Case report

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Amlexanox: A Promising Alternative to Steroid and Antihistamine Dependence in Patients with Mast Cell Activation Syndrome, Allergies, Asthma, and Autoimmunity–A Case Report Collection

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Abstract

This article explores under-recognized applications of amlexanox, a compound showing promise for patients with chronic inflammatory conditions, including mast cell activation syndrome (MCAS), asthma, and autoimmune diseases such as lupus. Increasing numbers of patients present with symptoms of mast cell overactivity, chronic inflammatory conditions, and dependence on anti-inflammatory medications and steroids to control their pain and inflammation. To address these challenges and reduce polypharmacy, we present 3 case studies exploring the integration of amlexanox in patient treatment regimens. Patient data were obtained from medical records of prescribing physicians and dispensing pharmacies. We discuss amlexanox's pharmacology, availability, dosing, and self-reported patient outcomes, including enhanced symptom management and reduced corticosteroid reliance. Amlexanox is a compound deserving of greater attention and formal research for its potential applications in patients diagnosed with conditions such as MCAS, cancer, erectile dysfunction, nonalcoholic fatty liver disease (NAFLD), diabetes, asthma, atopic dermatitis, lupus, long COVID and more.

Introduction

Amlexanox (C16H14N2O4), traditionally used as an antiallergic and anti-inflammatory drug, has recently been found to have broader applications, including use in metabolic disease, mast cell stabilization, immunomodulation, and the potential to influence gene expression. (1) Originally branded as Aphthasol oral paste, amlexanox was applied topically to treat recurrent aphthous ulcers in the mouth. (2) While no longer commercially available in the United States, it is only a compounded product, typically an oral capsule formulation. In other countries, such as Japan, amlexanox is used to treat asthma, allergic rhinitis, and conjunctivitis. (3) Due to its structural similarity to sodium cromoglycate, an antihistaminic mast cell stabilizer, amlexanox may function similarly to products such as Cromolyn, Nasalcrom, and Gastrocrom. Amlexanox demonstrates clinical effectiveness for atopic conditions and, more importantly, may play a significant role in modulating the immune system to manage inflammatory conditions, particularly in difficult-to-treat patients.

Integrative medicine practitioners use amlexanox in MCAS as an adjunct or replacement therapy for H1-blockers, H2-blockers, leukotriene inhibitors, and high-dose corticosteroids.

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The mechanisms of action (MOA) of amlexanox include inhibition of TANK-binding kinase 1 (TBK1) and nuclear factor kappa-B kinase epsilon (IKKε). Studies have demonstrated that the downregulation of the immune system and the attenuation of TBK1 and IKKε signaling are helpful in inflammatory conditions such as MCAS. (4,5)

Amlexanox may inhibit the release of the slow-reacting substance of anaphylaxis (SRS-A) and may also have antagonistic effects on interleukin-3 (IL-3) activity. Additionally, amlexanox was found to bind to fibroblast growth factor-1 (FGF-1), reducing Cu (2+)-induced oxidation by stabilizing FGF-1. (6,7,8)

Case presentations

Case 1: Amlexanox use in lupus to replace prednisone

Background

A 63-year-old female with a history of lupus presented to discuss alternatives to prednisone due to adverse effects from long-term use, including bone mineral loss and weight gain. Additional health concerns included hypertension, insomnia, chronic pain syndrome, anemia, Raynaud's syndrome, and hormone imbalance.

The patient had a known allergy to nonsteroidal anti-inflammatory drugs (NSAIDs), specifically naproxen, and was taking bupropion, baclofen, furosemide, losartan, meclizine, mycophenolate mofetil (CellCept), prednisone, sertraline, and zolpidem (Ambien), illustrating polypharmacy. Her occupation was a pharmacy technician.

Medical history

The patient had a hysterectomy, and her last menstrual period was in 2008. She reported an inability to exercise and had a family history of rheumatoid arthritis affecting both her mother and daughter. The patient was delivered vaginally and was formula-fed as an infant. She had completed the full schedule of childhood vaccinations and received 3 doses of the Moderna mRNA COVID-19 vaccine. She also reported tick exposure and symptoms of diffuse joint and muscle pain.

