Evaluation of CareSens® N Glucometer Glucose Monitoring System

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Introduction

❖Point-of-care testing (POCT) glucometers are widely being used for management of diabetes.

❖We examined the analytical performance of the recently developed glucometer CareSens N Glucometer (i-SENS Inc., Korea).

Materials & Methods

❖ The study subject
: CareSens N Glucometer (i-SENS Inc., Korea).

❖ Sample Selection
• Whole blood (Na-Heparin) and capillary blood for 100 outpatients

❖Comparison with other two glucometers
• Accu-Chek® inform (Roche Diagnostics LTD., Mannheim, Germany)
• Onetouch® ultra™ (Lifescan Inc., Milpitas, CA, USA)

❖Evaluation of the performance
• Linearity
• Precision : 4 levels of control material
• Method comparison to the reference method.
: hexokinase method by Hitachi 7600 (Hitachi Co., Japan)
• The effect of hematocrit

⇨ Evaluated according to CLSI guidelines(EP5-A2, EP6-A)

Results

❖ Linearity (Figure 1)
: maintained well (R^2=0.9965) in the range of 38.5-564 mg/dL

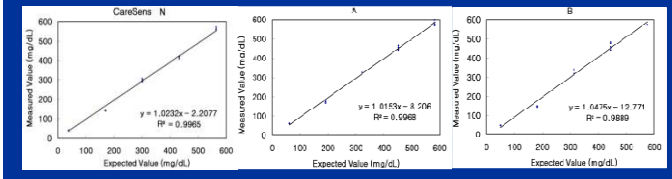

Figure 1. Linearity of glucose concentrations measured by the 3 glucometers, CareSens N, A, and B.

❖ Precision (Table 1)
• CVs of within-run precision : 0.73-1.97%
• CVs of total precision : 1.65-2.71%

Table 1. Precision of CareSens N including 2 different Lot. Numbers

Glucometer	Level	N	Mean (mg/dL)	SD	CV (%)	
					Within-run	Total
CareSens N Lot 1	Low	20	56.65	0.93	1.53	1.65
	Normal	20	139.95	2.85	1.98	2.04
	Mid	20	250.05	4.43	1.22	1.77
	High	20	368.85	7.50	1.46	2.03
CareSens N Lot 2	Low	20	55.45	1.50	1.56	2.71
	Normal	20	136.90	2.50	0.73	1.83
	Mid	20	244.15	5.27	1.36	2.16
	High	20	360.75	7.51	1.47	2.08

❖ Method comparision
• High correlation between CareSens N and Hitachi 7600 (r=0.9614)(Figure 2).

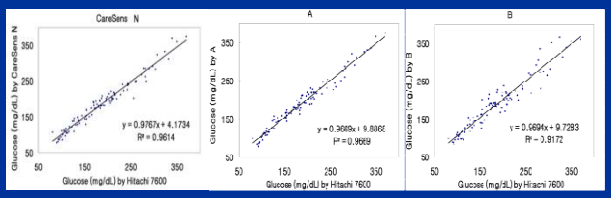

Figure 2. Correlation of glucose concentrations measured by Hitachi 7600 vs. the 3 glucometers, CareSens N, A, and B.

• Variable bias compared with the reference method (Figure 3).

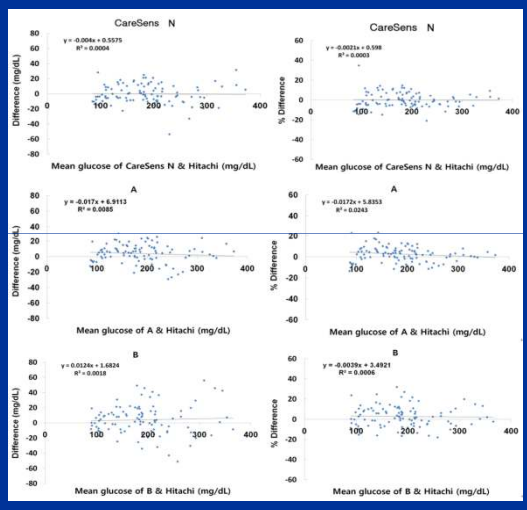

Figure 3. Bias plots of the difference (mg/dL) and % difference against the means between the glucometers, CareSens N, A, and B.

❖ The effect of hematocrit (Figure 4).
• Hematocrit range : 31.1 to 51.2%
• Relationship between hematocrit and glucose level
⇨ weak negative correlation (r=-0.370, *P*=0.0001)

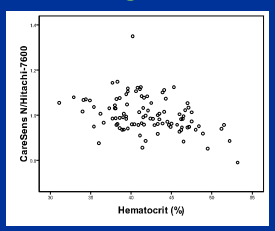

Figure 4. Effect of hematocrit on the glucose concentration measured on CareSens N.

Conclusions

❖CareSens N showed good linearity, precision, and correlation with reference method.

❖CareSens N provided reliable measurements of glood glucose. It could be appropriate for monitoring blood glucose values in diabetic patients.