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Diabetes Complications (DC) Review – A Tale of Two Paradigms

Owusu Akyiaw Bempah*

FV Supplement limited, United Kingdom.

***Corresponding author:**
Owusu A Bempah, FV Supplement limited, 59, Brewery Road, London, SE18 1NB, United Kingdom

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Abstract

Introduction: *The paradigm that diabetes complications (DC) are caused by hyperglycaemia is put in juxtaposition with the new paradigm by Bempah that polyuria is the cause of DC.*

Method: *The theories evolved from the two paradigms have been examined; the treatment methods used for treating manifestations of DC in the different organs have been evaluated; efficacy and end-point of treatment are assessed and conclusions drawn.*

The Glycation Theory that evolved from the glucose paradigm, does not offer any effective treatment so, physicians and health workers are left with their own improvisations. The result is that for each afflicted organ, there are numerous treatment methods; some of them invasive, none effective in curing or reversing the affliction.

Literature-sourced information has led to the insight that polyuria is the cause of DC. The polyuria paradigm has led to a therapy that has proven efficacious in curing and reversing symptoms of DC afflicting all organs with microcirculation. These organs are deemed to be the centres of glucose-fuelled energy production in the body.

Conclusion: *The vitamin deficiency theory is, possibly, the most significant development in diabetes research since Hunting and Best discovered Insulin in 1921. The therapy is promising and deserves to be tested more rigorously for use as standard treatment for DC.*

Keywords: Polyuria, Glycation Theory, Microcirculation, Vasodilation/Vasoconstriction, Vitamin-Bs Cure/Prevention.

Introduction

The International Federation of Diabetes Associations (IFDA), defines diabetes as "a chronic disease that occurs when the pancreas is no longer able to make Insulin or when the body cannot make a good use of the insulin it produces [1]. Inability to produce insulin or use it effectively leads to raised glucose levels in the blood (known as hyperglycemia)."

So, the complications associated with diabetes: *stroke, cardiovascular diseases, retinopathy, kidney diseases, nervous diseases, ulcers, including gum disease,* have been attributed to Impaired Glucose Tolerance (ITG). In other words, hyperglycemia causes diabetes complications (DC).

Is Diabetes Insipidus just an imagination? No, it is real and causes much the same complications as diabetes mellitus. It is excluded from this definition.

But, why is Insulin is so important to the body? In non-diabetic healthy persons, insulin performs two functions in the body.

A. Insulin regulates blood plasma glucose concentration by converting excess glucose to glycogen (stored in the liver), and having the glycogen converted back to glucose, on demand. This ensures equilibrium between glucose and glycogen in the blood plasma and thus, makes glucose always available for energy production in the organs with microcirculation.

In the diabetes mellitus patients, however, the regulatory equilibrium mechanism is lost due to inadequate insulin supply. The effect is that glucose concentration in the blood plasma can be lower (*hypoglycaemia*) or higher (*hyperglycaemia*) than the standard equilibrium glucose concentration of 83mg/dL. But, the IFDA definition cynically ignores hypoglycaemia.

B. In the organs with microcirculation, insulin controls access of equilibrated blood to, and exit from, the cell. The energy-producing cell has one door connected to the arteriole and another to the venule, serving as the boundary between oxygenated and deoxygenated blood. Insulin is the key that opens and closes the cell doors and also ensures the cell is airtight when completely empty of, or totally filled with, equilibrated blood.

Theories on the Development of Diabetes Complications

Despite the questions raised about the IFDA definition, researchers have continued to propound theories to explain how hyperglycemia causes organ dysfunction in order to find cure for (DC). The two main theories: glycosylation (glycation) and intracellular accumulation of sorbitol, are briefly discussed [2].

Glycosylation (Glycation)

Glycosylation is the uncontrolled reaction of glucose with proteins in the blood plasma. In persons with diabetes mellitus, it is argued, excessive glycosylation occurs in the red blood cells, in the lens of the eye and in the myelin sheath of the nerves. The reaction products are known as, "Advanced Glycosylation End-products (AGEs)". The AGEs are claimed to create: deactivation of enzymes, inhibition of regulatory molecule binding, cross-linking of glycosylated proteins, trapping of soluble proteins by the glycosylated extracellular matrix, abnormalities in nucleic acid function, altered molecular recognition and increased immunogenicity. Thus, glycosylation generally, leads to changes and functions in almost all the tissues in all organs in the body. It does not say anything about organs with microcirculation where (DC) occur.

