Results: In this study we found overall of 17% prevalence in DM cases with Thyroid disorders and amongst this, 11.76% with Primary Hypothyroidism, 76.48% with Sub clinical Hypothyroidism and 11.76% with Sub clinical hyperthyroidism. A statistical significant difference was noted between cases-DM and controls with respect to BMI (p<0.000), arm circumference (p<0.000), FT3 (p<0.004), TSH (p<0.000), FBS (p<0.000), PP(P <0.000), HbA1C (p<0.000), TC (p<0.000), TG(p<0.005) and LDL (p<0.018) respectively. In this study, the mean±SD of FT3, FT4 and TSH in control and DM were found to be (2.43±0.64 and 2.67±0.93 with p-value 0.004), (1.06±0.27 and 1.15±0.31 with p-value 0.31) and (2.62±1.42 and 3.70±5.13 with p-value 0.00). Analysis between serum FT3, FT4 and TSH with respect to baseline characteristics and biochemical parameter of the study subjects showed negative significant correlation (p<0.05) between FT3 with region in DM, positive significant correlation between FT4 with Age in DM, positive significant correlation (p<0.05) between TSH with TC in DM.

Conclusion: This study confirms that thyroid dysfunctions is also common among Nepalese type II DM patients. Our study also reveal that prevalence of thyroid dysfunction is more common in type II DM. It is thus recommended that these group of population should be routinely screened for asymptomatic thyroid dysfunctions besides their usual treatment.

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Graves disease: Patients with hyperthyroid status have a higher risk of developing type 2 diabetes

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Background. Graves' disease (GD) is a multi-systemic autoimmune disorder caused by thyroid stimulating antibodies that bind to and activate the thyroid stimulating hormone (TSH) receptor on thyroid cells (TRAbs). Common findings are low serum concentration of TSH, positive TRAbs, and high concentrations of anti-thyroid peroxidase antibodies (ATPO). In insulin-dependent diabetics, hyperthyroidism may aggravate glucose intolerance by multiple mechanisms, decreasing responsiveness to insulin. An association between type 1 diabetes mellitus (DM) and autoimmune reaction to thyroid antigens, including anti-thyroid antibodies (ATPO) in pediatric patients with positive TRAbs, was recently reported. The objective of this study is to investigate the association between thyroid status, serum TSH levels, positive TRAbs and ATPO, and the potential risk to develop type 2 DM based on insulin levels in adults. Methods. The study was conducted in 64 patients between May 2014 and October 2015. The mean subject age was 47 ± 18 years old and the male/female ratio was 11 (17.7% male):51 (82.3%female). Pregnant women and patients under 25 years of age were excluded. We measured TRAbs, ATPO, TSH, and insulin concentrations in euthyroids (TSH = 1.10 to 9.00 µU/mL) and hyperthyroids (TSH between 0.01 to 0.44 µU/mL). TRAbs were measured by second generation thyrotropin-binding inhibitor immunoglobulin (TBII) assay (DiaMetra, Italy). The cut-off for positive TRAbs was 1.50 UI/L. ATPO, TSH and insulin concentrations were determined by chemiluminescent microparticle immunoassay (CMIA) using a Advia Centaur (Siemens, USA). The cut off for positive ATPO was &gt 37 UI/mL, reference interval for TSH was 0.4 to 4.4 µU/mL and for insulin was 5 to 20 µU/mL. Data obtained for all measurements of TRAbs, ATPO, TSH and insulin in both groups was analyzed using the Student's t-test. A p value &lt 0.05 represented a significant difference. Data was expressed as mean ± standard error of the mean (SEM). Results. As expected, TSH serum concentrations were significantly decreased in hyperthyroid patients (0.13 ± 0.03) compared with euthyroid patients (3.31 ± 0.48) (t=12.79; p &lt 0.05). We observed a significant increase in TRAbs levels in hyperthyroid patients (7.67 ± 1.91) compared with euthyroid patients (2.23 ± 0.40) (t=2.07; p &lt 0.05). In addition, we reported a significant enhacement on ATPO levels in hyperthyroid patients (650.8 ± 84.82) versus euthyroid patients (296.2 ± 85.30) (t=3.03; p &lt 0.05). Similarly, higher insulin levels were observed in hyperthyroid patients (15.35 ± 1.94) versus euthyroid patients (9.94 ± 1.43) (t=2.51; p &lt 0.05). Conclusions. Based on the results of the present study we conclude that thyroid autoimmunity is associated with female gender, the presence of anti-thyroid and TSH receptor antibodies, and low levels of TSH. Importantly, higher mean insulin concentrations were observed in hyperthyroid patients. The presence of TRAbs and high insulin concentrations in patients with TSH between 0.01-0.44 µU/mL and positive ATPO, may indicate a higher risk of developing type 2 Diabetes Mellitus in adults. We recommend evaluation of TRAbs and insulin levels in at-risk populations.

