Case Report

Benefits and risks of off-label olanzapine use for symptom management in cancer patients—a case report

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Background: Cancer patients often experience symptoms such as anorexia, anxiety and insomnia, which can impact their quality of life. Randomized placebo-controlled trials support prophylactic use of olanzapine for the prevention of nausea and vomiting due to moderate and high-emetic risk chemotherapy. In the setting of palliative care, olanzapine is increasingly utilized as an off-label treatment of symptoms including anorexia-cachexia, anxiety, and insomnia. The following case reports will highlight the potential benefits and risks of off-label olanzapine use for symptom management in cancer patients.

Case Description: Patient 1 is a female in her 70s with stage IV infiltrating ductal carcinoma of the right breast was having trouble tolerating treatment with letrozole, palbociclib, and denosumab due to uncontrolled nausea resulting in weight loss. Her nausea was refractory to multiple anti-emetics. Low dose olanzapine (2.5 mg) prevented nausea and allowed her to tolerate treatment. Patient 2 is a male in his 50s with renal cell carcinoma, who was receiving treatment with cabozantinib, presented with uncontrolled pain improved with opioid rotation from oxycodone to morphine. He was also experiencing uncontrolled anxiety despite treatment with alprazolam. Alprazolam was weaned and replaced with olanzapine resulting in improvement of his symptoms. Patient 3 is a male in his 60s with pancreatic adenocarcinoma who presented with muscle weakness and fatigue resulting in discontinuation of gemcitabine plus cisplatin. He also had symptoms of depression, poor appetite, and sleep problems. He was prescribed short course of dexamethasone 4 mg by mouth twice daily and olanzapine 5 mg by mouth nightly to improve symptoms. One week after, he presented with confusion and workup revealed hyperammonia which was treated with lactulose, which led to the return of baseline mentation.

Conclusions: Olanzapine antagonizes multiple receptors and has potential to treat a host of symptoms including nausea, anorexia, anxiety, and insomnia, but healthcare providers should be mindful of potential risks and unclear benefits for off-label indications. More research and funding are needed evaluating off-label use of olanzapine for palliation of symptoms in cancer patients who are often frail and susceptible to adverse events.

Keywords: Nausea; olanzapine; cancer; adverse events; case report

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Introduction

Cancer patients may develop a host of symptoms including nausea, anorexia, anxiety, and insomnia which can impact quality of life. Olanzapine, a thienobenzodiazepine (1), is an atypical anti-psychotic, approved by the United States Food and Drug Administration (FDA), for the treatment of adult patients with schizophrenia and bipolar disorder. Compared with other antipsychotics, such as haloperidol, olanzapine has been reported to have less side effects, except for reported increased gain in weigh during chronic treatment (2). Olanzapine, based on clinical trials, is increasingly used for the prevention of chemotherapy-induced nausea vomiting (CINV) (3).

In the palliative care setting, 15–35% of all drugs are used off label due to a lack of funding for clinical trials and widespread use in the community (4). Unlike other atypical anti-psychotics such as quetiapine and clozapine, olanzapine is increasingly used as the antiemetic of choice, at least in the USA, and has been increasingly incorporated for the symptomatic treatment of anxiety, anorexia, insomnia, and potentially reduce craving for opioids (5,6). The following case series will highlight the potential benefits and risks of off-label use of olanzapine for symptom management in cancer patients. We present the following cases in accordance with the CARE reporting checklist (available at https://apm.amegroups.com/article/view/10.21037/apm-22-1167/rc).

Case presentation

Patient 1

A female patient in her 70s with stage IV infiltrating ductal carcinoma of the right breast with a history of right-sided mastectomy and metastatic disease involving her left breast, sternum and left proximal femur presents with difficulty tolerating treatment with letrozole, palbociclib, and denosumab due to symptoms.

For symptoms of nausea, intermittent vomiting and subsequent weight loss of 35-lbs, patient was referred to our Supportive Care Clinic. On the Edmonton Symptom Assessment Scale (ESAS), patient-rated nausea at 10/10 and anorexia at 7/10. Nausea was associated with diaphoresis, oral food intake, head movement, and hot showers. She denied early satiety, rumination, or anxiety but reported mild constipation. She reported being on multiple nausea medications—including ondansetron, promethazine and meclizine—without improvement. Addition of pantoprazole provided no noticeable benefit.

Physical examination was unremarkable other than tearfulness when discussing the negative impact of nausea on her quality of life. Her most recent labs showed mild chronic anemia (Hgb 10.9 g/dL), but otherwise unremarkable.