Intracellular Accumulation of Sorbitol

Sorbitol is a by-product of glucose metabolism in the cell. Normally, it is converted to fructose and then expelled from the cell. In persons afflicted with diabetes mellitus, the argument goes, conversion of sorbitol to fructose is not complete, and sorbitol build-up occurs. Sorbitol accumulation in the cell creates osmotic pressure. The built-up pressure initiates complicated processes resulting in the release of small molecules such as, glutathione, niacin, vitamin C, inositol, magnesium and potassium from the cell. The loss leads to cell damage.

While this theory apparently explains cataract in the lens of the eye, it does not seem to explain anything else, even though, it appears to affect cells in all parts of the body.

These theories have not been able to predict a therapy for curing or preventing DC. So, medical practitioners are left to cope, as best they can, with improvisations. As a result, manifestation of DC in each organ is treated with many healing techniques; none of them effective.

Current Treatment Regimes

There are over 53 ineffective different treatments for foot ulcers alone; ulcers on other parts of the skin have no dedicated treatments at all [3]. Lower limb amputation is, usually, the solution; or where amputation is not possible, the patient ultimately, dies.

Retinopathy has more than 7 different treatments; not one of them represses or reverses the progression of, or cures, retinopathy [4]. The patients gradually experience diminishing vision until officially certified and declared blind, finally.

Diabetes complications afflicting the other organs have no specific treatments at all. Dialysis does not treat the kidney; it only buys time for organ transplantation or death. Ischemic stroke and heart failures have no treatment at all or have treatments that are ineffective.

The efforts to find separate treatment for each manifestation of diabetes complications is, in itself, flawed. It implies that each organ has its own cause of affliction.

In summary, theories advanced from the glucose paradigm have failed to provide a therapy for the cure or prevention of DC.

Glycation Theory Treatment Methods

The improvised methods developed by the Glycation Theorists consist of measuring and classifying the size of ulcers regularly (daily) to know when to amputate the limb; or examining the eye regularly (annually) to determine when to declare and certify the patient "officially blind"; or testing regularly to collect data to determine when to put the patient on dialysis. Too much time and money were wasted by clinicians and patients.

Secondly, the treatment used involves interfering and tampering with the organs under treatment. For example, skin grafts and debridement were performed on ulcerated skin; operations are performed on the eye – sometimes, needles were inserted into the eye for injections; dialysis of the kidney or kidney transplantations were performed.

End-point of Treatment

In the glycation treatment, the patient became disabled: blind or amputated. Most people on dialysis died because suitable donor was not found in time. On the whole diabetes patients have shorter, and poorer quality, of life.

New Developments

Recognition that the IFDA definition excludes diabetes insipidus and its potential to cause DC in patients; and also address the question as to why DC afflicts only organs with microcirculation even in diabetes mellitus patients, intensified the search for the causes of DC by re-examining the various terminologies used in describing diabetes.

The Greek word "Diabetes" means "siphon" [5]. It was used to describe the condition that made patients "urinate copiously more frequently".

The urine was either honey–flavoured (by observing ants feeding

at dried-up urine spots) or flavourless. Patients with flavourless urine were described as suffering from "diabetes insipidus". Those passing flavoured urine were described as "diabetes mellitus" (from L. mel; honey) patients.

Diabetes mellitus patients have been divided into two groups for ease of reference.

Type 1 refers to the condition in which insulin is not produced at all or only produced marginally. The patient depends exclusively on external insulin supply.

Type 2 refers to inadequate production of insulin by the patient or inefficient use of the insulin produced. Tablets are usually used to help the patient.

Flow chart 1 illustrates the definitions graphically.

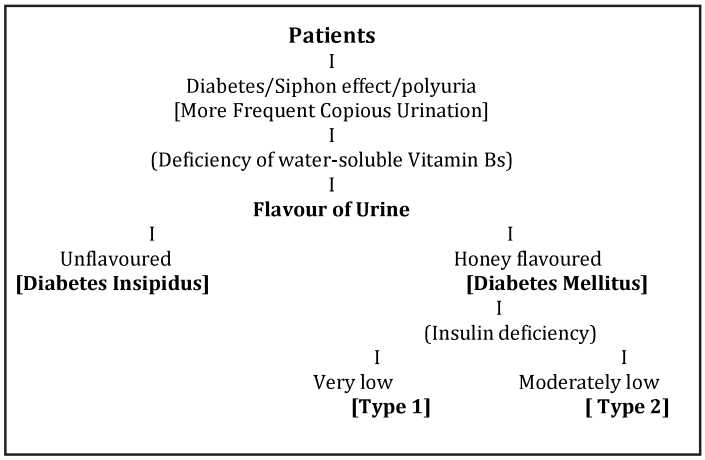

Figure 1. Flow Chart of definitions of diabetes.

