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Management of Migraine: An Overview

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Abstract

Migraine is a disabling type of headache due to a neurovascular disorder characterized by moderate to severe pain and specific associated features. Migraine has a high incidence and prevalence, affecting 20% of people at some point in their lives; women are more affected than men. There have been many pharmacologic options that have been used to treat acute migraine over the last years. Nevertheless, this article aims to point out the new drugs approved by the Food and Drug Administration (FDA), the calcitonin gene-related peptide (CGRP) inhibitor and review the traditional pharmacologic options and their combination available. There are two classes of CGRP inhibitors: small molecule CGRP receptor antagonists and anti-CGRP monoclonal antibodies. Their indications depend on the patient's comorbidity, preference, and side effects. Due to their non-vasoconstrictive property, CGRP inhibitors can be considered a treatment option for patients with a contraindication of triptans and ergot alkaloids use. Another strategy to treat migraine attacks after they start is triptans. Therefore, this drug is considered an abortive therapy. However, triptans have many contraindications and drug interactions. Additionally, it should not be used for more than ten days per month to avoid the development of medication overuse headaches. Another classic group of drugs proven to be effective and safe for mild to moderate headache therapy is non-steroidal anti-inflammatory drugs (NSAIDs). Their easy access and lower cost are the most attractive advantages of this drug. Migraine treatment is not easy, and it might be necessary to use more than one drug. Combination drugs can be used as a first-line or second-line therapy, and they can also be helpful for refractory migraine treatment. Due to the different mechanisms of action, it can enhance the results of another drug or improve its effects. This treatment regimen can be used as the first or second line, depending on the context of the patient. Since migraine is a prevalent condition, all medical professionals must be up to date on migraine treatment methods because studies in this area are lacking.

Keywords: Migraine; CGRP inhibitor; Gepants; Monoclonal Antibodies; NSAID; Triptans

Abbreviations: NSAID: Nonsteroidal Anti-Inflammatory Drug, CGRP: Calcitonin gene-related peptide, COX: cyclooxygenase, FDA: Food and Drug Administration, mAbs: Monoclonal Antibodies, RMTs: Rapid Melt Tablets, SSRIs: Selective Serotonin Reuptake Inhibitors, OTC: Over-the-counter, MOH: Medication Overuse Headache

Introduction

Migraine is a disabling type of headache caused by a neurovascular disorder that ranges from moderate to severe pain, and it is associated with specific features. The activation of trigeminal ganglion nociceptive neurons and the subsequent release of calcitonin gene-related peptide (CGRP) are implicated in migraine pathology [1]. Family history, female sex, hormonal changes are common risk factors associated with migraine [2]. The signs and symptoms are unilateral headaches with pulsating pain, nausea, vomiting, photophobia, or phonophobia. Duration can vary from 4 hours to 72 hours. The diagnosis of migraine is made based on patient history and symptoms. Migraine affects over 20% of people at some point in their lives; global studies suggest that approximately 1% of the world's population may have chronic migraine [3]. Female patients are more likely to experience migraines. The prevalence of migraine and severe

headaches in the US adult population is high, affecting 9.7% of males and 20.7% of females [4]. Approximately 38% of patients with episodic migraines would benefit from preventive therapy. Identifying and managing environmental, dietary, and behavioral triggers are helpful strategies for preventing migraines [5].

Pharmacological prophylaxis includes metoprolol, timolol, amitriptyline, valproate, botulinum toxin injections. Several pharmacological options can be used to manage acute migraine. This article will review the following therapeutic regimens: calcitonin gene-related peptide receptor antagonists, serotonin-receptor agonists, nonsteroidal anti-inflammatory drugs (NSAIDs) and combination therapy. Calcitonin gene-related peptide receptor antagonist directly competes for the binding site of the endogenous ligand CGRP and therefore inhibits the physiological and cellular effects of CGRP [1]. Serotonin receptor agonists inhibit trigeminal nerve activation, prevent vasoactive peptide release, and induce vasoconstriction. NSAIDs are commonly used in patients suffering from migraine by relieving pain and reducing inflammation and fever by reversible inhibiting the cyclooxygenase (COX) pathway (both COX-1 and COX-2), blocking prostaglandin synthesis. This article highlights the effectiveness of the newest medication to treat migraine. The goal of medical therapy is to reduce the frequency of headaches to the minimum. The CGRP inhibitors have a wide variety of presentations, making migraine treatment more comfortable for the patient. The most crucial factor in treatment success will be the appropriate medication for each patient that will reduce headache frequency and intensity, either with one type of drug or combination.