Initial vital signs included: height: 167.6 cm (66 inches); weight: 74.3 kg (163.8 lb); BMI: 26.44; blood pressure: 130/86 mm Hg; temperature: 36.8˚C (98.3˚F); heart rate: 80 bpm; respiratory rate: 16 breaths/min; oxygen saturation: 97%; pain scale: 5/10.

Laboratory findings

High-sensitivity C-reactive protein (hs-CRP): 2.8 mg/L (H); thyroid stimulating hormone (TSH): 4.43 mIU/L (H); complete blood count (CBC): normal with red blood cell count (RBC) of 3.74 x 10^6/µL (L), normal differential; omega-3 index: 2.29% (L); homocysteine (HCY): 10.3 µmol/L (mildly elevated); vitamin B12: 275 pg/mL; folate: normal; vitamin D: 68 ng/mL; fibrinogen and myeloperoxidase (MPO): within normal limits; total T4: 4.9 µg/dL; free T3: 3.1 ng/dL; reverse T3 (rT3): 10.2 ng/dL; comprehensive metabolic panel (CMP): within normal limits; luteinizing hormone (LH): 52.4 mIU/mL; follicle-stimulating hormone (FSH): 57.9 mIU/mL; progesterone 0.32 ng/mL; testosterone: 10.5 ng/dL; estradiol (E2): <25.0 pg/mL; sex hormone-binding globulin (SHBG): 78.8 nmol/L; dehydroepiandrosterone sulfate (DHEA-S): 69 µg/dL; AM Cortisol: 18 µg/dL; thyroid peroxidase (TPO) and thyroglobulin antibodies (TG-Ab): negative; interleukin-6 (IL-6): 3.4 pg/mL (H); human natural killer antigen CD57 (HNK1): 78 cells/µL (average but not robust, above 60); Lyme disease confirmed by Western blot single immunoglobulin G (IgG) band at P41 (CDC negative). Antinuclear antibody (ANA): negative; C-terminal telopeptide (CTx) bone turnover marker at ideal level. On July 3, 2024, SARS-CoV-2 IgG spike antibody: 6473 U/mL; hsCRP: 10.5 mg/L.

Supplements

The patient was taking a multivitamin and mineral supplement, curcumin and boswellia (Curaphen), omega-3, Burbur-Pinella as needed (PRN) for Herxheimer reactions, cordyceps and reishi (CordyChi), methylfolate (15 mg), AREDS 2 twice daily (BID), and nicotinamide mononucleotide (NMN), resveratrol, and trimethylglycine (Verso Cell Being).

Diagnosis

A clinical diagnosis of tick-borne disease, *Borrelia burgdorferi* (Lyme disease), was established based on presentation, history, and laboratory findings. The patient was unable to afford advanced tick-borne disease testing via IGeneX.

The patient's diagnoses included poor T4 to T3 conversion (functional hypothyroidism); discoid lupus erythematosus (confirmed by rheumatologist); insomnia; anemia (resolved); multiple systemic infectious disease syndrome (MSIDS); *Borrelia burgdorferi*; polypharmacy; spikeopathy (vaccine-related injury); minor Jarisch–Herxheimer reaction; fatigue; post-COVID and vaccine-related complications; myalgia; chronic regional pain syndrome (PS); elevated inflammatory biomarkers; menopausal disorder; homocystinuria with abnormal B-vitamin levels; and low omega-3 index.

