

## Research Article



## A Comparative Study of Blood Glucose Level Measurement between Glucometer, Semi-Auto Analyzer and Auto-analyzer.

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### ABSTRACT

Diabetes mellitus is an emerging medical health problem in both developed and developing countries. The early diagnosis and management helps in reducing the complications of the disease. Hyperglycemia is dangerous but hypoglycemia is fatal. The treatment for both hyperglycemia and hypoglycemia is different but timely management saves the life of the patient. In emergency situations glucometer play an important role compared to semi-auto and auto analyzer because earlier restoration prevents irreversible neuronal damage. The present study is an attempt to explore any difference in the readings obtained from glucometer, semi-auto and auto analyzer. The study included 60 diabetes mellitus patients and 60 controls from Shri Sathya Sai Medical college and research institute. Blood samples are collected. The blood glucose levels are estimated by Glucose Oxidase – Peroxidase method in both the auto analyzer and semi auto analyzer. Simultaneously, one drop of venous blood will be placed on the strip of the glucometer (ACCU - CHECK) which measures the glucose level by electrochemical sensor method. The datas were analyzed and expressed as mean  $\pm$  standard deviation.

**Keywords:** Diabetes mellitus, Glucometer, Semi auto analyzer, auto analyzer.

### INTRODUCTION

India is ranked second in the world in diabetes prevalence, just behind China. According to the International Diabetes Federation, 61.3 million people in India had diabetes in 2011 and that figure is projected to rise to 101.2 million by 2030. India aims to combat rising diabetes healthcare costs through the diabetes screening program; the National Program for Prevention and Control of Cancer, Diabetes, Cardiovascular Disease and Stroke (NPCDCS), that was approved in 2010 by the Cabinet Committee of Economic Affairs for 100 districts across 15 states and Union Territories. The program plans to screen 150 million people across the country.<sup>1</sup>

A national project to screen school children was also rolled out in March 2011 to identify diabetes prevalence in school. In these programs Glucometers and Blood Glucose Test Strips will be the preferred tool since they can be widely used in hospitals, outpatient clinics, emergency rooms, ambulatory medical care and home self-monitoring.<sup>2-3</sup> Glucometers are utilized by a diverse population of patients, representing all ages and acuteness of medical conditions. Both patients and doctors need reliability in the results of glucometers. In keeping with the trend with all medical devices, the Glucometers also have limitations. Establishing the accuracy of glucometers is challenging.<sup>4</sup>

Glucose is the major carbohydrate found in the blood and a chief source of energy in human body. The nervous system, including the brain, totally depends on glucose from the surrounding extra cellular fluid (ECF) for energy.

The concentration of glucose in the ECF must be maintained within a narrow range. When the concentration falls below a critical level, the nervous tissues lose the primary energy source and are incapable of maintaining normal function. Blood Glucose level monitoring is very important in an intensive care unit especially for diabetic patients.

Glucometers provide fast analysis of blood glucose levels and so in emergency situations, timely management decreases the mortality and morbidity. The advantage of using glucometer includes an easy to handle interface, quick, low blood volume is used, does not require technical knowledge and results are obtained swiftly. Most of the benefits for the Physicians, nurses, patients and administration are based on the belief that “faster is better” and that more rapid testing at bedside will improve medical care and decrease utilization of hospital resources.<sup>3-4</sup>

The accuracy of the blood glucose level may not be obtained from the gluco-meter.<sup>4-5</sup> Only the chemical analyzer (semi-auto and auto analyzer) will provide the accurate results. Compared to semi-auto analyzer, auto analyzer has minimum errors because more manual work is done in semi-auto analyzer. Auto-analyzer gives the most accurate result. The aim of the current study was to determine the accuracy of using the bedside glucometers (ACCU, CHEK) for blood glucose measurement as compared to laboratory chemical analyzer.



**MATERIAL AND METHODS**

This study included 60 diabetes mellitus patients and 60 controls from Shri Sathya Sai medical college & hospital and research institute. Blood samples are collected from venous blood from each patient in Sodium fluoride container for measuring blood glucose using the auto analyzer (COBAS-MIRA PLUS) and semi auto analyzer (NEO MISPA) by Glucose Oxidase – Peroxidase method. Simultaneously, one drop of venous blood will be placed on the strip of the Glucometer (ACCU - CHECK) by electrochemical sensors method in same patient. The data were analyzed and expressed as mean ± standard deviation.

