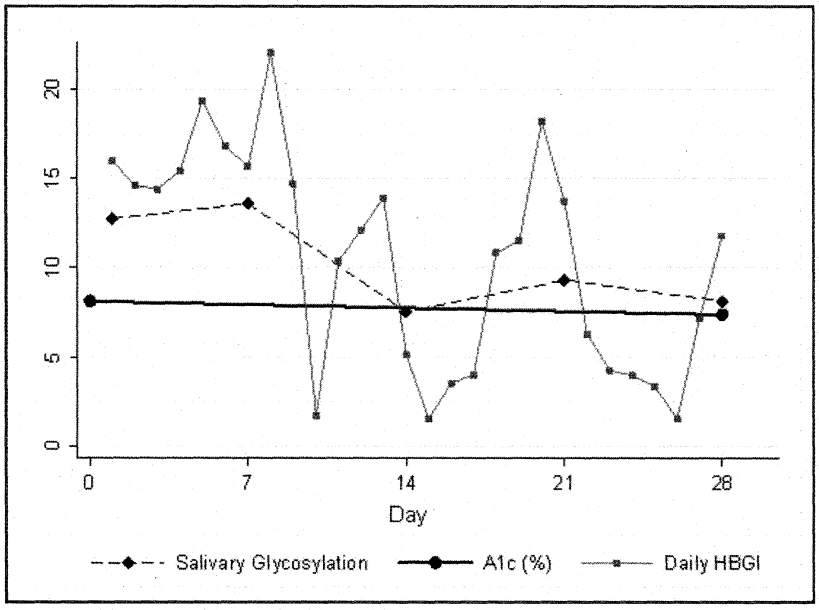
72nd American Diabetes Association. scientificsessions
JUNE 8-12, 2012 • PHILADELPHIA, PA

Control/Tracking Number: 2012-A-2965-Diabetes
Activity: Abstract
Current Date/Time: 1/6/2012 2:45:38 PM

Non-invasive salivary protein glycosylation as a short-term glycemic index

Author Block: SRINIVASA R. NAGALLA, CARYN A. SNYDER, JOHN A. MICHAELS, CHARLES T. ROBERTS, VISHNU PATURI, *Beaverton, OR*

Abstract:
The standard parameter for monitoring of glycemic index is hemoglobin A1c, which reflects average glycemia over the previous 3 months. Fructosamine and glycated albumin can provide potential assessment of more near-term glycemia, but all of these are invasive and require specific laboratory analysis. We evaluated salivary glycoprotein levels as a non-invasive alternative by comparing it to A1c and continuous glucose monitoring (CGM) in 8 type 1 and type 2 diabetics. Saliva was collected at days 1, 7, 14, 21 and 28 and blood collected at baseline and day 28. Salivary glycosylation was measured by lectin-binding immunoassays and was normalized for total protein concentration. To account for asymmetry in the blood glucose measurement scale and suppress normal fluctuation in the target range for glucose control, the High Blood Glucose Index (HBGI) was calculated to quantify glycemia from the CGM data. Daily, weekly, and 28-day HBGIs were computed and matched to the time of each study visit. The Figure shows weekly salivary glycosylation and daily HBGI over 28 days of CGM in a type 2 diabetic with beginning and ending A1c's of 8.1% and 7.4%, respectively. Six participants did not achieve optimal control as defined by baseline HbA1c's <7.0%. During CGM, these participants achieved a 33% reduction in HBGI. A1c only slightly changed over this time period (-0.4 $\pm$ 0.5%), and did not reflect the degree of glycemic variation observed. Average salivary glycosylation levels collected weekly over 4 weeks demonstrated a stronger correlation with CGM than A1c (r=0.81 vs. r=0.52) and represent a promising, non-invasive method for glycemia



monitoring.

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Author Disclosure Information: S.R. Nagalla: *Employee*; *Author*; DiabetOmics. *Stock/Shareholder*; *Author*; DiabetOmics. C.A. Snyder: *Employee*; *Author*; DiabetOmics. J.A. Michaels: *Employee*; *Author*; DiabetOmics. C.T. Roberts: *Stock/Shareholder*; *Author*; DiabetOmics. V. Paturi: *Stock/Shareholder*; *Author*; DiabetOmics.
Category (Complete): 01-A Clinical Therapeutics/New Technology - Glucose Monitoring and Sensing
Presentation Preference (Complete): Poster Preferred
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Financial Support (Complete):
* ADA Support: No

Keywords (Complete): saliva ; glycoproteins ; continuous glucose monitoring
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Status: Complete

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Control/Tracking Number: 2012-A-3180-Diabetes
Activity: Abstract
Current Date/Time: 1/6/2012 2:52:39 PM

First-trimester Maternal Serum Biomarkers for Prediction of Gestational Diabetes

Author Block: JUHA P. RASANEN, SRINIVASA R. NAGALLA, CARYN A. SNYDER, CHARLES T. ROBERTS, VISHNU PATURI, *Portland, OR, Beaverton, OR*