Treatment
All interventions were staggered to monitor for possible adverse side effects (ASEs) and positive outcomes. The patient was started on methylfolate (Deplin). Amlexanox was initiated at 40 mg daily, then increased to BID on January 9, 2024. Amlexanox replaced prednisone and mycophenolate mofetil (CellCept) in lupus management. *Borrelia burgdorferi* protocol was started for Lyme disease on September 20, 2022.
Liothyronine was added on August 6, 2024, to address low T3 levels, and progesterone therapy began in April 2024. Trazodone 150 mg was prescribed PRN for sleep to replace other sleep aids. Rapamycin therapy was initiated at 3 mg weekly and later increased to 5 mg weekly, beginning on January 9, 2024, for autoimmune management alongside low-dose naltrexone (LDN).
The patient was initially placed on curcumin plus *Boswellia serrata* for pain, administered BID. Low-dose naltrexone was started at 1.0 mg at bedtime, with the dose increased every 2 weeks until reaching a nightly dose of 4.5 mg.

Outcome and follow-up
On the April 16, 2024, visit, the patient reported improved symptoms and no longer needing prednisone. Amlexanox appeared to be more effective for her lupus. When she ran out of amlexanox, she experienced a mild lupus flare that improved after resuming treatment. She attributes a 31-lb weight loss over 4 months to amlexanox; she was also using bioidentical hormone replacement therapy (BHRT) for hormone regulation. Her most recent COVID-19 infection occurred in October 2023; she had received 3 doses of the Moderna mRNA vaccine.
At her August 6, 2024, visit, the patient reported being able to walk up to 3 miles following a hip replacement on July 15, 2024. She continued to experience muscle weakness, inflammation, and postoperative nerve pain. Low-dose naltrexone had been paused for surgery but was recently restarted. She continued weekly rapamycin at 6 mg and amlexanox at 40 mg BID, reporting improved well-being with these medications. The patient was placed on the McCullough Protocol for spike protein detoxification, which includes a natural oral regimen of nattokinase, bromelain, and curcumin. Recent thyroid function tests showed a free T3 level of 2.6 ng/dL and a reverse T3 of 19.0 ng/dL, with a ratio of 14, suggesting that an increase in the T3 dose might be necessary.
During the latest visit on August 6, 2024, the patient appeared to benefit from the combination of LDN, rapamycin, and amlexanox, likely addressing symptoms potentially caused by tick-borne disease. This combination eliminated the need for prednisone and other medications with ASE profiles, reducing polypharmacy issues and dependence on other medications. Patient feedback indicated that amlexanox was the most notable agent/intervention consistently allowing her to discontinue prednisone.

Assessment
Amlexanox proved to be an effective intervention, with no ASEs reported and positive outcomes documented during follow-up visits. It significantly reduced the patient's reliance on corticosteroids, specifically prednisone.

Case 2: Amlexanox as an alternative to allergy medication, seasonal allergies, and swollen tongue (MCAS)
Background
A 52-year-old female patient first presented on May 30, 2024, with neck swelling and pain. Her medical history included tick-borne illness, electromagnetic field/radiofrequency (EMF/RF) sensitivity, thyroid dysfunction, and spikeopathy (spike protein-related illness) associated with COVID-19 infections, despite not receiving any mRNA vaccinations. The patient noted exacerbated symptoms, potentially due to COVID-19 spike protein shedding. She was 163 cm (5 ft 4 in) tall and weighed 65.8 kg (145 lb).

Medical history
The patient had a history of prediabetes (insulin resistance syndrome), kidney stone removal in 2021, tonsillectomy, and anal fissure repair. She had experienced 6 pregnancies, all resulting in live births, with her last menstrual period in 2018. She reported no medication allergies but noted seasonal environmental allergies.
The patient was a nonsmoker and did not consume alcohol. She worked as a trauma therapist. Her family history included heart disease and various cancers. She was delivered vaginally and breastfed as an infant. She was up to date on childhood vaccinations but never received any mRNA COVID-19 vaccines.

Laboratory findings
Homocysteine: 11.9 μmol/L; ferritin: 67 ng/mL; vitamin B12: 328 pg/mL (L); vitamin D: 33.8 ng/mL (L); C-reactive protein (CRP) 3.38 mg/L. Western blot analysis showed an abnormal band at 41AB (classified as abnormal on the general panel by LabCorp).
Lyme disease was initially identified by a naturopathic doctor using a body scanner system. We con-

firmed the diagnosis based on an elevated Horowitz Multiple Systemic Infectious Disease Syndrome Questionnaire (HMQ) score and clinical presentation. The patient opted out of advanced serology testing.