**RESULTS**

**Table 1:** Comparison between Glucometer, Semi-Auto Analyzer and Auto-Analyzer (Controls & Patients).

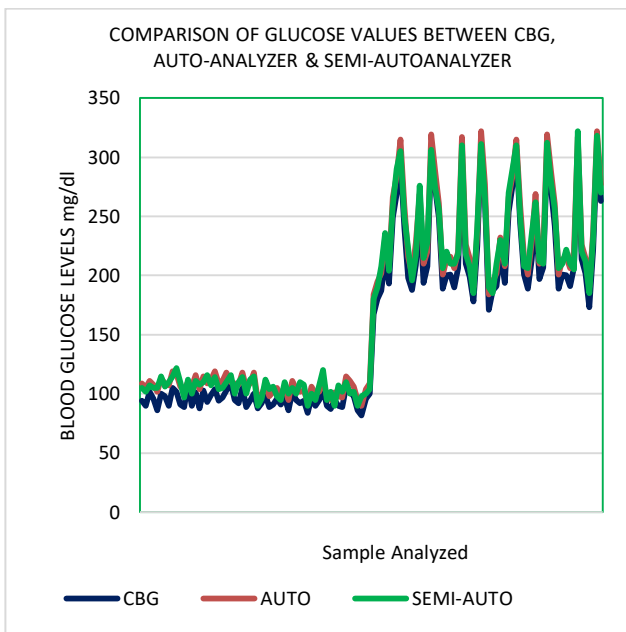
S.no.	CBG	AUTO	Semi-auto	CBG	AUTO	Semi-auto
	CONTROL			PATIENTS		
1	94	109	105	167	184	180
2	90	105	102	180	195	190
3	102	111	107	187	202	208
4	96	108	105	215	232	236
5	86	102	105	193	208	204
6	100	113	115	249	266	259
7	98	109	106	269	284	290
8	90	107	110	298	315	305
9	105	119	115	241	259	250
10	102	117	122	198	216	223
11	91	106	110	188	201	196
12	89	104	97	209	228	217
13	109	110	112	257	269	276
14	90	106	100	194	210	215
15	101	116	111	208	220	228
16	88	104	108	302	319	306
17	103	115	110	275	289	275
18	93	109	116	249	261	256
19	99	112	107	189	201	206
20	104	119	114	200	214	220
21	94	109	104	201	216	210
22	97	111	105	190	206	210
23	103	118	110	206	220	218
24	109	110	116	299	317	310
25	95	109	100	210	226	218
26	92	108	110	199	215	208

27	105	118	114	178	190	185
28	89	105	100	225	237	242
29	94	109	112	310	322	311
30	100	118	115	263	277	265
31	88	94	90	171	184	190
32	92	99	96	187	195	185
33	99	107	112	191	202	210
34	89	98	104	221	232	230
35	91	102	106	194	208	210
36	96	105	98	254	266	270
37	91	98	95	276	284	290
38	97	106	110	306	315	310
39	86	95	100	244	259	250
40	102	111	105	201	216	208
41	95	104	100	189	201	206
42	92	102	110	213	228	235
43	94	103	108	256	269	262
44	84	93	90	197	210	212
45	97	106	100	207	220	210
46	90	100	95	301	319	312
47	95	102	107	274	289	280
48	104	112	120	242	261	256
49	90	98	95	189	201	206
50	87	95	102	201	214	210
51	95	101	90	200	216	222
52	90	98	107	191	206	210
53	89	97	102	207	220	205
54	106	115	110	303	317	322
55	102	111	100	214	226	220
56	98	106	102	202	215	212
57	86	95	90	173	190	185
58	82	90	98	222	237	232
59	96	104	100	306	322	318
60	100	109	104	263	277	270

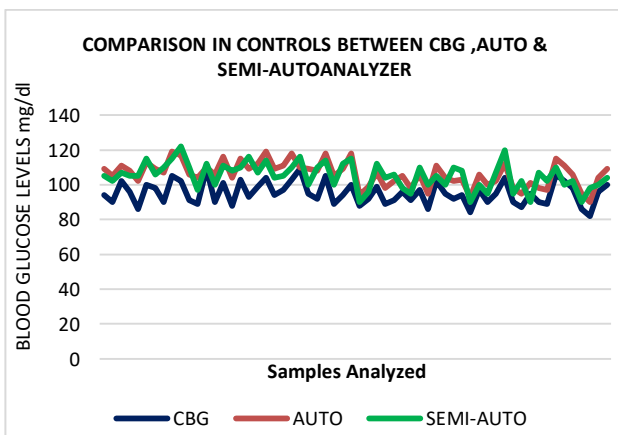
**Table 2:** Glucose values (both Controls and Patients) are expressed as Mean ± Standard deviation.

