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CASE REPORT

Significance of pharmaceutical excipients in prescribed medicines: a case report

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Key Clinical Message

Pharmaceutical excipients need careful observation as they play a significant role in treatment outcomes. It is imperative for a physician to collect complete patient profile before prescribing new medications for current treatment. We present a case report on the significance of pharmaceutical excipients in prescribed medicines.

Keywords

Clinical pharmacy practice, clinical practice, contraindication, diabetes, pharmaceutical excipient, prescribed medicines, syrup.

Introduction

It is well known that most medicines contain both pharmacologically active and inactive ingredients. Therapeutically inactive ingredients of a medicine are known as excipients [1]. The excipients are divided into various functional classifications, depending on purpose of use, such as binders, diluents, disintegrants, lubricants, wetting agents, solvents, fillers, emulsifiers, absorption enhancers, sustained release matrices, preservatives, sweeteners, and stabilizing, coloring or flavoring agents [1, 2]. These excipients play an important role in converting a pharmacologically active compound to an elegant pharmaceutical product with enhanced provision for therapeutic use. It is generally assumed that excipients are pharmacologically inactive and are deemed safe in patients. This assumption, however, may not always be correct and need a careful observation [1].

We report the case of a child with type I diabetes, well controlled on insulin, who was brought to a local hospital's emergency department with symptoms of diabetic ketoacidosis, likely due to high intake of sugar present in medicated syrups.

Case Report

The health of a 7-year-old male child with type I diabetes was maintained on a daily regimen of insulin. One day, however, the child developed sudden onset of cold-like symptoms such as runny and stuffy nose with a mild fever. He was diagnosed with acute sinusitis by a local general practitioner and prescribed three different medications namely paracetamol, chlorpheniramine, and a combination of amoxicillin and clavulanate at their regular doses in syrup form. On the third day of his treatment, the child was brought to a local hospital's emergency department with symptoms of nausea, vomiting, weak and rapid pulse, deep sighing breaths, drowsiness, and unsteady gait. On examination, his blood sugar was

extremely high and showed an arterial blood gas pH of 7.12 with base excess of −7 mmol/L, and a bicarbonate of 12.6 mEq/L. The WBC count was $15.2 \times 10^3/\mu L$, hemoglobin of 12.6 mg/dL, and hematocrit of 40.1%. His chemistry panel demonstrated a serum sodium of 134 mEq/L, potassium 4.5 mEq/L, chloride 91 mEq/L, BUN 11.6 mg/dL, creatinine 1.2 mg/dL, and a blood sugar of 440 mg/dL. The serum ketones were positive on urine dipstick. He was admitted as a medical emergency and treated for diabetic ketoacidosis with fluid replacement and insulin therapy to prevent further complications and achieve a normal health state.

Discussion

In the present case, three different medications – paracetamol, chlorpheniramine, and a combination of amoxicillin and clavulanate were given at a dose of 15 mg/kg per dose qid, 0.1 mg/kg per dose qid, and 22.5 mg/kg per dose bid, respectively, with a total sucrose content (including relative sugars) of ~90 g/day in the form of syrup base to treat the symptoms of acute sinusitis. However, the need for collecting the patient past medical history and evaluating the prescribed medications for their pharmaceutical excipients such as high sugar base in all three formulations went unnoticed by practitioner and the dispensing pharmacist. This led to the rise in blood sugar level of the child and subsequent diabetic ketoacidosis state. This situation could have been avoided if the child's past medical history had been collected and referred while prescribing medications for his current medical condition that is, treatment of acute sinusitis. Hence, it becomes important while dealing with a patient/guardian to collect a proper patient history for choosing the appropriate drug along with its therapeutic ingredient and pharmaceutical excipient. Evaluation of medication dosage formulation for its key ingredients is an essential component for improving the efficacy of pharmacologic agents and, hence achieving therapeutic outcomes in a given clinical condition [3]. Moreover, it is an important factor for pharmacists too when dispensing the said medication. Many drugs that are used for some pediatric patients are not in an appropriate dosage form for use by children [4]. Yeung et al. has cited that "liquid formulations are usually regarded as the gold standard in pediatric formulation; but sometimes, liquid formulations have stability and taste problems as well as being inconvenient for travelling" [5]. However, to ensure the availability of suitable dosage forms for all ages there needs to be the development of acceptable dose volumes and size, safety, excipient acceptability and a palatable taste [6]. Even though all of these parameters were met in this case, the underlying disease state prevented the use of the conventional formulation. The use of sugar-free formulations would have been the best possible alternative to deal with this situation. In other circumstances such as non-availability, another option would have to be utilized in the form of an oral dosage form such as dispersible tablets. Although this case highlights the significance of pharmaceutical excipients in therapeutic outcomes, however, the possibility of involvement of current underlying disease state (acute infective sinusitis) as a precipitating factor for diabetic ketoacidosis cannot be ruled out.

Conclusion

This case illustrates the need for prescribers to take into consideration the patient's complete medical history while formulating a prescription. It is important to remember that no excipient is inert and above a certain concentration can alter the treatment outcomes. Therefore, the selection and use of excipients should be justified and take into consideration the functionality and safety profile of the excipient across the patient profile, duration of treatment, and criticality of the condition to be treated. Further, it is the responsibility of a pharmacist to review the prescription for its key ingredients to ensure the safe use of medicines.

Conflict of Interest

None declared.

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