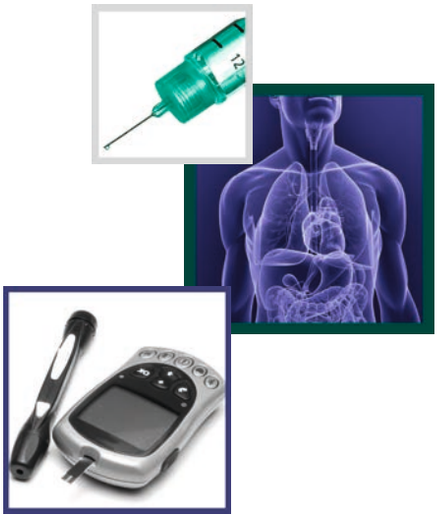
FOREWORD

Pioglitazone ODTs offer potential to improve treatment compliance in Type 2 diabetes mellitus



Kohei Kaku*

"The evidence presented here confirm the bioequivalence of the new orally disintegrating tablet pioglitazone formulation as monotherapy and when administered in fixed-dose combinations with glimepiride and metformin."

Treatment of Type 2 diabetes mellitus (T2DM) is aimed primarily at controlling blood glucose levels to prevent the onset of microvascular and macrovascular complications and their associated morbidity. In the early stages of disease, many patients are able to achieve glycemic control with a single antidiabetic agent. Over time, however, most will fail monotherapy and require the addition of at least one more antidiabetic agent. As is the case with most asymptomatic chronic diseases, the need for polytherapy can have a deleterious effect on treatment compliance.

Poor adherence to therapy has been shown to be a major reason why many patients suffering from chronic diseases do not achieve optimal responses to treatment. This is becoming more of a problem as the population of patients we treat steadily increases and we see more and more elderly individuals who often have problems swallowing conventional tablets. Therapeutic compliance is influenced by several factors, one being the pharmaceutical formulation. Thus, factors such as being easy to take and swallow, being convenient to use, and having a simple dosage regimen (once daily) can all positively influence patient compliance and satisfaction.

In view of the clinical benefits achieved in T2DM patients by using antidiabetic agents with complementary mechanisms, the concept of simplifying drug administration via the convenience of a fixed-dose combination tablet was clearly important. An initial requirement, however, was to demonstrate that such a formulation would be easy to administer and does not differ pharmacokinetically from that following co-administration of the individual components as conventional tablets.

To this end, a series of studies investigated the pharmacokinetics of a new orally disintegrating tablet (ODT) formulation of pioglitazone, taken with or without water to simulate situations where immediate access to water may not be available (e.g., while travelling) and/or circumstances where patients may find it difficult or inconvenient to swallow a solid oral tablet. Additional studies were conducted in healthy adult Japanese men to investigate the bioequivalence of pioglitazone–glimepiride and pioglitazone–metformin combination regimens using this new ODT formulation.

The evidence presented here confirm the bioequivalence of the new ODT pioglitazone formulation as monotherapy and when administered in fixed-dose combinations

*Division of Diabetes, Endocrinology & Metabolism, Kawasaki Medical School, 577, Matsushima, Kurashiki-shi, Okayama 701-0192, Japan; Tel.: +81 86 462 1111; Fax: +81 86 462 1199; kka@med.kawasaki-m.ac.jp

Future Medicine part of fsg

with glimepiride and metformin. This new ODT formulation has the potential to improve treatment compliance in patients with T2DM which, in turn, may enhance patient outcomes and reduce the overall burden of this endemic disease.

Financial & competing interests disclosure

K Kaku is Professor and Chairman of the Division of Diabetes, Endocrinology & Metabolism at Kawasaki Medical School and has acted as consultant and medical advisor to the pharmaceutical industry in Japan. The author has no other relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

Assistance with English language was provided by Content Ed Net.