Calcitonin gene-related peptide (CGRP) inhibitors

The role of CGRP in the pathophysiology of migraine is well known. Therefore, drugs that regulate CGRP action seem to manage pain transmission caused by activation of the trigeminovascular system [6]. These drugs are known as CGRP inhibitors. They were recently approved by the FDA and are considered safe drugs with few adverse effects. However, the long-term adverse effects are unknown due to short-term and newly approved drugs. There are two classes of CGRP inhibitors: small molecule CGRP receptor antagonists (also termed gepants) and anti-CGRP monoclonal antibodies [6]. The FDA has approved both classes of CGRP inhibitors. They are indicated for patients in whom triptans and NSAIDs are not well tolerated, are ineffective, or have contraindications (e.g., renal insufficiency, peptic ulcer disease, gastritis, bleeding diathesis, or aspirin hypersensitivity) to their use [6]. In addition, since they are rated as non-vasoconstrictive, CGRP inhibitors can be considered a treatment option for patients with a contraindication for triptans and ergot alkaloids use (e.g., history of myocardial infarction, stroke, or multiple vascular risk factors), which are considered vasoactive [6,7].

Small molecule CGRP receptor antagonists (Gepant)

Gepants are used for both acute treatments of migraine and prevention. They are small molecule drugs that inhibit the CGRP receptor [8-10]. Thus, gepants quickly infiltrate the brain and act rapidly, making them an excellent pharmacologic choice for acute migraine. Nevertheless, drug interactions are significant because they are metabolized in the liver, resulting in liver damage [7,11]. The first Gepant approved by FDA in December 2019 for acute treatment of migraine with or without aura in adults was Ubrogepant (UBRELVY, 50 mg, and 100 mg tablets, Allergan, Inc., Dublin, Ireland) [11]. However, it is not indicated for the prevention of migraine. The most common adverse effects include nausea, dry mouth, and insomnia; rare but potential hepatotoxicity should be considered [6]. The second FDA-registered Gepant (February 2020) for use in adult patients in the acute therapy of migraine was Rimegepant (NURTEC ODT, 75 mg orally disintegrating tablet) [6]. Unlike Ubrogepant, Rimegepant can also be used to prevent migraine due to its long half-life (48 h) [9,11]. The most common adverse effects include mild nausea and urinary tract infection; hypersensitivity reactions (including rash and shortness of breath) can be expected after several days of administration [11].

Drug interactions should always be considered when indicating Gepants, especially CYP3A4 inhibitors and inducers. Gepants doses should be adjusted when used concomitantly with moderate CYP3A4 inhibitors (e.g., ciprofloxacin, fluconazole, fluvoxamine, verapamil) because a rise in Gepants plasma level can be seen. These drugs should be avoided in patients using potent CYP3A4 inhibitors (e.g., clarithromycin, ketoconazole, itraconazole) because they can significantly raise Gepant's plasma level. On the other hand, potent CYP3A4 inducers (e.g., phenobarbital, phenytoin, rifampin, St. John's wort) can reduce Gepant's effectiveness [6,11]. A second dose of Ubrogepant should be avoided within 24 h of the starting dose when used with moderate CYP3A4 inhibitors. The second dose of Ubrogepant, 50 mg, may be administered at least 2h after the first dose if needed when Ubrogepant is used with weak inhibitors of CYP3A4 [6]. An administration of the next dose of Rimegepant should be avoided within the next 48 h when Rimegepant is concomitantly administered with moderate inhibitors of CYP3A4A [6].