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Homeostasis model assessment of insulin resistance in a general adult population in Korea: Additive association of sarcopenia and obesity with insulin resistance

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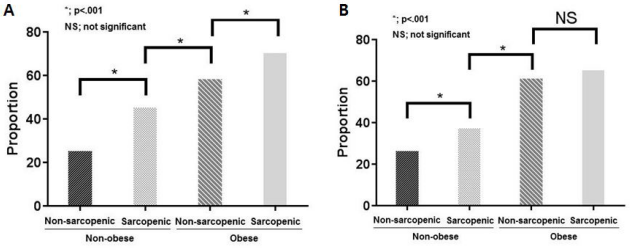
Background: Insulin resistance (IR) is a major factor associated with type 2 diabetes. The homeostasis model assessment of insulin resistance (HOMA-IR) is a useful method to assess IR in large populations. We aimed to elucidate the factors associated with IR risk, especially the cumulative effect of obesity and sarcopenia on IR. In addition, the appropriate cutoff of HOMA-IR for assessing IR was calculated.

Methods: This is a retrospective, cross sectional study. A total of 8,707 adults (4,192 men and 4,515 women) from the 4th and 5th Korean National Health and Examination Surveys were studied. Laboratory, anthropometric, and lifestyle factors were analyzed to reveal their association with HOMA-IR and IR risk. Subjects were divided into four groups according to the presence of obesity and sarcopenia to identify their effect on IR risk. For assessing the optimal cutoff of HOMA-IR for IR, the HOMA-IR of a healthy subgroup was used.

Results: We found that high triglycerides and alanine aminotransferase, low high-density lipoprotein cholesterol, obesity, and sarcopenia were independent risk factors for IR in both sexes. Obese men with sarcopenia had a significantly higher risk of IR than men who were obese or sarcopenic (but not both, figure 1A). The additive effect of sarcopenia with obesity on IR risk was not observed in women (figure 1B). Cutoffs of HOMA-IR for determining IR were calculated as 75 percentile value of young healthy subpopulation, 2.19 in men and 2.18 in women. These cutoffs could distinguish individuals with impaired fasting glucose from normal ones, with a sensitivity of 65.4% (men) and 73.3% (women), and a specificity of 68.8% (men) and 69.4% (women).

Conclusion: These data showed that obese men with sarcopenia exhibited a significantly higher IR risk than non-sarcopenic obese men. In women, body composition did not affect IR if they were already obese.



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Serum adiponectin levels in overweight and obese women; Discrimination between insulin resistance and abdominal obesity

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Introduction

Insulin resistance and abdominal obesity are both associated with lower serum adiponectin concentrations. Since insulin resistance and abdominal obesity are related, the extent to which the association of adiponectin with insulin resistance is dependent on its relationship with abdominal obesity is not clear. The present study investigated the association between insulin resistance and abdominal obesity in its relationship with serum adiponectin.

Methods

Eighty-eight overweight or obese women (BMI>23) in the age group 35-65 years were enrolled. Anthropometric measurements, blood pressure were recorded and a fasting blood sample was obtained for biochemical parameters. Insulin resistance (IR) was quantified by homeostasis model assessment of insulin resistance (HOMA-IR). Abdominal obesity was assessed by waist circumference (WC). Subjects were divided according to WC quartiles: Q1) WC < 89cm (n = 21); Q2) WC 89-96cm (n = 21); Q3) WC 97-102cm (n = 25); and Q4) WC > 102cm (n = 21) and on the basis of insulin resistance. Data were analysed by SPSS 16.0.

