol/L (126 mg/dL) would discourage continuing the test. Having a quick and accurate result at this first stage is essential in minimizing waiting times and decreasing the inconvenience to patients. The aim of the present study, therefore, was to assess the concordance between two POCT devices commonly used in Huesca, Spain and the standard laboratory method to improve the general care of pregnant women during an OGTT.

2 MATERIALS AND METHODS

Pregnant women who attended the laboratory between October 2017 and November 2018 and met criteria for an OGTT were invited to participate in the present prospective observational study. The laboratory is placed in San Jorge, a secondary hospital in Huesca, Spain that attends 150 000 people. Our laboratory is accredited for ISO 15189 by Spanish National Accreditation System (ENAC). Informed consent was obtained from all study participants. The project was approved by the ethical review board of Huesca (Comité Ético de Investigación Clínica de Aragón [CEICA]). Patients completed a survey about health habits, illnesses, pregnancy evolution, drugs, and subjective perception of the test.

Glucose levels were measured at all stages of the OGTT (fasting, 60 minutes, 120 minutes, and 180 minutes) from both capillary and venous samples. Two glucometers were randomly used for capillary sample testing: Accu-Chek (AVIVA-ROCHE) and Contour Next One (Ascensia Diabetes Care), both based on the glucose-dehydrogenase

method. The reference method used in the laboratory for venous samples was the AU5800-Beckman Coulter, based on the hexokinase method.

GDM was diagnosed when at least two of the four plasma glucose levels after the OGTT met or exceeded the criteria proposed by the National Diabetes Data Group (NDDG): fasting 5.8 mmol/L (105 mg/dL); 60 minutes, 10.6 mmol/L (190 mg/dL); 120 minutes, 9.2 mmol/L (165 mg/dL); and 180 minutes, 8.0 mmol/L (145 mg/dL) [3]. According to the suggestions from WHO and other studies, cut-offs were increased by 1.1 mmol/L (20 mg/dL) when using capillary samples: fasting 5.8 mmol/L (105 mg/dL); 60 minutes, 11.7 mmol/L (210 mg/dL); 120 minutes, 10.3 mmol/L (185 mg/dL); and 180 minutes, 9.1 mmol/L (165 mg/dL) [4, 23]. Women with two or more capillary values equal to or above these were classified as having GDM for statistical analyses.

Statistical analyses were performed using SPSS for Windows version 23 (SPSS Inc., Chicago, IL, USA). Linear regression and Passing–Bablok were used to compare fasting, 60 minutes, 120 minutes, and 180 minutes, for capillary and venous glucose. Bland–Altman plots were used to see if concordance was within the 95% limit. Crosstabs and the kappa coefficient were used to rate the nature of the concordance between methods. Criteria used for the kappa coefficient evaluation were those from Landis and Koch (1977) that stated agreement was: $\kappa < 0.2$, very low; $\kappa 0.21–0.40$, low; $\kappa 0.41–0.60$, moderate; $\kappa 0.61–0.80$, good; and $\kappa 0.81–1.00$, excellent.

3 RESULTS

A total of 109 women were recruited for the study between October 2017 and November 2018. Capillary glucose levels were measured with Accu-Chek in 57 patients and with Contour Next in 52 patients. All participants were analyzed for venous glucose levels using the reference method for all OGTT timings.

The Passing–Bablok regression analyses for both POCT at all stages showed moderate/good results, although correlation coefficients were discreet in all cases (< 0.95), (Table 1). In alignment with previous reports, there are no differences in fasting glucose measurements between capillary and venous samples for both POCT (Table 1, Fig. 1).

The Bland–Altman analyses showed good agreement between POCT and laboratory methods for all OGTT timings. Bland–Altman difference plots for fasting glucose are

shown in Figure 2. The mean bias predicted for the fasting glucose samples (capillary vs venous) was 0.15 (95% confidence interval [CI] -0.44 to 0.75) for Contour Next (Fig. 2a) and -0.19 (95% CI -0.73 to 0.35) for Accu-Chek (Fig. 2b).

Although Passing–Bablok statistical results suggested that capillary and glucose values were interchangeable for several stages of the OGTT (60 minutes for Accu-Chek; 60 and 180 minutes, for Contour Next), Bland–Altman analyses showed higher differences between capillary and venous glucose after glucose overload (Table 2). After glucose overload, mean bias between capillary and venous samples for these two POCT is in the range of 0.7–1.9 mmol/L (12 and 34 mg/dL) (Table 2).