PARAMETER	CONTROL			PATIENTS		
	CBG	AUTO	SEMI-AUTO	CBG	AUTO	SEMI-AUTO
MEAN VALUES	97	109	104.5	215	230.5	225
Standard deviation	4.242	0	0.707	67.882	65.760	63.639

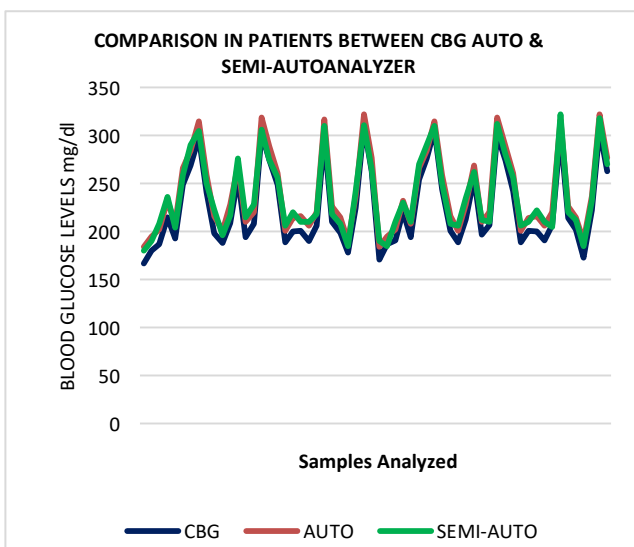




**Graph 1:** Comparison of Glucose values in both control and patients.



**Graph 2:** Comparison of Glucose values in controls



**Graph 3:** Comparison of Glucose values in patients

**DISCUSSION**

There are a number of opinions about ‘Technical Accuracy’ when comparing glucometers against a laboratory method.<sup>4-7</sup> The American Diabetes Association (ADA) has recommended that glucometers agree to within +15% of the laboratory method at all concentrations, with a future performance goal of +5% agreement at glucose concentration.<sup>2</sup> Since glucometer performance can change across the range of the glucose concentrations, some performance criteria differ between the hypoglycemic range and the hyperglycemic range. The International Standards Organization (ISO) and the United States Food and Drug Administration (USFDA) has set accuracy criteria to +20mg/dl for levels <100mg/dl or +20% for glucose levels > 100mg/dl for at least 95% of the results.

There is thus no single standard to assess the accuracy of a glucometer, so the determination of accuracy will vary by country and recommendation utilized for the judgment.<sup>4</sup>

The present study aimed to compare the blood glucose values between gluco-meter, semi-auto analyzer and auto analyzer. We have taken 60 controls and 60 diabetic patients. Blood glucose values were compared between glucometer, semi-auto analyzer and auto-analyzer for both controls and patients and are clearly shown in table1. Glucose values expressed as mean ± standard deviation were shown in table2.

The blood glucose values are lesser in gluco-meter compared to chemical analyzer. Similarly in the chemical analyzer, semi auto-analyzer values are lesser compared to auto analyzer. Glucose values compared for both control and patients were shown in graph 1, graph 2 and graph 3.

Previous studies have documented that unstable hemodynamic (edema and use of a vasopressor) and use of insulin were associated with increased error of blood glucose monitoring with glucose meters. The small difference seen can be attributed to the amount of blood used for measuring the glucose level and also it is known that readings of most glucometers fluctuate with changes in temperature and humidity.<sup>7</sup> In rural areas, the transport of blood to laboratories for analysis is problematic. Analysts such as glucose have to be collected and processed in a timely fashion to ensure accurate results. Capillary blood glucose testing using portable point of care devices may be an alternative to venous plasma samples, because they are easier, less expensive overall, and less invasive to obtain.<sup>3, 6</sup> Capillary blood glucose estimation can be widely used in health camps.

**CONCLUSION**

We concluded that the auto-analyzer is more accurate compared to semi-auto analyzer and glucometer for glucose estimation but glucometer can be used at bedside under emergency situations to monitor the



glucose level because timely management saves the precious life of the patients.

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