Abstract:
Gestational diabetes (GDM) confers an increased risk for pregnancy complications and development of subsequent type-2 diabetes. In this case-control study, we evaluated glycoproteins as alternative GDM biomarkers based on the hypothesis that increased hexosamine biosynthetic pathway flux secondary to hyperglycemia in GDM may affect the levels of serum analyte glycosylation. Maternal serum samples were collected between 9-11 and 16-27 gestational weeks from 150 Finnish women participating in a prospective observational cohort. GDM was diagnosed by a standard oral glucose tolerance test. Fibronectin glycosylation associated with Sambucus nigra lectin binding (FN-SNA), adiponectin, SHBG, and CRP levels were determined by immunoassay and analyzed using Receiver Operating Characteristic (ROC) curves from logistic regression modeling. First-trimester FN-SNA, adiponectin, and CRP levels were all significantly associated with subsequent development of GDM in 50 GDM subjects compared to 50 trimester-matched controls. The mean FN-SNA concentration was greater in participants who later developed GDM than in controls (102+30 mg/L vs. 56+15 mg/L; $p<0.0001$). At a false-positive rate of 4%, FN-SNA alone detected 84% of 1st-trimester GDM cases. The detection rate increased to 92% with addition of adiponectin and CRP. FN-SNA, adiponectin, and SHBG were all significantly associated with GDM in the 2nd trimester ($p<0.01$). The area under the ROC curve for FN-SNA alone was 0.92 (95% CI: 0.86, 0.98), which increased to 0.99 (95% CI: 0.98, 1.00) with the addition of adiponectin and SHBG. Similar discrimination was achieved with Aleuria aurantia lectin-reactive pregnancy-specific glycoprotein (PSG-1). Our data demonstrate that maternal serum FN-SNA represents a promising single-marker test for early identification of women at risk for GDM. Reliable early diagnosis using maternal serum glycoprotein biomarkers can facilitate new intervention strategies to prevent the complications of GDM.
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Author Disclosure Information: J.P. Rasanen: None. S.R. Nagalla: *Employee*; *Author*; DiabetOmics. *Stock/Shareholder*; *Author*; DiabetOmics. C.A. Snyder: *Employee*; *Author*; DiabetOmics. C.T. Roberts: *Stock/Shareholder*; *Author*; DiabetOmics. V. Paturi: *Stock/Shareholder*; *Author*; DiabetOmics.
Category (Complete): 01-A Clinical Therapeutics/New Technology - Glucose Monitoring and Sensing
Presentation Preference (Complete): Oral Preferred

Sponsor (Complete):

* At least one (1) author listed on this abstract is a current member of the ADA and therefore a sponsor is not required.: Yes

Financial Support (Complete):

* ADA Support: No

Keywords (Complete): gestational diabetes ; glycoproteins
Payment (Complete): Your credit card order has been processed on Friday 6 January 2012 at 2:49 PM.
Status: Complete

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Control/Tracking Number: 2012-A-3183-Diabetes
Activity: Abstract
Current Date/Time: 1/8/2012 3:33:56 PM

Diabetes Autoantibody Analysis in Human Saliva

Author Block: SRINIVASA R. NAGALLA, ROBERT BUCK, MARY A. LAUGHLIN, CARYN A. SNYDER, VISHNU PATURI, CHARLES T. ROBERTS, *Beaverton, OR*

Abstract:
Islet-directed autoimmunity and associated autoantibodies, previously thought to be differentially characteristic of T1 diabetes (T1DM), is now apparent in a proportion of individuals with putative T2 diabetes (T2DM), consistent with an increasing appreciation of diabetes as a continuous spectrum. The ability to non-invasively detect diabetes autoantibodies in children, adolescents with apparent T2DM, and in adults with potential latent autoimmune diabetes of adulthood will facilitate screening of at-risk populations, prevention of disease progression, and intervention with appropriate therapies. In this study, we investigated if a high-sensitivity antigen array-based immunoassay platform could detect autoantibodies in saliva. Recombinant GAD65, IA-2α, ZnT8 antigens containing the principal epitope domains targeted by diabetes autoantibodies were generated, and, along with commercial recombinant insulin, were used for autoantibody capture, and a universal detection probe was developed to detect human anti-IgG. In matched serum and saliva samples from 30 T1DM and 75 T2DM subjects whose serum autoantibody status was validated independently using WHO reference standards and commercial kits, GAD65, IA-2α, ZnT8, and insulin autoantibodies were reliably detected in saliva with a detection threshold 10 to 15-fold lower than in serum. To adapt this autoantibody detection system to a point-of-care, lateral-flow device, we evaluated blue latex and fluorescent carboxy-methyl europium latex particles coupled to anti-human IgG and recombinant IA-2α antigen, or mouse monoclonal anti-IA-2α, to print on nitrocellulose membrane-binding partners. Proof-of-concept studies with IA-2α-positive human saliva samples demonstrated semi-quantitative measurement of saliva anti-IA-2α IgG in this system. Further characterization of salivary autoantibody assessment and adoption to a point-of care device technology will provide a convenient, non-invasive test for rapid screening of at-risk populations.

Category (Complete): 14 Immunology
Presentation Preference (Complete): Poster Preferred
Sponsor (Complete):
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Financial Support (Complete):

* ADA Support: No

Keywords (Complete): autoantibodies ; saliva
Payment (Complete): Your credit card order has been processed on Sunday 8 January 2012 at 3:33 PM.
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