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PHARMACOKINETIC COMPARISON BETWEEN REGULAR INSULIN AND ORAL INSULIN BASED ON SUPERPOROUS HYDROGEL POLYMERS IN HEALTHY VOLUNTEERS

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Abstract:

Background: All contemporary methods of insulin administration are non-physiological. Insulin is not absorbed from the gastrointestinal tract because of its peptide nature. The aim of the present study was to examine the absorption of oral insulin from gastrointestinal tract, using novel oral formulation- adding a delivery agent superporouse hydrogel (SPH) and SPH composite (SPHC) in combination with insulin. Methods: Capsules containing insulin and SPH &SPHC were administered orally, to 15 non-diabetic subjects in order to assess its biological effects and safety. Plasma glucose, insulin and c – peptide serum levels were determined, at timed intervals up to 4 h. Results: In the present study, we showed that AUC of exogenous insulin in polymer -insulin group was higher than sub-cutaneous regular insulin group. It means that addition of SPHC polymer caused increase in insulin absorbtion.In addition, Insulin Tmax in polymer group was longer than sub-cotaneous insulin group. Blood glucose AUC in sub-cotaneous group was higher than polymer group.AUC C-peptide serum level in polymer group was higher than sub-cutaneous group. Conclusions: Insulin in combination with a novel delivery agent, SPH and SPHC, given orally is absorbed through the GI tract in a biologically active form. This was demonstrated by suppression of endogenous insulin secretion.

Keywords:

C –peptide , Oral insulin , SPH , SPHC

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