From the flow-chart, it is evident that although the nature of diabetes is still unknown, its presence is indicated by two effects. The primary effect – "increased frequency in copious urination" - is a common, shared experience of all diabetes patients. The secondary effect, observed only in diabetes mellitus patients, is that, diabetes causes the pancreas to stop producing *insulin* or produce it only partially. It is not known whether diabetes affects how the body uses the insulin produced.

There is no information in the literature to indicate the existence of a causal link between the primary and secondary effects. Nor indeed, is there direct evidence that diabetes stops the pancreas from producing insulin and how this is brought about.

The "more frequent copious urination" (polyuria) has been found experimentally, to drain the body of the water-soluble B-vitamins; causing daily deficiency of these vitamins in the blood plasma of patients [6]. The deficient vitamins include thiamine and niacin - the vasodilators of the microcirculation - and the "universal repair kit": calcium-d- pantothenate.

It was proposed that, during the period of the B-vitamin deficiency, (mainly during the fasting period at night), vasoconstriction occurs in the organs with microcirculation (brain, heart, eye, kidney, nerve and the skin) which are also the centers of glucose- fuelled energy-production in the body [7].

The vasoconstriction reduces the volume of equilibrated blood supply to tissues. To stop disruption of the energy production process (because half-filling of cells is not allowed), the organ shuts down blood supply to some cells, that subsequently die. Breakfast the following morning relieves the deficiency and some cell regrowth occurs.

Since the deficiency occurs every day, equilibrium shifts in favour of cell destruction in the long term. This causes daily tissue damage in organs with microcirculation. In the long term, (5-40 years), the cumulative tissue damage manifests as organ dysfunction which is also described as diabetes complication (DC).

Accordingly, Bempah's polyuria paradigm defines diabetes complications (DC) as "the long-term damage caused in the organs with microcirculation in diabetes patients" [8]. The damage manifests as **ischemic stroke** in the **brain**; **cardiovascular diseases** in the **heart**; **retinopathy** in the **eye**; **nephropathy** in the **kidney**; and in the **nerves** as **neuropathy**. In any part of the skin, including the gum, it manifests as **ulcer**; in male patients, as **erectile dysfunction**. Manifestation of (DC) in multiple organs with microcirculation at the same time, is commonly encountered.

Deductions from the Theory

The postulate that polyuria causes diabetes complications constitutes a change in the paradigm that guides scientific and clinical research into DC and has serious clinical implications.

Amongst these are: (a) the development of diabetes complications begins simultaneously in all these organs at the onset of diabetes and (b), the development and progression of (DC) are independent of blood plasma glucose concentration.

If the concatenation of events that leads to organ dysfunction can be interrupted, prevention or cure of chronic DC can be achieved. It follows also, that any therapy that cures or prevents any symptom of diabetes complication in any organ with microcirculation, will cure and prevent manifested symptoms in all the other organs.

Hypothesis

Consequently, it was hypothesised that, supplementation with niacin and thiamine, at the minimum concentration required to sustain full 24-hour vasodilation in the microcirculation, will stop cells destruction and tissue damage in the organs with microcirculation, and allow calcium-d-pantothenate to naturally, heal damaged tissues and prevent further damage.

This needs to be tested. The vitamins tablets formulated to test the hypothesis was given proprietary name, "fenomin".

Fenimin (Capsules/Tablets) Therapy

The therapy consists of tablet or capsule containing minimum concentration of the two vitamin B required to sustain 24-hour vasodilatation in the microcirculation as active ingredients, and calcium-d-pantothenate, the natural healer vitamin. The tablet/capsule is taken orally with water, one a day after meals and just before bed.

Fenomin Treatment - How it all Started

Diagnosed with Type 2 diabetes in 1988, the author started developing complications (tingling in the toes, erectile dysfunction, blurred vision) from around 2003. Disillusioned by the non-treatment received, he hit the literature to learn about diabetes. His efforts resulted in the fenomin therapy – tablets/capsule, containing three vitamins as active ingredients.