Results

The mean serum concentration of adiponectin in women were 5.93±1.9 µg/mL. In linear regression analysis, significant correlates of serum adiponectin were serum insulin (r = -0.439, p=0.000) and insulin resistance (r = -0.415, p<0.001). BMI, waist circumference, systolic and diastolic blood pressure, serum triacylglycerides and low-density lipoprotein (LDL) had negative correlations with adiponectin but statistically not significant (p>0.05). High-density lipoprotein (HDL) correlated positively with adiponectin level (p<0.05). Across quartiles of WC, insulin-resistant (HOMA-IR > 2.5) subjects had significantly lower (p<0.05) adiponectin levels when compared with insulin-sensitive (HOMA-IR < 2.5) subjects irrespective of the level of abdominal adiposity.

Conclusion

High adiponectin levels are associated with insulin sensitivity and a favourable lipid profile. Serum adiponectin levels are more tightly linked with insulin resistance than with abdominal obesity.

	WC<89 cm		WC 89-96 cm		WC 97-102 cm		WC >102 cm	
	IR< 2.5	IR>2.5	IR< 2.5	IR>2.5	IR< 2.5	IR>2.5	IR< 2.5	IR>2.5
Mean Adiponectin ±SD	6.1 ±1.49	5.6 ±1.94	7.27 ±1.36	5.40 ±1.72	6.50 ±2.95	5.18 ±1.69	7.05 ±2.82	5.57 ±1.79
p value	0.046*		0.03*		0.045*		0.03*	

Difference among WC quartiles by one-way ANOVA: IR<2.5 groups, p = 0.65, IR>2.5 groups, p = 0.32

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Validation of a new glycated serum protein assay on Siemens Vista analyzer

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Introduction: Glycated Serum Protein (GSP) or fructosamine, estimates the average blood glucose over a 2-3 week period versus over a 3-4 months period for HbA1c. GSP may be used to monitor diabetics with hemoglobinopathies or have conditions that affect RBC (red blood cell) lifespan. HbA1c is falsely decreased when the RBC lifespan is less than 120 days, while GSP is not affected. Fructosamine assay is widely used as an alternate test for certain diabetes patients with hemoglobinopathies and for pregnant woman. However, most of the fructosamine assays that are currently in the market are nitro blue tetrazolium (NBT) based colorimetric assays and they suffer from a variety of interferences like vit-c, bilirubin, glutathione which lead to inaccurate results. These analytical issues led us to investigate for an alternate assay that could be adapted to our existing Siemens Vista analyzer.

Study Objectives: The objective of this study is to evaluate and validate a user-defined application protocol for glycated serum protein (GSP) assay from Stanbio Laboratory - an EKF Diagnostics company on Siemens Vista chemistry analyzer. In addition to the method validation, we also established the specimen stability and adult reference ranges for GSP. **Materials and Methods:** GSP from Stanbio Laboratory - an EKF Diagnostics Company is a new FDA cleared three step enzymatic colorimetric assay based on trinder endpoint reaction measured at 546-600 nm for quantifying GSP in serum. The assay was evaluated on Vista chemistry analyzer using open channel user defined method. Performance of the assay was evaluated for inter and intra assay precision, accuracy, linearity, reference ranges and specimen stability.

Results and Discussion: With-in-run imprecision was 6.5 % for control 1 (mean=264 µmol/L) and 3.7% for control 2 (mean=715 µmol/L). Between-run precision with 17 days were 4.2% (mean= 267 µmol/L) and 2.5% (mean = 728umol/L). Analytical measurement range was verified using 5 level calibrators and acceptable across the range (40-1185 µmol/L). Accuracy and recovery of the assay was acceptable with a mean recovery of 100±5% across the analytical measurement range (AMR). All values were considered acceptable. Comparisons between laboratory assay and vendor predicted assay on Stanbio Sirrus clinical chemistry analyzer compared well (r-square=0.996, slope=1.0 and intercept=-1.49). Stability studies proved that samples stored at 2-4 °C are stable up to 7 days with no significant variations. Lab also verified the reference interval as 151-300 µmol/L using adult patient population (18-65 yrs).

