A study on the blood lactate level in Type II diabetic patients on oral antidiabetic drugs

S. Thamilarasi and S. Vijayalakshmi
Institute of Pharmacology, Madurai Medical College, Madurai, (TN) - India

Abstract
This study aimed to evaluate the change in blood lactate level in Type II diabetic patients on oral anti diabetic drugs – sulphonylurea & biguanides has been conducted in the Institute of pharmacology, Madurai Medical College Madurai after obtaining ethical clearance. 70 newly diagnosed without any prior treatment and without any complications Type II Diabetic patients were selected. After getting informed consent they are treated with the drugs. Blood estimation was done before & one month after the therapy. The studies reveal that biguanides produce increase in blood lactate level. Biguanides to be given with caution in patients prone for hypoxia.

Key-Words: Type II diabetes, Biguanides, Phenformin, Metformin, Sulphonylurea, Blood lactate

Introduction
Lactic acidosis with a high mortality rate occurs in disease producing hypoxia at the cellular level like ischaemia, infection, Pulmonary and cardiac insufficiency, hepatic and renal failures. It is also seen as a complication of biguanide therapy in NIDDM patients. When biguanides were introduced in 1950s in USA many deaths were reported due to lactic acidosis. Hence the drugs were banned. However the incidence of lactic acidosis is less with metformin and the cases reported invariably had renal or hepatic diseases. So the drug metformin alone is reintroduced in later years. Metformin has been widely-used in Europe and Canada for decades and is approved now for use in US also. The information available about the incidence and also the cause for lactic acidosis induced by phenformin and metformin, the two biguanide oral antidiabetic drugs is not very reliable and also not very authenticated. Some are of the opinion that lactic acidosis is produced perse by these two drugs themselves, and especially by phenformin and less by metformin. Others proposed that lactic acidosis occurs not due to the drugs but by the underlying hepatic and renal diseases. This is so especially in case of metformin administration. Both these observations are quite contradictory. This project was undertaken to enlighten the real cause for lactic acidosis and to establish whether it is due to these two oral anti diabetic drugs or due to the underlying diseases.

Material and Methods
This study is the comparison made of the blood lactate level in patients taking different oral hypoglycaemic agents. It is conducted at the endocrinology out patient department of Government Rajaji Hospital, Madurai from June 99 to March 2000(9 months) after getting the ethical clearance from the institutional ethical committee. 79 patients are selected out of which 9 patients dropped out due to personal reasons. Informed consent was obtained from all the patients included in the study. 20 patients were treated with Sulphonylurea, 20 with Metformin and 20 with Phenformin Therapy. 10 of them instructed to follow meal plan and exercise. For all these patients’ blood lactate level was estimated before starting the therapy. After one month, completing the therapy blood lactate was estimated.

For these entire patients liver function test, renal function test, blood glucose (fasting & post prandial 2 hours) cholestrol were estimated before and after therapy. The results were tabulated and student ‘t’ test is applied to find out the significance of the study.

Results and Discussion
There is no significant change in blood lactate in patients taking sulphonyl urea & mealplan but there is a significant increase in those on metformin & phenformin therapy. This study reveals that sulphonylurea are safer with reference to lactic acidosis as they do not increase lactate level, while phenformin & metformin has the tendency for hyperlactatemia eventhough there is a slight variation in the degree of rise. When prescribed
for the patients without having a tendency for precipitating lactic acidosis due to hypoxia, both the drugs are safer & equally effective in Type II diabetic patients.

**Conclusion**

This study reveals that sulphonylurea are safer with reference to lactic acidosis as they do not increase lactate level, while phenformin & metformin has the tendency for hyperlactatemia eventhough there is a slight variation in the degree of rise. When prescribed for the patients without having a tendency for precipitating lactic acidosis due to hypoxia, both the drugs are safer & equally effective in Type II diabetic patients.

**References**