

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

قال الله تعالى

﴿ قَالُوا سُبْحَانَكَ لَا عِلْمَ لَنَا إِلَّا مَا عَلَّمْتَنَا
إِنَّكَ أَنْتَ الْعَلِيمُ الْحَكِيمُ ﴾

صدق الله العظيم
سورة البقرة الآية (32)

Dedication

To

My wonderful family

To

**All those whom I always
love and respect**

Acknowledgments

**All and first thanks to the almighty ALLAH.
My all and deepest thanks to my family for
their support, bearing, and encouragement;
especially my father who gave me the moral
support, my mother for her prayers.
Deep thanks to my supervisor Dr.Abd Alhafiz
Hassan Khattab for his great effort and
patience.
Also great thanks to my friends who pushed
me forwards and encouraged.
My gratitude to all staff in Alban Jaded and
Diabetic and Endocrine Centre in Khartoum
North for their great assistance.
At last and not to forget my great thanks to
all people who helped me in this study.**

ABSTRACT

Background: Abnormal blood glucose levels are common in ill patients with diabetes and increase the risk of complications such as infection, metabolic problems, and/or cerebral damage. Frequent monitoring of blood glucose levels and aggressive management of hyperglycemia can decrease these complications. Although laboratory analysis is the most accurate method for evaluating glucose levels, because of cost and time delays; bedside point-of-care (POC) testing is often used to determine glucose levels when frequent monitoring of glucose is important.

The aim of this study was to compare glucose results obtained by Accu-Chek Active glucometer (dry chemistry) to glucose oxidase method (wet chemistry).

Method: Point of care values were compared with laboratory values in 60 diabetic patients who attended Alban Jaded Educational Hospital, and Diabetic and Endocrine Centre in Khartoum North, for routine follow up during the period from 18.11-9.12. First capillary whole blood samples were analyzed by glucometer (Accu- Chek Active), then venous blood samples were collected for plasma glucose analysis.

Results: This study showed that mean capillary whole blood glucose levels, measured in Accu- Chek Active glucometer (dry chemistry), were not significantly different from mean laboratory plasma glucose levels as measured by glucose oxidase method (wet chemistry) using independent-t test (P-value= 0.341).

Conclusion: Glucose values of point of care samples were not differ significantly from specific laboratory method values, therefore, the glucometer Accu-Chek Active can be used in the Sudan for monitoring of blood glucose level in diabetic patients, considering the appropriate use of the device.

ملخص الدراسة

إن مستويات جلوكوز الدم العاليه فى مرضى السكرى تزيد من خطر الإصابة بالمضاعفات. إن المراقبه المتكرره لمستويات جلوكوز الدم وعلاج إرتفاعه يقلل من خطر الإصابة بهذه المضاعفات. بالرغم من أن الفحص المعملى هو أكثر دقة لتقدير مستويات الجلوكوز, ولكن بسبب التكلفة وتأخير الزمن فإن قياس معدلات سكر الدم فى المنزل تستعمل بإستمرار عندما تكون المراقبه المتكرره مهمه وضروريه.

كان الهدف من هذه الدراسه هو المقارنه بين نتائج الجلوكوز لجهاز أكيو تشيك اكتيف (الكيمياء الجافه) وطريقة الجلوكوز أوكسيديز (الكيمياء الرطبه) .

إن هذه الدراسه أجريت على 60 مريض بمرض السكرى والذين قصدوا مستشفى البان جديد التعليمى ومركز السكرى والغدد الصماء بالخرطوم بحرى للمتابعه الدوريه فى الفتره مابين 11-18 الى 9-12, لتقييم نتائج جهاز قياس السكر فى الدم فى المنزل أكيو تشيك اكتيف مقارنة بنتائج المعمل. أولا أخذت عينات الدم من الإبهام لجهاز قياس سكر الدم فى المنزل, ثم أخذت عينات الدم من الوريد مباشرة بغرض تحليلها بطريقة الجلوكوز أوكسيديز .

كانت نتائج هذه الدراسه أنه لا يوجد فرق معنوى بين نتائج الجلوكوز لجهاز أكيو تشيك اكتيف (الكيمياء الجافه) وطريقة الجلوكوز أوكسيديز (الكيمياء الرطبه) .

بناءا على هذه النتائج فإنه يمكن إستعمال جهاز أكيو تشيك اكتيف لقياس سكر الدم فى المنزل فى السودان مع مراعاة طرق الإستعمال الصحيحه.