In 2009, he started using fenomin tablets. All his symptoms had disappeared as per his 2010 medical check-up. Fenomin was offered to friends, and friends of friends with diabetes, and they all achieved the same results. In 2012, he registered fenomin with the Ghana FDA, as Food Supplement and continued the research. His findings and the theory developed to underpin the therapy, have been published in peer-reviewed medical journals, some quoted in this write-up.

It has no side effects, not even the "the redness in the face and neck of Caucasians" associated with high dose vitamins therapies [9].

The therapy is self-administered, requiring no support/supervision from medical personnel. The organs affected need not be tampered with.

Claim of Cures

Fenomin contains vitamins that simply help the diabetes patients sustain 24-hour vasodilation in the microcirculation. This breaks the chain of events leading to the development of DC and sustains unbroken oxygen supply to all cells in the organs. But, to the patient this appears as cure of his afflictions and have reported these as such. For example [10, 11];

i. Ulcers afflicting any part of the skin, from head to toe, including the gum, are healed within eight weeks.
ii. Early-stage retinopathy is reversed so that vision is restored within twelve weeks.
ii. Early-stage symptoms of kidney failure are reversed in 12 weeks.
iv. Erectile dysfunction is reversed within eight weeks.
v. The effects on heart and brain complications are yet to be evaluated extensively. But, first time stroke patients with diabetes, completely recover within 12 weeks. The tell-tale foot dragging, associated with stroke, disappears.
vi. The body pains experienced in bed when one wakes up, but disappears after about 5 minutes when one gets out of bed, completely disappear.

Methodology of Study

The method of patient self-reporting, used to collect data in the fenomin study, has been criticized by the proponents of the Glycation Theory as not following their favorite methodology perfected by researchers guided by the Glycation Theory. But the methods used in these studies were perfected for a failed paradigm.

Fenomin Treatment Methods

In practice, patients administered their own treatment and self-reported the outcome of the treatment. Healed ulcer required no test; it is self-evident. Where chemical analysis or visual examination was needed, the appropriate confirmatory test was conducted after the patient reported that healing has been accomplished.

Fenomin therapy has no effect on hyperglycemia so, diabetes mellitus patients are advised to continue to use the drugs used to control high plasma glucose level.

End-Point of Treatments

No organ disfigurement occurred as a result of fenomin treatment. On the whole, the fenomin therapy makes it possible for diabetes patients to live normal economic, social and healthy life to the end of their day.

With fenomin therapy, it has been possible to cure complications arising from both forms of diabetes.

Discussion

The IFDA definition has been shown to be inadequate in many respects. Diabetes is still an unknown disease. Hyperglycaemia is a secondary effect of diabetes and has nothing to do with what has now come to be called "diabetes complications".

The definition excludes Diabetes Insipidus, but there is evidence that demonstrates that diabetes insipidus also causes the same complications in patients as diabetes mellitus (follow-up article coming soon).

It is suspected strongly that the pathogenesis of diabetes is genetic. In Akan society and other societies where the extended family relationships exist, it has been found that diabetes (insipidus or mellitus) is passed from either one or both diabetic parents to the offspring.

As a result of using the fenomin therapy and carefully questioning the patients, a list of diagnostic questions on DC was compiled. It is hoped this list will help clinicians in diagnosing diabetic complications irrespective of whether they had high blood glucose level or not

Recommendations

Fenomin is recommended to be classified as allopathic drug to be used as the standard treatment for diabetes complications. The classification is important to enable the advantages of fenomin to

be trumpeted to inform and educate all – doctors and medical personnel included. As another vitamin supplement for which claims of cure cannot be made, only a few will hear about it and no one will bother to use it.

It is recommended that more expansive clinical trials are conducted for more data on the range of cure (to answer question like: can retinopathy blindness be reversed at any stage?) and on DC symptoms of all organs with microcirculations to perfect the list of symptoms doctors and patients should look for.

Cure for diabetes can be found by concentrating research on the primary cause of diabetes. Of course, finding out whether diabetes causes the pancreas to stop producing insulin will also be beneficial.

Conclusion

The vitamin deficiency theory flowing from the polyuria paradigm is possibly, the most significant development in diabetes research since Hunting and Best discovered Insulin in 1921. The therapy for the cure and prevention of diabetes complication deserves further research to make it the standard treatment for diabetes complications.

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