Anti-CGRP monoclonal antibodies

Monoclonal antibodies (mAbs) are directed against CGRP peptide and CGRP receptors. Unlike gepants, anti-CGRP monoclonal antibodies are macromolecules [8,10]. Hence, their action slowly makes them not an excellent pharmacologic choice for acute migraine. In contrast, they are mainly used for migraine prevention because they have a longer half-life and can be administered subcutaneously. Furthermore, mAbs have few drug interactions and are less likely to cause liver or kidney damage. Four mAbs have been approved to prevent migraine: one against CGRP receptor (Erenumab) and three against CGRP peptide (Fremanezumab, Galcanezumab, Eptinezumab). Even though these drugs have a safety profile, some side effects have been reported. The most common adverse effects include injection site reactions, nausea, constipation, weight gain or loss, anxiety,

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insomnia, depression, irritability, worsening hypertension, and tachycardia. However, severe adverse effects should be considered as recommended by angioedema and anaphylactic reactions and discontinuing the drug [8,10]. Erenumab (AIMOVIG, for subcutaneous injection in a pre-filled syringe or pre-filled pen, 70 mg and 140 mg respectively, Novartis Europharm Limited) was the first monoclonal antibody for the treatment of chronic migraine in adults approved by the FDA and the EMA [6]. Eptinezumab (VYEPTI, 100 mg ampoules), approved by the FDA in February 2020, is the first drug in its class for acute migraine attacks administered intravenously [6].

As mentioned above, mAbs have the advantage of having few drug interactions making them an excellent pharmacologic choice for patients using other drugs. For instance, no significant drug interactions were observed in studies with the concomitant use of Erenumab with oral contraceptives or sumatriptan. Moreover, no drug interactions were reported with Eptinezumab and sumatriptan. Coadministration of a single dose, 300 mg of Eptinezumab (intravenous infusion over 1 h ± 15 min) with a single dose, 6mg, of sumatriptan administered subcutaneously did not significantly affect the pharmacokinetics of Eptinezumab or sumatriptan [6]. Also, acute migraine treatment (analgesics, triptans, ergots) and preventive treatment with Fremanezumab can be applied simultaneously.

Triptans

Another strategy to treat migraine attacks after they start is triptans. They are a group of drugs that act as selective agonists at the ligand-gated, G-protein linked serotonergic, or 5-hydroxytryptamine receptors. Triptans are believed to work in two main ways: the first is the stimulation of the 5-HT1B receptors on smooth muscle cells of blood vessels which causes cranial vasoconstriction. This was initially believed to be the principal mechanism of action of triptans in the treatment of migraine. The second is through 5-HT1D receptors localized on the perivascular trigeminal nerve terminals and the dorsal horn. Stimulating the receptors blocks the release of vasoactive, pro-inflammatory peptides from trigeminal neurons. It inhibits the liberation of neurotransmitters in the dorsal horn, which typically transfers nociceptive information to the thalamus [12,13]. There are seven triptans approved by the FDA at the moment, which include sumatriptan, zolmitriptan, naratriptan, rizatriptan, almotriptan, eletriptan, and frovatriptan [14,15]. To determine which triptan will be better for a particular patient is vital to consider patient preference, the clinical features of the migraine attack, and the presence of contraindications to a specific drug. Triptans are contraindicated in patients using monoamine oxidase inhibitors or those who stopped using them within two weeks because they may double the bioavailability of sumatriptan. Serotonin syndrome is possible in patients simultaneously taking serotonin reuptake inhibitors (SSRIs) and triptans. However, this interaction seems to be uncommon.