Patients in the study were stratified as GDM or non-GDM based on the aforementioned venous or capillary glucose measurements. The consistency in classifying GDM between capillary and venous criteria was evaluated using crosstabs and overall indicator kappa. Accu-Chek showed good agreement ($\kappa=0.629$) compared to the laboratory reference method. One patient was misclassified as healthy and three as GDM from capillary values, with an inter-evaluator bias of 3.5% ($P<0.001$). This means Accu-Chek classifies 3.5% more patients as GDM than the laboratory reference method. The Contour Next showed moderate agreement ($\kappa=0.545$) with nine false positives and one false negative and an inter-evaluator bias of 15.4% ($P<0.001$).

Moreover, additional statistical analyses (independent-samples t-test) showed no significant differences between GDM and healthy patients related to patient hemoglobin, maternal age, or gestational age ($P>0.010$; Table 3).

Accuracy of capillary glucose was assessed using the ISO 15197 standard, which states that 95% of the individual results for the glucose meter should be within ± 0.8 mmol/L (± 15 mg/dL) of the result at glucose concentrations below 5.6 mmol/L (100 mg/dL) and $\pm 15\%$ at glucose concentrations above 5.6 mmol/L (100 mg/dL). All results for both POCT in the present study met the ISO 15197 standard.

The survey completed by patients during the study showed that all of them agreed to use a POCT method to shorten the overall period of the OGTT. Most of the women (83 [76.1%]; 43 [75.4%] for the Accu-Chek, and 40 [76.9%] for the Contour Next) stated that the finger prick was not painful at all, while 25 (22.9%) women (13 [22.8%] for the Accu-Chek and 12 [23.1%] for the Contour Next) stated that the finger prick was a bit painful

but bearable. Only 1 (0.9%) patient (from the Accu-Chek sample) stated that finger prick was very painful.

4 DISCUSSION

An OGTT using a venous sample is the “gold standard” in the diagnosis of GDM. However, use of POCT is common and can reduce inconvenience for patients, reduce laboratory costs, and be used in regions with difficult access to specialized medicine [13, 14, 18]. A recent study even evaluates the usefulness of POCT in diagnosing diabetes mellitus 6–12 weeks after gestational diabetes [24], concluding that POCT is clinically useful in identifying women with diabetes at early postpartum evaluation. They also conclude that use of POCT can decrease the need for routine laboratory glucose testing after GDM and may reduce cost and increase the probability of postpartum glucose evaluation after GDM.

The results of the present study showed that both POCT met the ISO 15197 standard and fasting capillary glucose was interchangeable with fasting venous glucose in accordance with previous studies [4, 9–14]. Therefore, both POCT can be used to obtain fasting values and start the OGTT immediately, decreasing the overall waiting time for patients. Impacts on the global costs to laboratories will be analyzed later.

Although post-glucose overload capillary measurements showed a good correlation with venous values, higher levels were found in capillary samples, in accordance with previous studies [13, 14, 18]. Applying the same cut-off criteria to capillary measurement as venous samples would suppose an overdiagnosis of GDM and an unnecessary increase in the medicalization of pregnancy. Nevertheless, specific capillary cut-offs for OGTT, as proposed before [4, 18, 23], can be used in special areas to accurately screen for diabetes. In the present study, Accu-Chek showed good concordance with the laboratory method in diagnosing GDM when applying a specific capillary cut-off. Huesca has a low and disperse population with some rural locations over 100 km from the reference hospital. In such situations, Accu-Chek can be used to test for GDM in pregnant women, in local physicians' offices and supervised by a nurse or midwife, thus improving the quality of health care and reducing patient inconvenience.

Moreover, the patients in the present study were satisfied with the changes applied to the OGTT in the laboratory and the finger prick was not unpleasant for most of them.

The main advantage of the present study is that includes the two most commonly used POCT devices in Huesca. Furthermore, the present study also collected the perceptions from patients and this can be applied to everyday work by reducing the waiting time during OGTT. A limitation of the present study is that the number of women tested is low, although it properly represents the population. According to the results of the present study, only Accu-Chek can be used to diagnose GDM. In cases using Contour Next, positive results should be confirmed by the laboratory reference method to avoid false-positive results due to a higher inter-evaluator bias. A larger amount of data or the use of other POCT devices would have made this study stronger.