Conclusion: The user defined application for GSP assay enhances the versatility of the Vista system for specialized glycemic monitoring for a specific diabetic subpopulations where the patient has either a genetic variant of hemoglobin (hemoglobinopathy) or a condition or treatment that affects RBC turnover. Furthermore, this application provides laboratories with a simple, sensitive, fast, and convenient alternative glycemic monitoring test with no endogenous substance interference that are typically observed in NBT based colorimetric fructosamine assays.

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Free thyroid hormone measurements in pregnancy: Comparisons of immunoassays and mass spectrometry

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Background: Second trimester maternal thyroid deficiency has been associated with adverse neurological development in children and a high rate of subsequent permanent hypothyroidism in the mother (1). Accurate assessment of thyroid hormone concentrations during pregnancy is therefore essential. In pregnancy, measurement of free thyroxine (FT4) and free triiodothyronine (FT3) is complicated by increased binding protein levels. Ultrafiltration or equilibrium dialysis followed by tandem mass spectrometry (MS) is a recommended method for improved sensitivity of FT4 concentrations; however, these techniques are expensive and laborious. The present study compares multiple immunoassay methods for FT4 and FT3 with MS to determine suitability of automated assays for large population-based studies in pregnancy. Previously, MS results for FT4 and FT3 have been compared to a limited number of immunoassay methods.

Methods: Residual sera (n=60) for the comparative study were collected, aliquoted, and distributed by the Women and Infants (WIH) laboratory; TSH concentrations were within the reference interval (0.3-5.0 µIU/mL) in 50 samples, elevated in 8 samples, and low in 2. Ultrafiltration followed by liquid chromatography-tandem mass spectrometry was performed as previously described (2). Immunoassay platforms for FT4 and FT3 testing included the Abbott Architect $i2000_{SR}$, Roche cobas e602, Beckman Coulter Dxl, and Siemens Immulite 2000. Formal pairwise method comparisons were performed, after logarithmic transformation. This study was approved by the WIH IRB.

Results: Of the 60 samples, one failed MS quality control for FT4 (hypothyroid) and 18 for FT3 (14 euthyroid and 4 hypothyroid); 41 samples remained. FT4 correlations between the four immunoassays ranged between 0.82 and 0.93; correlations between MS and the four immunoassays, however, were lower (r values: 0.74, 0.74, 0.66, and 0.71 for Architect, cobas, DxI, and Immulite, respectively). Among the three samples with TSH elevations, all four immunoassays ordered the FT4 results the same as MS. FT3 correlations between the four immunoassays ranged between 0.46 and 0.89; correlations between MS and the immunoassays were low (r values: 0.27, 0.40, 0.37, and 0.18, respectively).

Conclusions: FT4 immunoassay measurements appear to be a reasonable surrogate for MS in pregnant euthyroid patients. Agreements between immunoassays for FT4 are high. MS was unable to reliably determine FT3 in 18 pregnancy samples, and agreement between the remaining 41 FT3 MS results with immunoassays was poor. Agreement was also poor between FT3 immunoassays. These results generate concern regarding the reliability and usefulness of FT3 assays in samples from pregnancy. The measurement of total T3 as an alternative to fT3 is currently under investigation.

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Inappropriate Inpatient HbA1c Repeat Testing

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Background: There is presently much interest in reducing waste in health care. In laboratory medicine, unnecessary repeat testing is such a focus and HbA1c measurement with its known biological half-life and monitoring requirements is a good model test. This study examined the pattern of repeat HbA1c testing in inpatients at a 1400 bed general hospital in Singapore (note that HbA1c is not used for diagnosis of diabetes mellitus in Singapore). **Methods:** Anonymised details of all HbA1c testing (Beckman-Coulter DxC-800 immunoturbidometric assay) for 2014 were extracted from the laboratory information system for analysis in Excel. Inappropriate repeat testing was defined as a retest interval < 60 days (Association of Clinical Biochemistry UK Minimum Retesting Interval guidelines). Logistic regression analysis was performed using age, sex, HbA1c, race and hospital discipline to predict repeat testing within different time frames. **Results:** There were 13875 tests (38 per day). 1152 (9%) were repeat samples (1012 duplicates, 127 triplicates, 13 quadruplicates). The cumulative distribution of the repeat tests was: 8.5% within 3 days of the initial test, 11.1% within 7 days, 13.7% within 14 days, 15.6% within 21 days, 18.3% within 30 days, 29% within 60 days and 42.9% within 90 days. The significant predictors