The American Headache Society states that the limited evidence provided by case reports does not support limiting triptans with SSRIs or serotonin-noradrenaline reuptake inhibitors used as combination therapy [16,17]. Triptans should not be used for more than ten days per month to avoid the development of medication overuse headache, which presents as a tension headache or migraine-like attack. Significant side-effects, including death, can be caused by Triptans in patients with cardiovascular diseases such as severe hypertension, ischaemic heart disease, previous myocardial infarction, stroke, or coronary vasospasm due to their vasoconstriction effect and inhibition of CGRP release. Therefore triptans are contraindicated in patients with cardiovascular risk and patients with severe hepatic or renal injury and basilar or hemiplegic migraine (uncommon forms of migraine with aura) [15]. To avoid the adverse effects of 5-HT stimulation, the US FDA recently approved a new drug called Lasmiditan. Although the precise mechanism is still unidentified, studies suggest that this drug can relieve migraine through 5-HT1F agonist activity that leads to inhibition of neuropeptide and neurotransmitter release and inhibition of peripheral nervous system's trigeminovascular and CNS pain signaling pathways [18]. Lasmiditan appears to be a new therapeutic option for patients with contraindications for triptan use or patients with unwanted side effects. In this manner, the choices of acute migraine therapies are growing.

Nonsteroidal Anti-Inflammatory Drugs

Some patients can use nonsteroidal anti-inflammatory drugs (NSAIDS) as abortive therapy [19-21]. Simple analgesics that have been proven effective as abortive migraine therapy are the following: Aspirin, Naproxen, diclofenac, celecoxib, Indomethacin, among other over the counter medications [19,22] NSAIDs act by blocking cyclooxygenase enzymes. Therefore, we can summarize that their primary function reduces prostaglandin effects [20]. Some NSAIDs have also been linked to impacting transcription factors, nuclear factor kappa B and Activator protein among them [20]. They also decrease the availability of L-selectins, affecting leukocyte migration during the inflammatory process [20]. NSAIDs, while considered safe and effective in patients with simple migraines, have a large variability of results depending on each patient and their migraine severity; therefore, they can be recommended to patients who have uncomplicated migraines, without other side effects as they are over the counter medicine and of lower cost [20,21,23]. It is essential to note that they interact with CYP-2AC and glucuronidation; Drugs that are cleared by those pathways result in increased drug concentration [20]. Patients who suffer from migraines tend to overmedicate, and as a counterpart, they start suffering from Medication overuse headaches, resulting in worsened symptoms [21,24,25]. NSAIDs are used in this case as bridge therapy, the pathway to which chronic analgesic use is discontinued as treatment [25].

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Most specifically, studies show that the effect of naproxen after ergotamine withdrawal was beneficial in reducing pain, nausea, and vomiting. Therefore, a suggested dosing of 550 mg twice daily in a range of two to four weeks has been used as bridge therapy [25].

Combination Therapy

Migraine treatment is not easy, and it might be necessary to use more than one drug. Combination drugs can be used as a first-line or second-line therapy, and they can also be helpful for refractory migraine treatment. This treatment's efficacy consists of combining different mechanisms of action for better results, or they can also work by potentiating the effect of another drug. One of the combinations that can be used successfully as a first-line abortive treatment is the analgesic combination of acetaminophen 250 mg, aspirin 250 mg, and caffeine 65 mg [26,27]. It is considered superior to acetaminophen monotherapy. It is safe to use in patients with contraindication to vasoconstrictors. The effectiveness of its mechanism of action is that caffeine enhances the NSAID analgesic effects [28]. A study showed that caffeine induces faster absorption and prolongs the half-life of acetaminophen, which is a positive effect but must be considered in patients with liver problems [27]. Caffeine has anti-inflammatory, anticholinesterase, anti-TLR-4, and antioxidant properties. NSAIDs, as mentioned before, inhibit cyclooxygenases (COX) and suppress levels of prostaglandins. The adverse effects that can be seen with this medication depend on each of its components. Caffeine can cause nervousness, dizziness, abdominal discomfort, nausea, irritability, and sleeplessness. Acetaminophen and aspirin may cause skin reactions, hepatotoxicity, and gastrointestinal bleeding. It should never be used in children and teenagers because aspirin can cause Reye's syndrome. This combination is available as an over-the-counter (OTC) treatment and has a low cost.

