Evaluation on safety and efficacy of a polyherbal antidiabetic formulation-DIASOL

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Abstract. In spite of all the advances in therapeutics, diabetes still remains a major cause of morbidity and mortality in the world. Herbal formulations are becoming popular nowadays particularly in the treatment of type2 diabetes. Diasol, a herbal antidiabetic formulation manufactured by Jyothy herbal laboratory, Chidambaram, India has been screened for its safety and efficacy as follows:

5 groups of male wistar albino rats (140-175 g body weight) after 18 hrs fasting were selected, each comprising of 6 animals, the first group consisting of healthy animals, while the other 4 groups having animals with streptozotocin induced diabetes. The first & second group of animals received orally 2 ml of normal saline, the third and fourth group were given orally the polyherbal antidiabetic formulation-Diasol in doses of 125mg/kg bw and 250mg/kg bw respectively and the fifth group treated with 1.5mg/kg bw, p.o of Glibenclamide as reference standard and the efficacy of Diasol (DAS) was assessed in comparison with the reference standard ‘Glibenclamide’ and reported and the safety of the herbal formulation-DAS was also established in the toxicological study that was carried out upon albino mice.

The polyherbal product (Diasol) produced 63.4% reduction of blood glucose level in a dose of 250mg/kg bw, p.o given for 14 days and this effect was identical with that of glibenclamide and 125mg/kg bw, p.o of the same for 14 days produced only 50.25% reduction of plasma sugar level. No abnormal changes were observed in safety study.

Keywords: Type-2 diabetes; Chemotherapy; Glibenclamide.

INTRODUCTION

Although oral hypoglycemic agents provided dramatic relief in the management of non-insulin dependent diabetes mellitus (NIDDM), about 15-20% of patients with newly diagnosed NIDDM has little or no response to sulphonyl ureas. It is being realized that several synthetic drugs produce receptor upregulation leading to drug tolerance and many of the adverse effects. Therefore we are in need of alternative safer herbal formulation particularly for type 2 diabetes. Our objective is to evaluate the Polyherbal antidiabetic formulation-DIASOL (DAS) on its safety & efficacy upon albino mice and rats respectively.

MATERIALS AND METHODS

The polyherbal antidiabetic formulation-DIASOL was obtained from Jyothy herbal laboratory, Chidambaram-608002, India and a suitable extract was prepared out of it to be used for the experiment to give a stock solution of 10mg/ml of aqueous suspension.

The formulation-DIASOL consists of the following plant extracts – Eugenia jambolana (Jamun), Foenum graecum (Fenugreek), Terminalia chebula (Harithaki), Quercus infectoria (Machakkai), Cuminum cyminum (Cumin), Taraxacum officinale (Dandelion), Emblica officinalis (Amla), Gymnema sylvestre (Shakkarai koll), Phyllanthus nervui (kizha nelli) and Enicostemma littorale (Mamijava).

Experimental model selected for this work. Streptozotocin (STZ) is a naturally occurring nitrosoamide that has been used extensively to produce diabetes in experimental models. Healthy Wister strain male albino rats (150-200g) and male albino mice (20-30 g) were used for antidiabetic screening and safety study respectively.

Antidiabetic screening. The albino rats were divided into five groups each comprising of six animals. The first group consisted of normal healthy rats while the other four groups of animals were given intravenously Streptozotocin in a dose of 65 mg/kg, to induce diabetes. The animals were checked regularly and maintained properly and kept for 18 hrs fasting before experiment. These hyperglycemic rats were then divided into four groups, The first & second group of animal...
mals received orally 2 ml of normal saline, the third and fourth groups were given orally the polyherbal antidiabetic formulation-Diasol in doses of 125mg/kg bw and 250mg/kg bw respectively and the fifth group treated with 1.5mg/kg bw, p.o of Glibenclamide as reference standard and blood glucose levels in all the animals in all groups were estimated at 1hr,2hr,4hr,7days and 14days after treatment by using glucometer and recorded and the efficacy of Diasol (DAS) was assessed in comparison with the reference standard ‘Glibenclamide’ and reported.

Study on safety of the formulation. Five groups of 18 h fasted mice each comprising of six animals were administered with Diasol by oral route in logarithmic doses of 125 mg, 250 mg, 500 mg, 1000 mg and 2000 mg per kg respectively as a single dose and observed for three days in order to calculate Lethal Dose50.

Histopathological study. The liver of a Diasol treated mouse and that of a normal healthy mouse were dissected out and kept in 10% formalin and sent for histopathological study to report for organ toxicity.

Biochemical estimation. The blood samples of the treated and normal albino mice were collected and subjected to biochemical estimation of the following parameters-glucose, urea, SGOT and SGPT and these values reported.

RESULTS AND DISCUSSION

Antidiabetic effect. The polyherbal product (Diasol) produced 63.4% reduction of blood glucose level in a dose of 250mg/kg bw, p.o given for 14 days and this effect was identical with that of glibenclamide and 125mg/kg bw, p.o of the same for 14 days produced only 50.25% reduction of plasma sugar. Diasol produced no change in blood sugar level in normal healthy rats (Group1). Refer to Table 1 and Figure 1.

<table>
<thead>
<tr>
<th>Dose (mg/kg)</th>
<th>No. of mice / No. of mortality</th>
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<td>6h</td>
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<tr>
<td>125</td>
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<td>250</td>
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<td>500</td>
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Table 2. Effect of Diasol on lethal dose selection in mice: safety study. (Dose given orally).

Figure 1. Hypoglycemic action of Diasol on plasma glucose level of albino rats.

Safety study. The test drug did not show any signs of toxicity or mortality up to 2000 mg/kg which was fixed as the cut off point for the maximum tolerated dose and therefore the formulation- Diasol was considered to be safer drug. (Table.2). Gross observation and even microscopic histological study of the vital organ liver on autopsy did not reveal any abnormalities. The stained liver slides (Figure 2) showed normal hepatocytes and no congestion in the central canal or biliary duct. These clearly indicate that the formulation-Diasol has no liver toxicity.

Biochemical estimation. All the values of plasma bio-
chemical constituents and enzymes that were estimated for drug treated samples were identical with those of the control group and were within the normal limits documented for laboratory rats (Table 3).

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<th>Control: Saline 2ml/kg/day/p.o</th>
<th>Diasol</th>
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<tr>
<td>Fasting blood glucose (mg/dl)</td>
<td>75.4±1.78</td>
<td>70.4±0.83</td>
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<tr>
<td>Urea (mg/dl)</td>
<td>25.8±2.92</td>
<td>26.1±0.63</td>
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<tr>
<td>SGOT (U/l)</td>
<td>11.3±0.33</td>
<td>11.08±11.08</td>
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<td>SGPT (U/l)</td>
<td>13.18±0.33</td>
<td>12.86±0.27</td>
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Table 3. Effect of Diasol pretreatment (7 days) on blood in mice.

**CONCLUSION**

Therefore, the polyherbal product (Diasol) can be accepted as an efficacious and safer antidiabetic/hypoglycemic formulation devoid of liver toxicity to be given orally particularly in Type II diabetes as a safer substitute for synthetic oral hypoglycemic agent.

**REFERENCES**


