

Acute Dystonia following brand confusion: where are we heading?

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Abstract

A child with trivial trauma was prescribed Serronak which is a Fixed Dose Combination of serratiopeptidae (10mg) and diclofenac sodium (50mg) by a treating physican. He instead received Serenace (Haloperidol 10mg) which lead to him presenting as acute dystonia to pediatric emergency department. We report this preventable adverse drug reaction and highlight the importance of avoiding such prescription errors.

Key words: Dystonia, prescription, haloperidol

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Introduction

Prescription errors are quite common especially in developing countries and lead to large number of adverse drug reactions which can sometimes have serious consequences. The prescription audit is virtually non existent in developing countries and the errors which come into notice are not reported.

Case report

A 5 year old boy weighing 15 kg presented to the pediatric out patient department with the complaint of mild dull aching pain in the back for one day. History revealed fall on the back while playing at home. There was no history suggestive of any trauma to the head or neck, altered sensorium, vomiting, difficulty in walking or any shooting pain. On examination, there was mild tenderness over the left side at the level of L5-L6. Signs of inflammation were positive locally. Rest of the systemic examination was non specific. Physician prescribed him tablet Serronak (STEDMAN Pharma, India) half tablet thrice a day after food. The tablet is a Fixed Dose Combination (FDC) of serratiopeptidae (10mg) and diclofenac sodium (50mg).

The next day patient presented to the pediatric emergency department with the complaint of bizarre, involuntary and frequent abnormal movements of right upper limb. Neurological examination did not reveal any other sign. There was no history of seizure disorder or any such episode in the past. Family history was insignificant. The patient's medications were reviewed and it was found that the patient actually received Serenace 10mg (RPG life sciences, India) half tablet thrice, instead of Serronak. Thus the patient had ingested total of 15 mg of haloperidol in a day. The maximum recommended dose of haloperidol in children is 10mg/day [1].

Serenace is haloperidol, a potent antipsychotic agent, which is known to cause extrapyramidal adverse effects [2]. Diagnosis of drug induced dystonia was made and intramuscular promethazine injection was given immediately. Reaction subsided within half an hour. Thereafter no such episode was reported and no medications were started for the isolated event. The patient's guardian provided the written informed consent for publication of this report. The case was reported to the zonal centre under national pharmacovigilance programme.

Discussion

The two brand names Serenace and Serronak are identical orthographically (look alike) although their generic contents are distinctly dissimilar. The illegible handwriting of the physician, untrained pharmacist and functionally illiterate patient, were other contributory factors which resulted in this medication error. The patient on the receiving end suffered a potentially preventable Adverse Drug Reaction (ADR). Adding to the present confusion we also have brands Servace (Servetus, India) [3] which is ramipril, an antihypertensive and Seromark (Glenmark, India) [3], a combination of diclofenac sodium, serratiopeptidase and paracetamol.

This case report brings us to the two important issues i.e. preventable ADR due to medication error and look-alike or sound-alike (LA/SA) health products. The IoM report, Preventing Medication Errors [4], finds that medication errors are surprisingly common and costly to the nation. The committee concluded that there are at least 1.5 million preventable Adverse Drug Events (ADEs) that occur in United States each year. The evidence suggests that the number is likely to be under estimated and the true number may be much higher. Look-alike and sound-alike medication names play a part in almost one quarter of all medication errors [5]. As for now, in Indian context, large gaps exist in the knowledge about incidence and prevalence of medication error.

Rataboli et al [6] in an interesting study have analysed look-alike and sound-alike brands of drugs available in the Indian market. They have systematically divided these drugs into twelve different categories based on the nature of the drug, the dosage form, the similarities and the manufacturer. The classification is based on visual and phonetic similarity. Each category listed by Rataboli et al represents an area for potential error, although the two brands mentioned above do not fall in any of the XII categories graciously explained by them. Serenace and Serronak are look alike brands with different generic names, different manufacturers and one of the brands are the combination of two molecules. This example can be a further extension to the category I explained by them.

Levenshtein distance has been used to predict error pairs [5,7]. It is the number of edit operations (e.g., substitutions, insertions, or deletions) needed to transform one word into another. In this particular case of Serenace and Serronak four edit operations are required. Thus, the Levenshtein distance between the two names is 4 and a threshold for Levenshtein distances has been proposed as greater than 5. Therefore this test may have predicted the problems associated with Serenace and Serronak.

The implications of this case are relevant to the large proportion of patients in India where medications are dispensed mostly by the private pharmacies/chemists which are supposed to be manned by pharmacy trained personnel but the ground reality is entirely different. These pharmacists (mostly untrained) are known to substitute prescriptions. The illiterate patient usually accepts whatever he gets without cross-checking with the doctor. If two drug names differ by just an alphabet, syllable, suffix or prefix, it becomes difficult for the patient to realize that there is a difference. The proliferation of numerous brands has made the patient more vulnerable. To add to this, physician's illegible handwriting, incomplete knowledge of brand names, noisy workplace and extended working hours often confounds the problem.

Medication use is a multifaceted process that begins with prescribing, processing of the prescription, dispensing and monitoring the effects of medication. Each step is vulnerable to errors. Moreover, with increasing access to medical care the susceptibility to error is more common. Thus reducing medication error is a challenging job. Analysis of medication error suggests that prevention strategies that target systems rather than individuals are more effective in reducing in reducing errors [8]. One of the most effective ways to reduce medication errors, the IoM report, Preventing Medication Errors [4], concluded, is to move toward a model of health care where there is more of a partnership between the patients and the health care providers. One of the approaches suggested is Medication Reconciliation. This is a process designed to prevent medication errors at patient transition points. The simplified three step approach is as follows:

- Verification (collection of medication history/list)
- Clarification (ensuring that the medications and doses are appropriate)
- Reconciliation (documentation of changes)

In conclusion, our case throws light on how the medication error leads to a preventable ADR. The issue of medication error in India is extremely complex, demanding the proactive role of all the stake holders for the safe use of medicines.

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