Supplements

At the time of presentation, the patient was taking the following supplements: Japanese knotweed, Irish moss, adrenal/pancreas support, cayenne pepper, reishi mushroom, vitamin C, zinc, N-acetylcysteine (NAC), vitamin D, apple pectin, and other immune support supplements, including LymeStat, grapeseed, black cumin seed, andrographis, cat's claw (Samento), and colloidal silver. She was also using a nicotine patch for cognitive support.

Treatment

The initial encounter was conducted via telemedicine, with plans for an in-person follow-up to assess vital signs and perform a physical examination.

After the initial visit, the patient was started on ImmuCore (an immune-support supplement) and baobab powder as a "shedding shield." She was also prescribed vitamin D3 with K2 at 5000 IU per day. The McCullough Protocol was initiated, which includes nattokinase, bromelain, and curcumin (CuraPro). A clinical diagnosis of MCAS was added.

Outcome and follow-up

On June 5, 2024, the patient's second visit was conducted in person.

A physical examination revealed the following: height: 162.6 cm (64 inches); weight: 65.8 kg (145 lb); BMI: 24.9; blood pressure: 132/87 mm Hg; temperature: 36.2°C (97.2°F); heart rate: 74 bpm; respiratory rate: 16 breaths/min; oxygen saturation, R/A: 97%; pain scale: 7/10.

Her supplement shipment was delayed at this time, and she was still awaiting its arrival. Her previous symptoms of explosive diarrhea, blood and parasites in the stool, and left-side swelling had resolved. On examination, her tongue appeared swollen, and symptoms consistent with mild hypothyroidism, including constipation, swollen ankles, hair loss, and a swollen tongue, were discussed. A thyroid examination showed mild sensitivity to palpation and swelling, and an ultrasound of the neck and thyroid was ordered.

Her Horowitz Questionnaire score was 113 (with scores above 62 considered abnormal), and LDN was recommended and prescribed. She was advised to continue the cat's claw tincture and andrographis supplementation for possible *Borrelia burgdorferi* persister cells. The thyroid ultrasound, reported on June 10, 2024, showed normal findings.

During her telemedicine follow-up on August 7, 2024, the patient reported ongoing pain since her last health visit while taking LDN but noted some improvement in inflammation. However, her hands and toes remained numb, and she continued to experience leg muscle fatigue and a sensation of heaviness. Reduced hand strength made tasks like opening jars difficult, likely due to chronic Lyme disease. The patient also reported experiencing a significant illness in January, describing it as the worst period to date.

Amlexanox was reported to have helped with allergic reactions, although her tongue remained swollen and pale. She used local honey for allergies, which she noted "worked wonders." Concerned about heavy metal exposure, we discussed a detox regimen using chlorella (Sun Chlorella), with instructions to take 2 tablets twice daily on Monday, Tuesday, and Wednesday each week for heavy metal and toxin detoxification.

Laboratory findings

MTHFR polymorphisms were identified with two single nucleotide polymorphisms (SNPs) reported. The patient's free T3 (fT3) level was 2.8 ng/dL, reverse T3 (rT3) was 16.4 ng/dL, and a thyroid hormone ratio (fT3:rT3) was 17.07, leading to a diagnosis of functional hypothyroidism.

Although a short-term patient, she initially reported feeling only 20% toward her optimal health baseline. Following treatment adjustments, she noted an improvement of 35% to 40%, attributing much of this progress to the gradual integration of amlexanox into her therapeutic regimen.

Additional laboratory values

Antistreptolysin O (ASO) Ab01: <20.0; absolute CD8-CD57+ lymphs: 132 cells/mL; MTHFR: 677 T/T, 1298 A/A; vitamin B12: 422 pg/mL; free T3: 2.8 ng/dl; reverse T3: 16.4 ng/dL; thyroid hormone ratio: 17.07.

