ABSTRACT

Background: Ayurveda, an ancient Indian system of medicine, mentions several plants that are useful in the correction of metabolic disorders such as diabetes mellitus. Plants have been exemplary source of drugs in the treatment of diabetes mellitus [DM]. Many of the currently available drugs have been directly or indirectly derived from them. Ethno pharmacological surveys indicate that more than 1200 plants are used world wide in traditional medicine for their alleged hypoglycaemic activity. The investigation of antidiabetic agents of plant origin which are used in traditional medicine is of great significance. Herbal medicines are in great demand in the developed as well as developing countries for primary healthcare because of their wide biological activities, higher safety margins and lesser costs. In India, the herbal drug market is about one billion US Dollars and the export of plant based crude drugs is around 80 million USD.

[YXK12 [Name changed] is a recently introduced, commercially available, polyherbal product being used in diabetic patients. This product contains P. Emblica 80mg, Terminalia Chebula 80mg, Eugenia Jambolina 80mg, Eurycoma longa 80mg, Swertia chirata 80mg, Gymnema sylvestre 60mg, Litchi chinensis 40mg, Tinospora cordifolia, 80mg, Curvularia lunata 80mg, Asparagus racemosus 60mg, Herbsulactone 80mg, P. Emblica 80mg, Terminalia Chebula 80mg, Eugenia Jambolina 80mg, P. Emblica 80mg, Tinospora cordifolia, 80mg, Swertia chirata, 80mg, Tinospora cordifolia. In this preparation are successfully tested in animals for anti diabetic activity. But no data is available in literature on the safety and efficacy, of this polyherbal combination. Starting human dose of YXK12 as recommended by manufacturer in severe diabetics is 10,000 mg per day to be increased later depending upon the blood sugar levels. This dose is equivalent to a dose of 1000mg/kg in rats.]

Objectives

To evaluate the dose dependent hypoglycaemic activity of YXK12 in Alloxan induced diabetic rats.

MATERIALS AND METHODS

Animals: Adult albino Wistar rats of either sex, weighing 150-200g, housed in standard cages under standard conditions in the animal house. Fasted animals were deprived of food for 18 h, but had free access to water. 

EXPERIMENTAL SET UP

Alloxan monohydrate [150mg/kg body weight] dissolved in normal saline and injected intraperitoneally in 18h previously fasted rats to induce diabetes. After one hour animals were allowed food and water ad libitum. After 72hours Blood glucose levels were estimated and animals having blood glucose levels of more than 150mg/dl were selected for study. There were four groups of six animals each. Animals in vehicle control group and standard drug group [Glibenclamide] were administered 10mg/kg of TWEEN 80 and 0.5mg/kg of aqueous suspension of Glibenclamide in 0.5 ml of TWEEN 80 orally. Two doses of test drug YXK12 were [1000mg/kg and 2000 mg/kg] administered orally to other two groups of animals. Blood sugar was estimated in all the animals, immediately before drug administration and two hours after drug administration by glucometer. Percentage of reduction in blood glucose was calculated and compared.

Statistical analysis

One way analysis of variance is used to compare percentage of reduction of blood glucose levels in various groups, followed by Dunnet’s multiple comparison tests using SPSS package version 10. P<0.05 was considered statistically significant.

RESULTS

Table 1 shows the results of effect of drugs on blood glucose levels in Alloxan induced diabetic rat (n=6). Percentage of reduction in blood glucose levels after administration of the drugs is compared between different groups for statistical significance. Hypoglycaemic effects of YXK12 in a dose 2000mg/kg was found significant when compared to hypoglycaemic effects in control group. Lower dose of 1000mg/kg did not show significant reduction in blood glucose when compared to vehicle control group [p>0.05]

DISCUSSION

Many of the individual ingredients of this polyherbal product [YXK12] have been shown to have hypoglycaemic effect in earlier studies. Triphala which contains three of the ingredients also has been shown to have hypoglycaemic effect in diabetic rats. But Triphala was demonstrated to have hypoglycaemic effect in a dose of 100mg/kg. Current study has shown hypoglycaemic effects only in high doses [2000mg/kg]. A study carried out in our laboratory in normal rats has also shown hypoglycaemic effect only in higher doses.
doses. Drug interactions could be one of the reasons why large number of ingredients has increased the effective dose in comparison to earlier studies with products which had lesser number of ingredients. The dose which has produced hypoglycaemic effect in rats is equivalent of high doses recommended in humans. As lower doses of YXK12 are also recommended in diabetic patients, efficacy of lower doses requires further evaluation.

CONCLUSION

YXK12 is a combination of 12 herbs. Current study has demonstrated hypoglycemic activity only in very high dose in diabetic rats. This dose [2000mg/kg in rats] if converted to human dose is equivalent to highest human dose recommended. As lower doses have not demonstrated any hypoglycemic activity, lower doses in humans needs to be evaluated.

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