In conclusion, both POCT contribute to an improvement in the care of pregnant women in Huesca during OGTTs by obtaining fasting values and Accu-Chek can also be applied to diagnosing GDM in remote locations.

Author contributions

AGC and JPF contributed to the conception and development of the study, data collection, and writing of the manuscript. RRC contributed with statistical analyses and writing of the manuscript. CLF and ISB contributed with data collection to the study and revising the manuscript.

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Conflicts of interest

The authors have no conflicts of interest.

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Figure legends

Figure 1. Passing–Bablok regression for fasting capillary glucose vs fasting venous glucose (mmol/L) for (A) Contour Next and (B) Accu-Chek.

Figure 2. Bland–Altman plot: difference between fasting glucose for capillary POCT and venous laboratory method (mmol/L) for (A) Contour Next and (B) Accu-Chek.

Table 1. Passing–Bablok regression analyses for Contour Next and Accu-Chek during OGTT.^a

	Contour Next vs Laboratory			Accu-Chek vs Laboratory		
	r ^b	Intercept	Slope	r	Intercept	Slope
Fasting	0.781	−0.64 (−1.71 to 0.17)	1.15 (1 to 1.36)	0.703	−0.39 (−1.46 to 0.33)	1.04 (0.89 to 1.25)
60 min	0.757	21.16 (−0.55 to 2.67)	1.06 (0.90 to 1.26)	0.772	1.14 (−0.30 to 2.51)	1.03 (0.87 to 1.20)
120 min	0.769	27.00 (0.19 to 2.73)	1.00 (0.85 to 1.16)	0.753	2.09 (1.05–3.00)	0.87 (0.73 to 1.00)
180 min	0.938	6.43 (−0.25 to 0.94)	1.10 (1 to 1.21)	0.850	0.74 (0.12–1.35)	0.97 (0.87 to 1.08)

Abbreviation: OGTT, oral glucose tolerance test.

^a Values in parentheses are 95% confidence intervals.

^b Simple linear regression coefficient.

Table 2. Bland–Altman mean bias for the differences between capillary and venous glucose in POCT and the laboratory method (mmol/L (mg/dL)).

	Contour Next vs Laboratory		Accu-Chek vs Laboratory	
	Mean bias	95% CI	Mean bias	95% CI
Fasting	0.15 (2.77)	−0.44 to 0.75 (−7.97 to 13.51)	−0.19 (−3.40)	−0.73 to 0.35 (−13.19 to 6.38)
60 min	1.90 (34.17)	−0.04 to 3.83 (−0.66 to 69.01)	1.29 (23.26)	−0.22 to 2.80 (−3.91 to 50.44)
120 min	1.49 (26.79)	−0.38 to 3.36 (−6.93 to 60.51)	1.00 (17.95)	−0.54 to 2.53 (−9.69 to 45.58)
180 min	0.96 (17.21)	−0.06 to 1.97 (−1.14 to 35.57)	0.72 (12.93)	−0.49 to 1.93 (−8.83 to 34.69)

Abbreviations: CI, confidence interval; POCT, point-of-care testing.

Table 3. Independent-samples t-test results between GDM and healthy patients related to maternal age, gestational age and hemoglobin.

		n	Mean	SD	Sig ^a (Levene Test)	t-value	df	Sig ^b (2-tailed)
Accu-Chek								
<i>Maternal age (years)</i>								
Venous	GDM	5	33.0	2.24	0.115	0.202	55	0.841
	Healthy	52	33.5	5.03				
Capillary	GDM	7	33.6	2.64	0.141	-0.087	55	0.931
	Healthy	50	33.4	5.09				
<i>Gestational age (weeks)</i>								
Venous	GDM	5	25.8	1.10	0.213	-0.311	50	0.757
	Healthy	47	24.9	6.59				
Capillary	GDM	7	22.0	6.90	0.267	1.353	50	0.182
	Healthy	45	25.4	6.13				
<i>Hemoglobin (g/L)</i>								
Venous	GDM	5	123.0	10.05	0.633	-0.383	55	0.703
	Healthy	52	121.4	8.92				
Capillary	GDM	7	124.9	9.17	0.937	-1.053	55	0.297
	Healthy	50	121.1	8.90				
Contour Next								
<i>Maternal age (years)</i>								
Venous	GDM	11	36.1	4.23	0.277	-0.990	50	0.327
	Healthy	41	34.3	5.59				
Capillary	GDM	19	36.2	4.26	0.147	-1.597	50	0.116
	Healthy	33	33.8	5.75				
<i>Gestational age (weeks)</i>								
Venous	GDM	8	23.5	4.50	0.176	0.820	42	0.417
	Healthy	36	25.8	7.72				
Capillary	GDM	14	23.8	4.76	0.060	1.015	42	0.316
	Healthy	30	26.2	8.12				
<i>Hemoglobin (g/L)</i>								
Venous	GDM	11	124.5	11.92	0.714	-1.051	50	0.298