Another potent combination therapy is sumatriptan and naproxen. There are tablets available in the presentation of sumatriptan 10 mg/ naproxen 60 mg or 85 mg/500 mg. Currently, many different routes of triptan administration are available in the US. These include subcutaneous injections, oral tablets, rapid melt tablets (RMTs), and nasal sprays. Subcutaneous sumatriptan injection was the first commercially available triptan formulation in the world. It is the most excellent effective presentation for patients who tolerate this route of administration because it gives the fastest relief of migraine since it has the most rapid onset. On the other hand, oral tablets are the most commonly prescribed formulations, and patients prefer them for the reason that they are easy to administer and generally have good bioavailability and efficacy, nevertheless is not recommended for patients who cannot tolerate oral route due to nausea and vomiting because it decreases the concentration and effectiveness of the drug. Sumatriptan is a serotonin receptor agonist, and naproxen is an NSAID; their mechanism of action has been discussed previously. Together these compounds mitigate migraine symptoms by reducing neurogenic inflammation, diminishing neuronal excitability, and eliciting vasoconstriction [29]. It can be used in acute attacks but is often a second-line treatment because of its cost [26,30]. Patients achieve good relief when medication is taken early in the episode. Adverse events are less frequent with naproxen than with sumatriptan [31]. Some of the side effects of this medication are dizziness, somnolence, fatigue, nausea, and chest discomfort. A third multidrug oral treatment regimen is isometheptene 65 mg, dichloralphenazone 100 mg, and acetaminophen 325 mg. This regimen is effective in the early treatment of mild-to-moderate migraine [32] and is used primarily on acute attacks.

The FDA approves the use of this combination therapy. Isometheptene is a sympathomimetic drug that causes vasoconstriction. Dichloralphenazone is composed of chloral hydrate and phenazone and works as a sedative. Acetaminophen is an NSAID. Combinations of analgesics containing isometheptene are contraindicated in patients with vascular disease because of its vasoconstrictor properties. The side effects of this medication are drowsiness, dizziness, and nausea. Therefore, patients using any combination therapy must be monitored closely. They must limit the use of this treatment to less than ten days per month to avoid the development of medication overuse headaches (MOH).

Conclusion

Managing migraine is sometimes challenging and depends on the patient's comorbidities, adverse drug effects, and drug interactions. Therefore, every patient should be evaluated in the context to determine the most appropriate course of treatment. Different groups of drugs have been considered in this review. CGRP inhibitors drugs are safe due to their few short-term side effects. However, since they are newly approved drugs, their long-term side effects are unknown. Gepants are helpful in the acute treatment of migraine due to their rapid action caused by their small molecule. However, they have an extremely significant drug interaction, so they must be used with caution to avoid liver damage. On the other hand, the mAbs are macromolecules, they have a slower action, so they are better for preventing migraines. Plus, they have few drug interactions, so they cause less liver or kidney damage. Therefore, they can be applied concomitantly with the treatment of acute migraine.

Triptans are drugs that attack migraine after it begins. Although there are 7 FDA-approved triptans, their pharmacokinetics and administration routes differ, resulting in varying efficacy. In addition, these drugs have significant side effects, such as death in patients with cardiovascular diseases due to their vasoconstrictor effects. Today, we also find the lasmiditan considered the first Ditan. This medication appears to be a new therapeutic option for patients with contraindications for the use of triptans. NSAIDs can be used as abortive therapy for migraine in certain patients. They have variable results depending on the patient and the severity of the migraine. As a result, they are safe and effective in patients

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with uncomplicated or straightforward migraines. Additionally, these drugs can be used as bridging therapies in overmedication cases. Due to the different mechanisms of action, combined therapy can enhance the results of another drug or improve its effects. This treatment can be used as the first or second line, depending on the context of the patient. For first-line abortive treatment of migraine, the American Headache Society and the FDA recommend using acetaminophen, aspirin, and caffeine. Use of sumatriptan and naproxen mitigates migraine symptoms but is used as second-line combination therapy due to cost; and isometheptene, dichloralphenazone, and paracetamol are indicated for the early treatment of mild to moderate migraine in acute attacks. Furthermore, it should be noted that combination therapy is effective but should be monitored and limited to avoid medication overuse headaches. Since migraine is a prevalent condition, all medical professionals must be up to date on migraine treatment methods because studies in this area are lacking.

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