In an outside facility, an extensive workup was conducted and included a normal gastro-motility study, an unremarkable upper and lower endoscopy, and a negative computerized tomography scan of the abdomen. Patient's primary care physician was concerned about migraines mimicking nausea and referred to a local neurologist. Neurological evaluation included a negative magnetic resonance imaging (MRI) of the brain, but a possible abnormal electroencephalogram (EEG). A preliminary diagnosis by her neurologist of pre-seizures triggering nausea was made and the patient was treated with levetiracetam and topiramate which were both ineffective and discontinued.

For her symptom burden, we recommended olanzapine 2.5 mg po. every 12 hours for nausea. Patient reported complete resolution of her symptoms with a singly nightly dose of olanzapine, and she was tolerating treatment without symptoms of nausea on 2- and 6-month follow-up visits.

Patient 2

A man in his 50s with renal cell carcinoma with rhabdoid features with a history of nephrectomy and metastatic involvement of the lungs and bone presents to supportive care center (SCC) with abdominal pain. He had received first-line pembrolizumab plus axitinib complicated by colitis and hepatitis, followed by lenvatinib plus everolimus, and

Highlight box

Key findings

- In the palliative care setting, olanzapine is increasingly used off-label for the treatment of symptoms.

What is known and what is new?

- Randomized placebo-controlled trials support the use of olanzapine for the prevention of nausea and vomiting due to moderate and high-emetic risk chemotherapy.
- Olanzapine may be useful for the treatment of anorexia-cachexia syndrome, anxiety, and insomnia.

What is the implication, and what should change now?

- More research is needed on off-label use of medications in the palliative care setting, and healthcare providers should be mindful of potential adverse events of olanzapine prior to prescribing.

currently cabozantinib.

His left lower quadrant pain was rated 8/10 and described as aching, stabbing, radiating to right side of his abdomen and lower back. Pain was uncontrolled despite extended-release (ER) oxycodone 20 mg every 12 hours and immediate-release (IR) oxycodone 10 mg every 4 hours around the clock. The patient had recently been rotated to ER morphine 15 mg every 12 hours and IR morphine 15 mg every 4 hours as needed for breakthrough pain, averaging 4 doses per day.

In addition, patient rated anxiety (9/10) and depression (8/10) high despite being treated with escitalopram 10 mg daily and alprazolam 2 mg as needed, averaging 2–3 pills per day. Patient also noted profound fatigue (9/10). His physical examination and laboratory workup were unremarkable.

At consultation, the patient's ER morphine was increased 30 mg every 12 hours with morphine 15 mg every 4 hours as needed. For anxiety, the patient was instructed to wean alprazolam to 1 mg three times daily with gradual taper over 2 weeks and treated with olanzapine 5 mg every 8 hours as needed for anxiety and insomnia. He denied anhedonia, hopelessness or suicidal ideations and receptive to ongoing expressive supportive counseling.

At 1 month follow-up, with titration of ER morphine 30 mg every 8 hours, his pain improved to 4/10 and anxiety decreased to 3/10. The patient was able to taper off alprazolam without complications. At subsequent monthly follow-up visits, he continued escitalopram and olanzapine, decreased to 2.5 mg prn. during the daytime and scheduled 5 mg at bedtime to help maintain sleep, without side effects and good control of his symptoms. At 6-month follow-up visit, patient developed immunotherapy mediated pneumonitis with complications of dyspnea resulting in discontinuation of treatment and eventual referral to hospice care at home.

Patient 3

A man in his 60s with pancreatic adenocarcinoma complicated by biopsy-proven peritoneal disease, ascites, and portal vein thrombosis was referred to a Supportive Care Clinic for symptom management. His chemotherapy, including gemcitabine plus cisplatin, was discontinued after a single cycle due to complications of melena and muscle weakness.

Patient's ESAS was negative for pain and nausea, but was positive for progressively worsening fatigue, depression, poor appetite, and sleep problems (scores were 8, 6, 8, and 5, respectively). Wife reported that the patient previously was very functional, able to ambulate and perform all his activities of daily living, but now his Eastern Cooperative Oncology Group score was 4. His vital signs and physical examination were unremarkable. The patient was previously prescribed duloxetine, lorazepam, and dicyclomine, which were ineffective in controlling his symptoms and believed to be contributing to his fatigue and were discontinued. He was prescribed short course of dexamethasone 4 mg by mouth twice daily for fatigue, and olanzapine 5 mg by mouth nightly to improve appetite and sleep.