Abbreviations

ADP	Adenosine Diphosphate
ACTH	Adrenocorticotrophic Hormone
ATP	Adenosine Triphosphate
BGMg	Blood Glucose Monitoring
BGM	Blood Glucose Monitor
CDC	Center for Disease Control
CDRH	Center for Devices & Radiological Health
DM	Diabetes Mellitus
ECF	Extracellular Fluid
EDTA	Ethylendiamine-tetra Acetic Acid
EMI	Electromagnetic Interference
ER	Emergency Room
FDA	Food and Drug Administration
GDM	Gestational Diabetes Mellitus
HbA1c	HemoglobinA1C
HBGM	Home Blood Glucose Monitoring
HCT	Hematocrit
HMP	Hexose Monophosphate Shunt
ICU	Intensive Care Unit
IDDM	Insulin Dependent Diabetes Mellitus
MODY	Maturity Onset Diabetes of the Young
MRDM	Malnutrition Related Diabetes Mellitus
NADP	Nicotinamide Dinucleotide Phosphate
(NADPH	Nicotinamide Dinucleotide Phosphate (reduced form

NCCLS	National Committee for Clinical Laboratory
Standards	
NIDDM	Non Insulin Dependent Diabetes Mellitus
NIH	National Institute of Health
POL	Physician's Office Laboratory
SMBG	Self Monitoring of Blood Glucose
SPSS	Statistical Package for Social Science
TCA	Tricarboxylic Acid Cycle

Contents

.Subject	Page No
الأداة.....	I
Dedication.....	II
Acknowledgements.....	III
Abstract (English).....	IV
Abstract (Arabic).....	V
Abbreviations.....	VI
Contents.....	VII
List of figures.....	XI
List of tables.....	XII
CHAPTER ONE. INTRODUCTION AND LITERATURE REVIEW	
Introduction.....	1 1.1
Literature review.....	6 1.2
Diabetes Mellitus.....	6 1.2.1
Diagnosis.....	6 1.2.1.1
Glucose.....	7 1.2.2
Glucose metabolism.....	8 1.2.2.1
Fate of glucose.....	10 1.2.2.2
Regulation of blood glucose concentration.....	12 1.2.2.3
Methods of glucose measurement.....	14 1.2.2.4
Stability of glucose in body fluids.....	14 1.2.2.4.1
Portable blood glucose devices.....	17 1.2.2.5
Background.....	17 1.2.2.5.1
Device description.....	19 1.2.2.5.2
Human factors studies.....	20 1.2.2.5.3

Performance considerations for regulatory clearance.....	22	1.2.2.5.4
Quality control.....	25	1.2.2.5.5
Limitations.....	27	1.2.2.5.6
Rationale.....	28	1.3
Objectives.....	29	1.4
General objective.....	29	1.4.1
Specific objectives.....	29	1.4.2
CHAPTER TWO. MATERIALS AND METHODS		
Materials and methods.....	30	2
Study design.....	30	2.1
Study area.....	30	2.2
Study population.....	30	2.3
Inclusion criteria.....	30	2.4
Ethical consideration.....	30	2.5
Samples.....	30	2.6
Materials.....	31	2.7
Methodology.....	32	2.8
Estimation of plasma glucose by enzymatic glucose oxidase method	2.8.1	
	32	
Estimation of blood glucose by glucometer(Accu Chek Active)...	33	2.8.2
Quality control.....	34	2.9
Data analysis.....	34	2.10
CHAPTER THREE. RESULTS.....		
CHAPTER FOUR. DISCUSION, CONCLUSION, and		
RECOMMENDATIONS.....		
Discussion.....	39	5.1
Conclusion.....	41	5.2
Recommendations.....	41	5.3
REFERENCES.....		
	42	

APPENDIX.....	47
----------------------	-----------

List of Figures

.Figure	Page No
Figure 1.2.2 The pathways used in carbohydrate metabolism.....	9
Figure 1.2.2 Out line of glycolysis.....	11
Figure 1.2.3 The pathway of aerobic metabolism.....	12
Figure 1.2.4 Insulin is the key for glucose entrance into the cell.....	13

List of Tables

.Table	Page No
Table 3.1 Comparison between means of glucose results obtained by glucometer (Accu-Chek) Active and glucose oxidase method.....	37
Figure 3.1: Scatter plot show strong positive correlation between glucose results obtained by Accu-Chek Active glucometer & glucose oxidase method ($r=0.97$).....	38