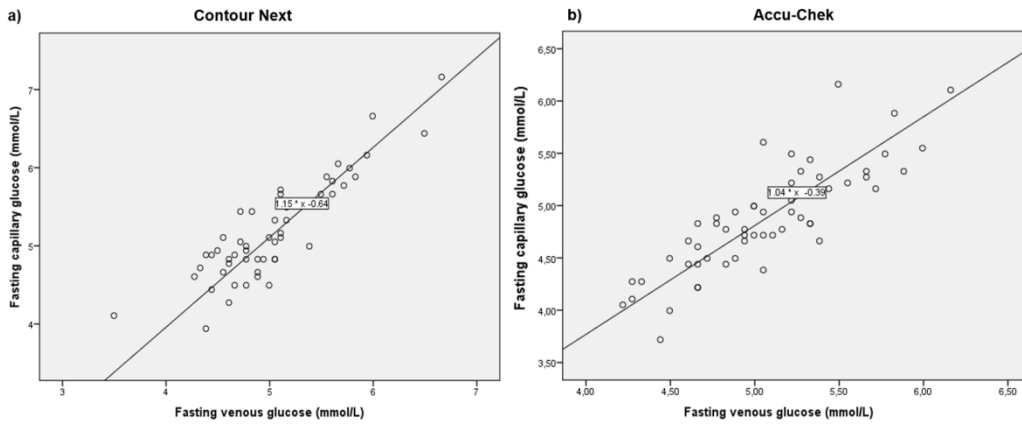
	Healthy	41	120.1	12.43				
Capillary	GDM	19	124.8	11.55	0.660	-1.700	50	0.095
	Healthy	33	118.9	12.43				

Abbreviations: df, degree of freedom; GDM, gestational diabetes mellitus.

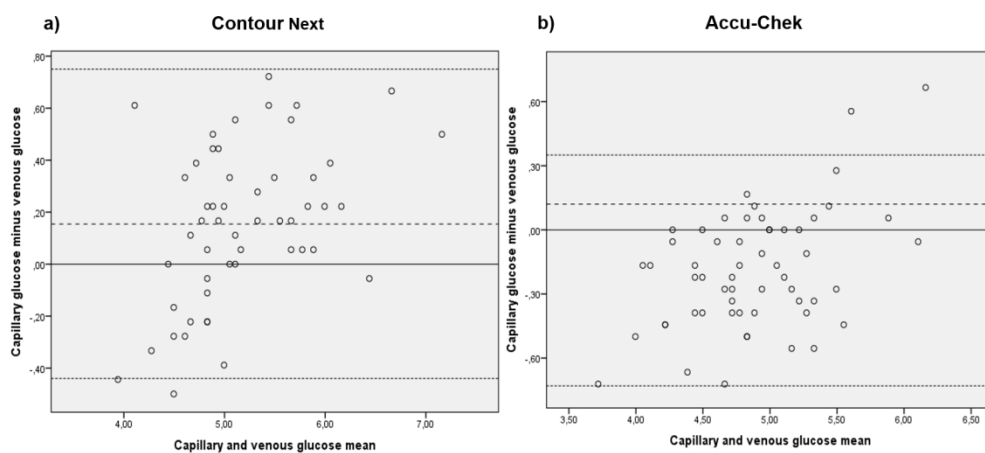
Bold values (P value) showed no significant differences between GDM and healthy patients ($P > 0.010$)

^a Sig: *P* value.

^b Sig (2-tailed): *P* value bilateral.



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