Treatment

Amlexanox was increased to 40 mg 3 times daily (TID). Sun Chlorella (500 mg) was administered BID on Monday, Tuesday, and Wednesday, with no doses for the remainder of the week. Methyl Benefits, taken as 2 capsules daily, was provided for B-complex supplementation. Nutra-BRL and Nutra-BRT were prescribed for *Borrelia burgdorferi* and Bartonella infections, and iron supplementation was recommended every other day instead of daily.

Low-dose naltrexone therapy initiated on June 5,

2024, began at 0.5 mg daily and was increased to 2 mg on July 20, 2024, based on patient feedback. This dose was determined to be optimal for the patient.
Amlexanox was initially prescribed at 40 mg daily on June 13, 2024, then increased to BID on July 1, 2024, and further increased to TID on August 7, 2024, due to positive patient feedback and effectiveness at this dosage. Rescue medications were made available as needed, including cetirizine (Zyrtec) and famotidine (Pepcid).

Assessment
Amlexanox, administered at 40 mg TID, effectively managed allergic symptoms associated with MCAS, allowing other medications to be reserved for PRN use.

Case 3: Amlexanox use in asthma and severe MCAS
Background
A 60-year-old female presented in August 2023 with treatment-refractory MCAS and extensive inflammation affecting her eyes, hands, feet, and knees. She frequently reported side effects from medications and supplements consistent with the typical Jarisch-Herxheimer reaction, though unusually severe and not limited to antibiotic use.
One notable adverse reaction following a dose of oral lysine-proline-valine included eye blisters, puffy eyes, swelling of the hands, intense redness and swelling in the ears resembling sunburn, severe pruritus affecting the mouth, nose, face, and torso, along with a swollen tongue and darkened lips. The patient also described a sensation in her calves as if they "were about to pop," accompanied by a "spongy" feeling on her scalp, pruritus, headache, and dry heaving.
Physical activity or any lymphatic mobilization, such as sauna use or dry brushing, would leave her bedridden for 1 to 2 days, requiring extended recovery. At baseline, she was heavily dependent on oral antihistamines and inhaled steroids for both maintenance and rescue purposes. On some days, her medication regimen included total daily doses of ketotifen 4 mg, sustained-release diphenhydramine 180 mg, chlorpheniramine maleate 16 mg, and ibuprofen 1800 mg to manage daily activities. (9)

Medical history
The patient's medical history included uncontrolled asthma, food allergies, thyroid and sex hormone dysregulation, edema, poor digestion, and severe intolerance to most medications and supplements. She had clinically confirmed Lyme disease, Bartonella, and Babesia, with positive test results for blood biofilms. Additionally, she had a history of multiple adverse reactions to medications and supplements, including extreme sensitivity and severe inflammation.

Diagnosis
The patient was diagnosed with postural orthostatic tachycardia syndrome (POTS), MCAS, hypothyroidism, malaise, symptomatic menopause, candidiasis, allergic rhinitis, Lyme disease, asthma, and age-related osteoporosis without current pathological fracture. (9)

Outcome and follow-up
In November 2023, a comprehensive blood panel—including CBC with differential and platelet count, plasminogen activator inhibitor-1, thrombin-antithrombin complex, prothrombin fragment 1+2 (MoAb), and CMP14+2AC—showed all values within a normal range (Labcorp). Brightfield microscopy of a blood smear (TLab Inc.) revealed a high-positive result for biofilms, positive neutrophil extracellular traps (NETs), and the presence of both small and large red blood cell inclusions. (9)
In December 2023, the patient was managing a regimen of 81 different medications and supplements, illustrating a classic case of polypharmacy. This regimen addressed symptoms of histamine intolerance, Lyme disease, leaky gut, inflammation, adrenal dysfunction, Babesia, biofilms, viral infections, neuropathy, candidiasis, MCAS, indigestion, and insomnia. Additional therapies included albuterol inhalers, nebulized solutions, pulsed electromagnetic field (PEMF) therapy, Flowpresso lymphatic drainage, and IV therapies, including ozone therapy, glutathione, ultraviolet blood irradiation, and Myers' cocktails, administered 3 to 7 days per week. (9)

