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Dose switch to another dosage form of Neoral® increase the risk of medication error?

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Summary

Background: One of the most significant ways to avoid medication errors is to study the errors that have occurred in other institutions and to use the information to prevent similar accidents at other practice sites.

Case Report: We report a cyclosporine overdose that was caused, in part, by misinterpretation of the medication order of a transplanted patient. In transplantation regimen, a 15 mg BID dose of cyclosporine was supposed to be given as part of the immunosuppressive therapy. Unfortunately the patient received a total of 1500 mg but survived the overdose.

Conclusions: This case should be considered in the development of strategies to prevent unfavorable outcomes resulting from such errors.

Key words: **medication error • dosage form • Neoral**

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Background

Medication errors are frequent and associated with significant adverse events in a population which has to comply with a complex drug regimen such as transplanted patients [1]. Since medication errors are associated with significant clinical adverse outcomes, education of healthcare providers regarding these regimens may avoid adverse outcomes.

Case report

A 54 year old female was admitted to the hospital with anuria and massive Deep Vein Thrombosis (DVT) in the left leg. Three months ago, she had undergone single lung transplantation for end stage pulmonary fibrosis. She was admitted for further work-ups and enoxaparin (80 mg, SC, BID), warfarin (2.5 mg, PO) and furosemide (20 mg, IV, BID) was started at the admission.

The patient medications before admission was consisted of mycophenolate mofetil (1000 mg, PO, BID), prednisolone (25 mg, PO, daily), cyclosporine (25 mg, PO, BID), metoprolol (25 mg, PO, daily), spironolacton (25 mg, PO, BID), diltiazem (30 mg, PO, TDS), omeperazole (20 mg, PO, daily), and gancyclovir (150 mg, IV, daily).

Due to compromised renal function (serum creatinine level: 2.2 mg/dl), patient was on low dose of cyclosporine therapy (Neoral 25 mg, PO, BID). Cyclosporine trough level was 221 ng/ml (Target level: 102–307). A rise in serum creatinine level (2.7 mg/dl) was noted on the day 3 of admission and cyclosporine dose was decreased to 15 mg BID. The formulation was changed in the order sheet (Figure 1) from 25 mg capsules to 15 mg of oral solution for the convenient administration. There is not any form of capsule with less than 25 mg cyclosporine.

By mistake the patient was given 15 ml of cyclosporine instead of 15 mg. After 5 minutes, she developed signs and symptoms consistent with cyclosporine toxicity (nausea, vomiting, weakness, tremor, hypertension and abdominal pain). Cyclosporine trough level was 400 ng/ml. Emesis induction and lavage were not applied due to the spontaneous nausea and vomiting of the patient after ingestion of the drug. Glyceryl trinitrate (5 µg/min, Infusion) was administered to control high blood pressure.

The report was made by a supervising nurse but no detail was found in nursing note. Luckily, the

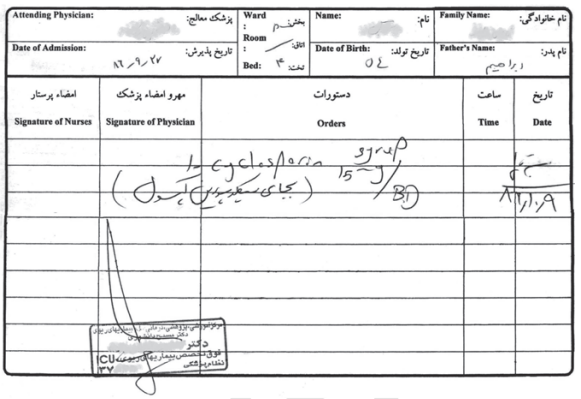

Figure 1. The order sheet of the patient.

100 fold overdose did not lead to serious harm. After 5 days the patient was discharged with 25 mg cyclosporine twice daily.

Discussion

Medication error is an important clinical issue. A medication error can occur at any step of the medication use process. Prescribing errors involving medication dosage forms have been reported to account for more than 10% of all errors detected in a long-standing medication errors detection and prevention program [2]. A number of factors appear to contribute to the problem of medication errors relating dose formulations. Many of these factors are not unique to medication formulation errors and usually result from multiple deficiencies in the medication use system. The most important contributors to errors are insufficient safety processes in the health care organization, inadequate knowledge of dose form issues, confusing nomenclature, and poor packaging and labeling [3].

In our case, the nurse mistakenly administered cyclosporine with a dosage of 100 times higher than intended, giving the patients a dose of 1500 mg or 15 ml (100 mg per ml) instead of the dosage of 15 mg (0.15 ml which could be further diluted with room temperature milk, chocolate milk or orange juice) [4]. Increased dose could result to serious side effects in our patient.

Acute intoxication due to misreading of the initial order has been reported by Koren et al. [5]. Many of the dosage form errors are related to improper route of administration by either nurse or patient [6]. Also there are reports on errors due to the lack of available medication strength which needs compounding [7]. Measurements errors of liquid medications have been reported

by others [8,9]. In our case the source of the error was inadequate drug therapy knowledge of the caregivers about the unusual dosage form. Healthcare givers are generally insufficiently updated about the properties, availability, and correct use of the different marketed dosage forms. This may lead to the potential adverse effects from inappropriate use. Improved caregiver and patient education regarding proper use of dose formulations can play an important role in reducing risk for errors [3].

No detail report was found in nursing notes. Many nurses mistakenly believe that colleagues who have made several medication errors are not very careful or competent. Only 5% or less of medication errors are reported at all. Nurses who report their own errors or the errors that they discover are probably conscientious and know that reporting errors helps identify and correct recurring problems. Nurses may fail to report one or more errors during their nursing career for fear of personal or professional repercussions. Although failing to report errors can't be condoned, it is a predictable result when nurses are afraid of disciplinary action by their employers or by organizations [10].

A main measure for error reduction of this type is to ensure that all who prescribe, dispense, and administer for transplanted patients are qualified to safely manage the use of these specialized medications. Such staff would be in the best position to distinguish and prevent a potentially serious overdose. Since mix-ups continue to occur, our prior error-reduction strategies are: 1) Have the nurses identify cyclosporine products that are prone to mix-ups, 2) Have pharmacy staff apply visible labels to the bottles dispensed to patient care units, 3) Have the physicians write both in mg and ml when applicable, 4) Have unit-dose drug distribution for some products which would reduce errors of this type [11], 5) Have the nurses apply a colored sticker on patient chart whenever a formulation is changed. 6) Have a pharmacist or nurse familiar to the dosage form supervise the process of drug administration.

Conclusions

Experienced and trained personnel should be devoted to transplanted patients care. This could reduce the hazard of medication errors.

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