

METHOD AND TEST STRIPS FOR THE MEASUREMENT OF FAT LOSS DURING WEIGHT LOSS PROGRAMS

BACKGROUND OF THE INVENTION

In Weight-Loss Programs, whether initiated as a diet and/or exercise regiment due to obesity or as a treatment in certain diseases such as diabetes, cardiovascular disorders or epilepsy, excess fat in the body is metabolized into smaller chemical units, called ketone bodies, comprised of three components: β -hydroxybutyrate, acetoacetate and acetone.

This invention relates to methods for the measurement of a biochemical marker, ketone bodies i.e. (a) total ketone bodies consisting of all three components i.e. β -hydroxybutyrate, acetoacetate, and acetone. (b) β -hydroxybutyrate in conjunction with acetoacetate or (c) β -hydroxybutyrate alone. The invention particularly relates to its convenient use at home to measure loss of fat during weight-loss programs. The invention includes a disposable, convenient test strip configuration as a solid-phase or dry-chemistry test, which measures Total Ketone bodies, all three components— β -hydroxybutyrate, acetoacetate and acetone. Additionally, the invention relates to a disposable strip which measures β -hydroxybutyrate and acetoacetate in one step, and a strip that measures β -hydroxybutyrate alone which when dipped in urine produces a positive signal, such as a color indicative of fat loss during weight-loss program. The intensity of the color on the strip is an indicator of relative concentration of the analyte(s) present in the sample, thus relates to the relative loss of fat. Such a non-invasive tool can prove to be very useful as a psychological stimulator for a person who needs to lose weight.

There are millions of people who are obese and go on some of type of diet, for example Weight-watcher®, Jenny-Craig, NutriSystem, Atkins diet, The New Beverly Hill Diet, Liquid diet, The Pritlin Principle diet, in order to lose weight. However, the majority of people who go on diets gain back all lost weight within a short period of time. In the U.S. alone, it is estimated that more than 60% of the population is obese. Obesity is the leading cause of many serious diseases such as diabetes, hypercholesterolemia that eventually leads to kidney and liver failure.

Just mere weight loss measurement on a weighing scale during dieting is not sufficient as overweight people must lose fat during dieting, not protein. Therefore, it will be of great social and medical benefit if a biochemical marker is invented which when used on a daily basis can indicate to a person whether indeed fat loss is taking place or not while one is dieting. Such a psychological tool can considerably enhance the efforts of a person in losing weight as well as maintaining his or her ideal weight.

It has been known that when body fat, i.e. fatty acid, is degraded, which is the principal component of body fat, it breakdowns ultimately into small molecules in the form of ketone bodies. Ketone bodies consist of a group of three chemicals: β -hydroxybutyrate, acetoacetate, and acetone. β -hydroxybutyrate is a major ketone body comprised of about 75–80% of total ketone bodies, acetoacetate comprised of about 20–25% of total ketone bodies and acetone which is present only in trace quantities less than 2%). Because of acetone's low concentration and its instability, it is seldom measured by itself. Instead, acetoacetate and acetone are measured by a nitroprusside reaction in alkaline conditions. Several patents describe methods and devices for measurement of acetoacetate using nitroprusside reaction,

such as U.S. Pat. No. 3,212,855 to Mast; U.S. Pat. No. 4,147,514 to Magers and Tabb; U.S. Pat. No. 4,440,724 to Tabb and Burrows. Acetoacetate test strips have been commercially available for many years (Bayer diagnostics, Roche diagnostics), which measure acetoacetate and acetone in urine. They produce purple color and the intensity of the color approximates the concentration of acetoacetate present in urine or serum. These strips are generally used by a patient who has diabetes (especially Type I diabetic patients). These strips are erroneously referred as to "Test for Ketone or Ketone body", even though they only measure the minor component of ketone bodies i.e. acetoacetate and acetate which comprise less than 20–25% of total ketone bodies and these strips do not measure the major component, that is, β -hydroxybutyrate at all. Even though, these strips are insensitive to β -hydroxybutyrate, such strips have been successfully used in some diet programs such as the Atkins' diet that is comprised of high fat and very low carbohydrates.

Similarly, U.S. Pat. No. 5,260,219 to Fritz teaches the use of test strips in the measurement of acetoacetate in diet programs. Surprisingly, it has been found by the present invention that these strips measuring acetoacetate/acetone are mostly insensitive when dipped in the urine of those individuals who are on 1000–1500 calories/day of "balanced" diets, unlike the Atkins' diet which is high in fat and very low in carbohydrates content, and therefore are not useful as biochemical markers for general or common utilization in weight loss programs. In contrast, the present invention is based on the discovery that strips, which measure (a) β -hydroxybutyrate alone (which is about 3 to 4 time more in concentration than acetoacetate) or (b) both β -hydroxybutyrate and acetoacetate or (c) total ketone bodies, that is, all three components are very sensitive and can measure even very small amount of these chemicals in urine and other biological fluids. Such sensitive strips can successfully be used during any weight loss program and color produced is reflective of the presence of these chemicals in the fluid.

SUMMARY OF THE INVENTION

It is, therefore, an object of the present invention to a provide convenient and sensitive solid-phase methods for measurement of (a) total ketone bodies, that is all three components, β -hydroxybutyrate, acetoacetate and acetone; (b) β -hydroxybutyrate and acetoacetate in one step; and (c) β -hydroxybutyrate alone in biological samples, by means of a non-invasive sample, such as urine, which produces color that can be used for detecting the breakdown of fat (or fatty acids) in persons who are on weight-loss programs.

It is also an objective of the present invention to provide a convenient, and sensitive solid-phase or dry chemistry device that can be used for measurement of (a) Total Ketone bodies that is all three components, β -hydroxybutyrate, acetoacetate and acetone; (b) β -hydroxybutyrate and acetoacetate in one step; and (c) β -hydroxybutyrate alone in biological samples, with non-invasive samples, such as urine which produce color that can be used for detecting the breakdown of fat (or fatty acids) in persons who are on weight-loss programs.

It is also an objective of this invention to provide strips for detection of breakdown of fat (or fatty acid) in persons who are on Weight-Loss programs and are on low calories diet 1000–1500 or less per day. These strips show positive color when dipped in morning urine whereas the commercially available strips for ketone, which only measures acetoac-