ABSTRACT

(Evaluation of Influence of Herbal Anti-Diabetic Formulation on Allopathic Anti-Diabetic Drugs)

BACKGROUND-

Many herbal medications have been recommended to treat diabetes. Numerous ancient literature reports more than 800 herbal plant species with anti-diabetic properties. Herbs are also known to provide an alternative therapy to manage diabetic complications, addition to lowering of cholesterol. Furthermore, people believe that using herbs along with drugs have better safety and efficiency. Although commercially available poly-herbal formulation (Mehagni) is utilized by the patients with type-2 diabetes (T2DM), its interaction with widely used anti-diabetic drugs [Glibenclamide (GLB) and Glimepiride (GLM)] have not been evaluated so far.

OBJECTIVE-

The present study was undertaken to assess the possible interactions of poly-herbal (Mehagni) which is an anti-diabetic formulation with GLB and GLM which are commonly used oral allopathic anti-diabetic drugs in T2DM.

METHODOLOGY-

Total of 157 patients were screened based on their case history. As per the exclusion criteria, 23 patients were excluded from the study. The remaining 134 patients were divided into three groups; Group A (51 patients) with the GLB therapy (2.5 mg tablet/day, after food), Group B (38 patients) received the poly-herbal formulation (mehagni-500mg, 2 tablets thrice a day, after food) and Group C (64 patients) with the GLM therapy (2 mg tablet/day, after food) from the last six months. Baseline anthropometrics and clinical characteristics were assessed in all patients. Group A and C patients were further subdivided into two groups; Group A1 (32 patients) with the continuation of GLB therapy and Group A2 (22 patients) received combined therapy [GLB (1.5 mg tablet/day, after food) + mehagni-500mg (2 tablets twice a day, after food)]. Similarly, in Group C1 (32 patients) with the continuation of GLM therapy and Group C2 (33 patients) received combined therapy [GLM (1 mg tablet/day, after food) + mehagni-500mg (2 tablets twice a day after food)]. The specific instructions regarding diet and amendments in life style were provided by the study co-ordinator to patients.

RESULTS-

At the end of the 12th week, in combination therapy the significant reduction in fasting blood sugar (FBS) [149.2±8.1 to 130.4±9.4 (Group A2) and 147.1±7.0 to 129.8±9.8 (Group C2) (p<0.05)], postprandial blood sugar (PPBS) [210.1±2.0 to 171.2±12.2 (Group A2) and 212.4±11.9 to 164.3±14.3 (Group C2) (p<0.05)] and glycated hemoglobin (HbA1c) [9.2±1.0 to 7.8±1.3 (Group A2) and 9.1±1.0 to 7.3±0.9 (Group C2) (p<0.05)] levels were observed in Group A2 and Group C2 patients from baseline. In addition, the level of low density lipoprotein (LDL) was significantly decreased [123.2±4.0 to 109.5±2.3 (Group A2) and 118.0±9.5 to 112.5±2.4 (Group C2) (p<0.05)]. Decreased level of triglycerides (TG) [168.4±2.18 to 136.4±5.4 (Group A2) and 163.2±3.8 to 152.4±5.8 (Group C2) (p<0.05)] and total-cholesterol (T-Chol)
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[167.1±2.2 to 146.8±4.5 and 162.4±3.4 to 156.8±4.7 (p<0.05)] were also observed in this study. The levels of high density lipoprotein (HDL) were significantly increased [42.0±6.2 to 48.1±3.2 (Group A2) and 43.1±6.5. to 47.4±3.4 (Group C2) (p<0.05)]. Furthermore, the pharmacokinetic study (PK), the $C_{max}$ of allopathic drugs increased significantly [183.07±15.19 (Group A2) and 197.37±6.27 (Group C2) (p<0.05)], in combination therapy as compared to individual treatments and no patient has experienced hypoglycemia.

CONCLUSION-

Based on these results, we conclude that administration of poly-herbal formulation in combination with allopathic anti-diabetic formulations GLB and GLM has significant effect in reducing the dose of allopathic anti-diabetic formulations to achieve better therapeutic response with minimal side effects. The co-administration of poly-herbal formulation with allopathic anti-diabetic drugs exhibited better glycemic control along with lipid lowering effect.

**KEYWORDS:** Diabetes; Blood glucose; Lipid profile; Pharmacokinetics; Poly-herbal formulation; Mehagni; Glibenclamide; Glimepiride; Type 2 diabetic patients.