

## DIAGNOSTIC PERFORMANCE OF A POINT-OF-CARE GLUCOSE ANALYZER IN GESTATIONAL DIABETES

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**Background:** Oral glucose tolerance test (oGTT) with laboratory measurement of venous plasma glucose (VPG) at fasting, 1 and 2 hours after a 75g glucose load is the recommended diagnostic procedure for gestational diabetes mellitus (GDM). The inconvenience of multiple venipunctures and notorious instability of glucose in venous blood samples, together with the complexity of the oGTT procedure seriously compromise the choice of the GDM diagnostic test procedure, particularly in remote and under-resourced areas. Considering the dramatically rising prevalence and recently introduced recommendations for universal screening of GDM, suitable alternatives for simplifying GDM diagnostic procedure are urgently needed in order to provide appropriate level of pregnancy health-care and improve patient outcomes.

**Aim:** The aim of this study was to validate the diagnostic performance of the Nova StatStrip Glucose point-of-care (StatStrip) analyzer (Nova Biomedical, USA), designed and approved for hospital use, in the GDM diagnosis. Considering a lack of defined cut-points for capillary plasma glucose (CPG) in GDM diagnosis, we also aimed to determine a set of StatStrip-specific CPG diagnostic criteria.

**Methods:** After providing informed consent, CPG was sampled and StatStrip glucose measured at fasting (F-CPG), 1- and 2-hour after a 75g oral glucose load. Blood samples for VPG were collected within 5 minutes of respective CPG sampling in heparin tubes, immediately refrigerated, processed and analysed within 30 minutes with the reference laboratory procedure (hexokinase, Olympus AU400, Beckman Coulter, USA). Glycaemic status was classified as either normoglycaemic (NG) or GDM, according to WHO-2013 venous plasma-based criteria.

**Results:** 49/166 (30%) pregnant women [median age: 31 years (range 18-42)] were diagnosed with GDM, while 70% were classified as NG. Fasting VPG (F-VPG), either alone or combined with 1h- and 2h-VPG was able to identify 33/49 (66%) GDM cases, while post-load-VPG identified further 3 (6%), 6 (12%) and 8 (16%) GDM cases for 1h-, 2h- and combined 1h+2h-VPG, respectively. Bland-Altman analysis showed a slight, but significant bias between F-CPG and F-VPG (mean: 0.27 mM,  $P < 0,001$ ) and a more pronounced positive bias at 1h and 2h (mean: 1.2 and 0.9 mM,  $P < 0,0001$ , respectively), reflecting a well-known difference between the CPG and VPG in post-load conditions. ROC-curve analysis for F-CPG revealed an optimal cut-point at  $>5,2$  mM, whereas 1h- and 2h-CPG cut-points were assessed as  $>11.0$  and  $>9.5$  mM, respectively. Re-classification of the patients according to StatStrip-CPG cut-points identified 53 (32%) GDM subjects [39/53 (74%) with F-CPG criterion and 5/53 (9%), 5/53 (9%) and 4/53 (8%) with 1h-, 2h- and combined 1h+2h CPG criteria, respectively]. Inter-rater agreement analysis demonstrated a good agreement between the established StatStrip-CPG procedure with the VPG-based reference procedure (weighted kappa = 0.745; SE=0.0563, 95%CI=0.635-0.856).

**Conclusion:** Our study demonstrate a high level of diagnostic accuracy of the Nova StatStrip Glucose point-of-care analyzer for GDM diagnosis, provided that specific CPG-based diagnostic criteria are followed. State-of-the-art point-of-care glucose technology can be a valuable and reliable tool within global efforts dedicated to an universal screening for gestational diabetes mellitus.