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Pregabalin induced balance disorder, asthenia, edema, and constipation in an elderly adult: A case report

Li-Ping Ma, Cheng Wen, Tong-Xiang Zhao, Xiang-Ming Jiang, Jin Gu

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Abstract

BACKGROUND

Pregabalin is widely used to treat neuropathic pain associated with postherpetic neuralgia. To our knowledge, this is the first report on simultaneously occurring dose-related adverse drug reactions (ADRs) of balance disorder, asthenia, peripheral edema, and constipation in an elderly patient after pregabalin.

CASE SUMMARY

A 76-year-old female with a history of postherpetic neuralgia was prescribed pregabalin (300 mg daily). After taking pregabalin for 7 d, the patient developed balance disorder, weakness, peripheral pitting edema (2+), and constipation. On days 8-14, the pregabalin dose was reduced to 150 mg/d based on creatinine clearance. The patient's peripheral edema improved significantly with the disappearance of all other adverse symptoms. On day 15, the pregabalin dose was increased to 225 mg/d to relieve pain. Unfortunately, the symptoms mentioned earlier gradually reappeared after 1 wk of pregabalin treatment. However, the complaints were not as severe as when taking 300 mg/d pregabalin. The patient consulted her pharmacist by telephone and was advised to reduce the dose of pregabalin to 150 mg/d and add acetaminophen (0.5 g, q6h) to relieve pain. The patient's ADRs gradually improved over the following week.

CONCLUSION

Older patients should be prescribed a lower initial dose of pregabalin. The dose should be titrated to the maximum tolerable dose to avoid dose-limiting ADR. Dose reduction and the addition of acetaminophen may help limit ADR and improve pain control.

Key Words: Pregabalin; Dose-dependent AEs; The elderly population; Adverse drug reaction; Case report

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Core Tip: This is the first report regarding dose-related adverse drug reactions (ADRs) of balance disorder, asthenia, peripheral edema, and constipation simultaneously in an elderly patient after treatment with pregabalin, which suggests that older patients whose creatinine clearance < 60 mL/min should be prescribed a lower initial dose. Titration to the highest tolerable dose should be done cautiously to avoid dose-limiting ADRs. Dose reduction and the addition of acetaminophen for pregabalin may be useful for limiting ADRs and improving patient pain control.

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INTRODUCTION

Pregabalin was approved by the United States Food and Drug Administration in 2014 to treat neuropathic pain associated with postherpetic neuralgia[1]. The drug can cause several adverse drug reactions (ADRs), including dizziness, somnolence, and weight gain[1-3]. However, the simultaneous occurrence of dose-dependent ADRs of balance disorder, asthenia, facial and peripheral edema, and constipation is rarely reported. Here, for the first time, we present the case of a 76-year-old female who experienced these ADRs while taking pregabalin.

CASE PRESENTATION

Chief complaints

A 76-year-old Chinese female presented to the hospital with balance disorder and weakness. The patient was taking pregabalin (300 mg daily) for the past 7 d for postherpetic neuralgia.

History of present illness

Balance disorder, weakness, facial and peripheral edema (2+), and constipation.

History of past illness

Approximately 2 mo prior to presentation, the patient came to a local hospital with back and chest pain. On physical examination, blisters were found on the chest and back. The patient was taking prednisone for immune thrombocytopenia. Herpes zoster simplex was diagnosed based on the signs and symptoms presented, and a 3-wk treatment of valacyclovir was prescribed. After treatment, the blisters improved, but the pain persisted. Pregabalin (300 mg/d) was prescribed for suspected herpetic neuralgia. Other medical history included hypertension and type 2 diabetes. The patient was also taking danazol and repaglinide. The patient had no history of allergies or psychiatric illness.

Personal and family history

The patient denied any family history of postherpetic neuralgia.

Physical examination

Current vital signs were body temperature of 36.8 °C, blood pressure of 130/80 mmHg, heart rate of 70 beats/min, and respiratory rate of 18 breaths/min. Furthermore, before pregabalin treatment, the patient had painful facial expression, and postherpetic chest tenderness. A few herpes and herpetic imprints were found as well.

Laboratory examinations

Routine blood analyses were normal (white blood cells, $6.2 \times 10^9/L$; red bloodcells, $3.83 \times 10^{12}/L$; hemoglobin, 121 g/L; platelets, 160×10^9 ; serum creatinine 80 $\mu\text{mol}/L$). Liver function was normal (aspartate transaminase, 15 IU/L; alanine aminotransferase, 14 IU/L; total protein, 59.1 g/L; albumin 33.9 g/L; total bilirubin; 16.7 $\mu\text{mol}/L$; direct bilirubin, 5.6 $\mu\text{mol}/L$). Blood glucose was 16.06 mmol/L.