One week after, he presented to the emergency center (EC) for confusion, as reported by his wife, with visual and auditory hallucinations, dizziness after receiving olanzapine for 5 consecutive nights. As the days progressed, he developed joint stiffness, muscle rigidity, tremulousness of all extremities, and one episode of urinary incontinence.

Internal medicine, neuro-oncology, and gastrointestinal medicine consultations were completed and an extensive workup for altered mental status revealed no clear etiology. Computed tomography of the head and MRI of the brain were unremarkable. His vital signs were within normal limits, and the physical examination was notable for lethargy, disorientation, and active hallucinations, memorial delirium assessment scale (7) had increased from a previous score of 5 to 21/30.

Laboratory workup was significant for anemia unchanged from baseline. His liver function tests were normal except for an elevated alkaline phosphatase (ALP) (347 U/L) and an elevated blood ammonia level at 141 mmol/L on presentation, peaking at 190 mmol/L the following day (12 hours after the presentation). Of note, patient had one prior normal blood ammonia level measured less than 3 weeks prior.

Neuro-oncology consultant was concerned that olanzapine was causing hyperammonemia based on a single published case report (8) and discontinued the medication. He was treated with lactulose enema, followed by oral lactulose, which led to the return of baseline mentation associated with resolution of his elevated blood ammonia level. He was discharged 6 days after presentation with normal mentation.

All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from patients who remained alive. Informed consent was not requested for patients who were deceased,

and no subjects are identifiable by case presentation. A copy of the written consent is available for review by the editorial office of this journal.

Discussion

Olanzapine is increasingly used off-label for the treatment of anxiety, insomnia, and anorexia in cancer patients. Olanzapine is known to act as an antagonist to dopamine (D1-4); serotonin (5-HT2A/2C, 5-HT type 3 and 6); catecholamines at alpha1-adrenergic receptors; and at muscarinic acetylcholine receptors (M1 to M4) at higher concentrations (9,10). In animal models, the anxiolytic properties of olanzapine may be due to indirect activation of the GABA-ergic system via allopregnanolone, a neuroactive steroid (11).

National Comprehensive Cancer Network guidelines recommends the use of prophylactic olanzapine as part of a 4-drug regimen with a 5-HT3 receptor antagonist, a neurokinin-1 receptor antagonist, and dexamethasone to treat CINV in patients receiving moderate to highly emetogenic chemotherapy (12). The addition of prophylactic olanzapine, dosed at 5–10 mg during day 1–4, decreased the occurrence of delayed late stage emesis (25 to 120 h) after receiving chemotherapy and studies report sedation as the main adverse event (13-16). Of note, one randomized placebo-controlled trial reported the 5 mg dose of olanzapine was just as effective as the higher dose of 10 mg (13) and, in Japan, is the approved dose for the prevention of CINV.

The first case presented with severe nausea and cachexia while on a low emetogenic risk cancer treatment refractory to a host of anti-emetics. One approach to managing nausea emphasizes treating the underlying mechanism, which was unclear in our case presentation, and an alternative is a broad-spectrum anti-emetic therapy, such as olanzapine (17). The patient elected a trial of low dose (2.5 mg every 12 hours) of olanzapine, due to concerns about side effects of sedation. Despite the low dose, treatment resulted in dramatic improvement of nausea and eventual weight gain. A recent systematic review of olanzapine concluded that while 10 mg/day prophylactic dose is statistically and clinically superior to control CINV, there is paucity of data to support the use of a lower doses (5 mg/day or less) (18). Preliminary studies report olanzapine is also highly effective in treating chronic nausea and vomiting unrelated to chemotherapy (19,20), and may improve appetite and caloric intake in advanced cancer patients (21,22).

In case 2, the patient was experiencing uncontrolled anxiety despite escitalopram and high doses of alprazolam with complications of sedation. Secondary to concerns of respiratory depression due to combination of benzodiazepine and opioids (23), which were being titrated upwards, alprazolam was successfully weaned and discontinued and supplemented by olanzapine as needed to control anxiety. Olanzapine in combination with escitalopram plus counseling improved the patient's symptom burden. Limited evidence exists for the treatment of anxiety and depression with olanzapine as an adjunct treatment or monotherapy in cancer patients. The efficacy of olanzapine for treatment of depression (either depressed bipolar 1 disorder or major depressive disorder) has only been established in combination with fluoxetine in patients without cancer (24). For anxiety, olanzapine has been evaluated for refractory generalized anxiety disorder in non-cancer patients taking fluoxetine alone and reported to be superior to a placebo (25). Of note, a rare case of olanzapine with benzodiazepines has been published highlighting complications of respiratory depression when taken together (26) and patients should be instructed to avoid co-administration.