Amlexanox initiated
At the January 2024 follow-up, the patient's Lyme-literate medical doctor increased her imatinib dosage from 100–200 mg daily. Despite this adjustment, she continued to rely on her albuterol HFA inhaler and nebulized albuterol solution to relieve wheezing, chest tightness, and congestion. Following this visit, her physician introduced amlexanox at 40 mg daily, which yielded positive results. During the first 2 days of amlexanox therapy, the patient continued using the inhaler and nebulizer daily. By the third day, however, she required only the inhaler and no longer needed nebulized albuterol. Within 1 week of initiating amlexanox at 40 mg daily, she reported a marked reduction in airway mucus produc-

tion. She continued the amlexanox regimen at this dose for 60 days, noting improved breathing and significantly reduced symptoms of mast cell overactivation, ultimately eliminating her need for inhaled and nebulized albuterol. (9)

In September 2024, the patient reported a dramatic reduction in MCAS symptoms, with significantly fewer occurrences of eye blisters and an almost complete resolution of immediate adverse reactions to foods, supplements, and medications. She noted that her body now required only hours, rather than days, to recover from adverse reactions. During this visit, she emphasized that after completing her 60-day course of amlexanox therapy, she did not need to use her albuterol HFA inhaler or nebulized albuterol solution.

Significant reduction in polypharmacy

Notably, the patient reduced her medication and supplementation regimen from 81 agents at baseline to 17, attributing this significant reduction in polypharmacy primarily to the introduction of amlexanox therapy. (9)

Assessment

Since amlexanox functions primarily as a mast cell stabilizer, its daily use likely provided the intervention needed to address the patient's mast cell overactivity. In turn, this appears to have enabled her immune system to more effectively self-regulate, promoting overall healing and significantly reducing her dependence on the extensive list of medications and supplements she had previously required. Notably, she achieved lasting symptom resolution and a marked reduction in polypharmacy after only 60 days of amlexanox at a daily dose of 40 mg.

Conclusion

Based on published medical literature, observational studies, and clinical experience, amlexanox appears to be an effective option for managing specific conditions. It may serve as both an effective antihistamine and a viable alternative to traditional anti-inflammatory drugs, such as prednisone. Additionally, amlexanox shows potential for reducing polypharmacy by decreasing the reliance on H1 and H2 blockers, leukotriene inhibitors, and high-dose corticosteroids. The cases presented underscore its potential in treating autoimmune conditions, such as lupus, and managing symptoms in patients with MCAS.

Patients with MCAS often present with near-normal laboratory results, yet their clinical symptoms can fluctuate markedly from day to day and between appointments, often leading to skepticism from evaluating physicians. Based on our experience managing MCAS, identifying an effective initial intervention to mitigate mast cell overactivity is one of the most challenging yet essential steps in establishing a successful treatment plan. Mast cells interact extensively with a wide range of mediators in the body, including hormones, histamine, high-affinity immunoglobulin E (IgE) and immunoglobulin G (IgG) receptors, toll-like receptors, receptors for stem cell factor, complement proteins, cytokine receptors, neuropeptides, and opioids. (10) Achieving initial mast cell stability is crucial, as it allows other contributing factors to illness to be addressed on an individual basis.

These case reports offer valuable clinical insights into patient-reported symptom improvements, focusing on reductions in inflammation and mast cell overactivity. Additional case studies and reports are needed to further validate amlexanox's safety and efficacy profile. Based on our observations, amlexanox appears to play a significant role in stabilizing the immune system for treatment-refractory patients, especially those experiencing a downward progression of inflammation or autoimmune activity. Finally, we remain optimistic that lifelong treatment with amlexanox may not be necessary for patients to achieve lasting stability and full recovery.

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