Urine analyses were normal except for (2+) sugar.

Imaging examinations

No special notes.

MULTIDISCIPLINARY EXPERT CONSULTATION

After taking pregabalin, the patient complained about balance disorder, weakness, facial and peripheral edema, and constipation. However, the patient was also taking danazol, prednisone, and repaglinide. Only danazol and repaglinide have ADRs of balance disorder and weakness listed in the package inserts, but the incidence rates are less than 0.01%. Therefore, these complaints were considered to be caused by pregabalin. The pregabalin dose was reduced to 150 mg/d based on creatinine clearance of 40 mL/min. The dose change was communicated to the patient and her husband. On days 8-14, after the dose of pregabalin was reduced, peripheral edema improved with the disappearance of adverse symptoms. However, on day 15, the patient increased the pregabalin dose to 225 mg/d to relieve pain. Unfortunately, adverse events gradually reappeared after 1 wk of treatment. However, the symptoms were not as severe as when the previous dose was 300 mg/d.

FINAL DIAGNOSIS

The Naranjo ADR Probability Scale yielded a score of 9 (definite), indicating that these dose-related ADRs were caused by pregabalin[4].

TREATMENT

The patient consulted the pharmacist by telephone. The pharmacist advised the patient to reduce the pregabalin dose to 150 mg/d and add acetaminophen (0.5 g, q6h) for additional pain relief. After dose reduction, the ADRs gradually improved over the following week.

OUTCOME AND FOLLOW-UP

The patient stopped acetaminophen and continued taking pregabalin (150 mg/d) for approximately 1 year. No ADRs reappeared, and the pain gradually improved.

DISCUSSION

Patients starting pregabalin treatment are at increased risk of several adverse events, particularly those that affect cognition and coordination. Adverse events appear according to a particular dose-response pattern, possibly reflecting the severity of the dysfunction of different anatomic structures[3]. These balance disorders and asthenia may be caused by the inhibition of the depolarization-dependent calcium influx in the P-, Q-, and N-type voltage-gated calcium channels in the vestibule cerebellar brainstem[1]. Advanced age is a significant risk factor for unsteadiness, suggesting that pregabalin should be used with caution in older patients[5].

The development of edema may be associated with the opening effect of pregabalin on plasma-lemmal mitochondrial ATP-sensitive K(+) channels in smooth muscle cells[5]. Elevated serum creatinine levels are predictive factors for the development of edema[6]. The ADRs of edema and constipation related to pregabalin are slightly less common, and their pathogenesis is unclear. Pregabalin can cause constipation by binding to the calcium channel alpha 2-delta type 1 protein subunit in smooth muscle cells of the gastrointestinal tract.

In our case, the time correlation between pregabalin and balance disorder, asthenia, edema, and constipation might be atypical. The median intervals between the use of pregabalin and the time to the onset of these adverse events are 15 d, 16 d, and 29 d, respectively[7]. However, most ADRs emerge within the first 21-28 d after pregabalin treatment, except for peripheral edema[8]. In the current case, the patient developed symptoms after 7 d of pregabalin therapy, both at 300 mg/d and 225 mg/d.

Meanwhile, this case demonstrates that higher doses of pregabalin lead to increased severity of ADR. However, the time to onset and types of ADRs are similar. Pregabalin should be prescribed at a low dose and titrated to the maximum tolerable amount, especially in older patients with reduced renal function. Pregabalin exhibits linear pharmacokinetics, which may explain the dose-response

relationship of ADRs in this patient. Pregabalin is approximately 90% unchanged when excreted in the urine[9]. In this case, the creatinine clearance of the patient was estimated to be 40 mL/min, for which a total daily dose of pregabalin of 150 mg/d was recommended. The reduced renal function could explain the appearance of ADRs when the pregabalin dose was at 300 mg/d and the reappearance of ADRs when the dose increased from 150 mg/d to 225 mg/d. Dose-dependent ADRs may appear when taking high initial doses of pregabalin or increasing the amount to provide complete pain relief.

CONCLUSION

This is the first report of dose-related ADRs of balance disorder, asthenia, peripheral edema, and constipation co-occurring in a patient after taking pregabalin. Older patients or individuals with renal insufficiency should start a low dose of pregabalin. The dose should be slowly titrated to the maximum tolerated dose to avoid ADRs. The addition of acetaminophen may help limit ADRs and improve pain control.

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