In both case 2 and 3, olanzapine was prescribed off-label at bedtime to help promote sleep. In a small double-blind, randomized, placebo-controlled trial, olanzapine has been shown to improve sleep efficiency, total sleep time, and sleep latency in patients with depression and bipolar disorder (27), superior to haloperidol in bipolar patients during manic episodes (28), and more effective than risperidone for the treatment of paradoxical insomnia (29).

In case 3, duloxetine, lorazepam and dicyclomine were discontinued secondary to concerns of polypharmacy. A short steroid course was prescribed to improve fatigue, and olanzapine at bedtime was initiated to improve sleep and appetite. Unfortunately, the patient in case 3 developed confusion with hallucinations resulting in hospitalization. Medical workup was unremarkable except for hepatic encephalopathy resulting in confusion. Hepatic encephalopathy with elevated ammonia levels was most likely due to portal vein thrombosis but less likely exacerbated by use of olanzapine, which neuro-oncology consultants based on a single case report (8). It is unclear if other factors, such as the prescription of steroids, may have also contributed to patient's confusion, which is often multifactorial in patients with advanced cancer making it difficult to attribute his confusion to olanzapine alone.

Of note, olanzapine is being evaluated as a treatment

Table 1 Common adverse events of olanzapine (34)

Frequency	Adverse event
Very common ≥1/10	Weight gain/increased appetite
	Somnolence/drowsiness
	Orthostatic hypotension
	Increased prolactin
Common ≥1/100 to <1/10	Akathisia/dyskinesia
	Dizziness
	Parkinsonian-like symptoms
	Neutropenia/agranulocytosis
	Elevated cholesterol & triglyceride
	Anticholinergic effects
	Transient elevations of hepatic aminotransferases
	Arthralgia
	Fatigue
	Increased serum alkaline phosphatase
Uncommon ≥1/1,000 to <1/100	Diabetes
	Seizures (prior history reported in most cases)
	Restless leg syndrome
	Amnesia
	Stuttering
	Bradycardia/QTc prolongation
	Thromboembolism
	Urinary incontinence/hesitation
	Increased total bilirubin
Rare ≥1/10,000 to <1/1,000	Thrombocytopenia
	Neuroleptic malignant syndrome
	Ventricular tachycardia/sudden death
	Pancreatitis
	Hepatitis
	Rhabdomyolysis
	Priapism
	Discontinuation syndrome

QTc, corrected QT interval.

for agitated delirium. Preliminary open label studies report olanzapine improving the control of agitation in cancer patients with delirium (30), but in a small subset of patients, 1.3%, developed increase agitation (31). Recently, a multicenter, randomized clinical trial of advanced cancer patients with delirium reported similar response rates to either haloperidol or olanzapine (32). Olanzapine-induced delirium has been attributed to the stimulation of muscarinic acetylcholine receptors, even at low doses, and noted to be more common in the elderly and patients with pre-existing CNS disease (33).

Health care providers need to be vigilant for potential adverse events when prescribing medications off-label. *Table 1* lists potential adverse events associated with the use of olanzapine published by the Electronic Medicines Compendium based in the United Kingdom (34). Common adverse events include orthostatic hypotension, akathisia, increased appetite and weight gain which is dose dependent. Rare but serious adverse events of olanzapine include corrected QT interval (QTc) prolongation, neutropenia and seizures especially in patients with a history of seizure disorder.

Conclusions

Olanzapine is increasingly prescribed to cancer patients for off-label indications including the management of anxiety, insomnia, and appetite stimulation. Olanzapine antagonizes multiple receptors and has potential to treat a host of symptoms, which makes it appealing to prescribe, but healthcare providers should be mindful of potential risks and unclear benefits for off-label indications. More research and funding are needed evaluating off-label use of olanzapine and other drugs for palliation of symptoms in cancer patients who are often frail and susceptible to adverse events particularly in the advanced stages of illness.

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Footnote

Reporting Checklist: The authors have completed the CARE reporting checklist. Available at https://apm.amegroups.

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Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. All procedures performed in this study were in accordance with the ethical standards of the institutional and/or national research committee(s) and with the Helsinki Declaration (as revised in 2013). Written informed consent was obtained from patients who remained alive. Informed consent was not requested for patients who were deceased, and no subjects are identifiable by case presentation. A copy of the written consent is available for review by the editorial office of this journal.

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