INNOVATIVE HEADACHE DELIVERY SYSTEMS WILL BE BETTER THAN WHAT WE CURRENTLY HAVE: YES

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Acute headache medication is the best option in patients with infrequent attacks and/or bad compliance. The aim of acute medications is to relieve or stop the progression of the attack eliminating the pain and the associated symptoms in order to finish with the attack. With the traditional delivery routes, we can obtain this in 70-80% of attacks; for this reason, we need to develop new delivery systems to improve the efficacy of the acute treatments.

DHE is only an alternative in very selected patients with migraine, due to the limited efficacy and adverse events. An orally inhaled and self-administered formulation of DHE delivered to the systemic circulation (known as MAP0004), has been developed. MAP0004 aerosol DHE provides desirable activation of 5-HT1B/1D receptors, resulting in effective antimigraine effect. Unlike intravenous DHE, MAP0004 is less likely to bind with other serotonergic, adrenergic, and dopaminergic receptors, resulting in fewer side effects. MAP0004 administered alone shows no statistically significant drug-related increase in nausea compared to conventional intravenous DHE, which is generally administered with an antiemetic medication. MAP0004 is less arterio-constrictive than intravenous DHE. MAP0004 has been proven to be effective and well tolerated for acute migraine treatment. It provides statistically significant pain relief and freedom from photophobia, phonophobia, and nausea compared with placebo. Both Phase II and III clinical trials support its antimigraine efficacy. MAP0004 has a superior tolerability, compared to intravenous DHE. MAP0004 may be a promising first-line agent for migraine treatment, with lower rates of nausea and vomiting than other DHE routes of administration (35-37).

Sumatriptan was the first triptan introduced in the market and it was available as a subcutaneous injection, an oral tablet, a nasal spray, dispersible tablet, and rectal suppository. In the last years new formulations that offer more advantages over the traditional have been developed.

The newest transdermal way of administration by using transdermal iontophoretic patches was recently approved by the US FDA. This way of application bypasses hepatic first-pass metabolism and avoids gastric transit delay. An excellent tolerability (with no triptan-related adverse events) and superior efficacy versus placebo has been demonstrated. Transdermal sumatriptan was superior to oral triptans for migraine patients whose nausea is the reason for delay or avoidance of acute treatment. The patches are a promising choice of treatment in patients with intolerable triptan-related adverse events, as well as in migraineurs with disabling vomiting and poor absorption of oral medication. A needle-free device for sumatriptan injection is available in the USA with efficacy similar to traditional sc administration. Also, a new formulation of breath – powered powder sumatriptan with intranasal administration is in research, trying to increase the speed of action and to reduce the adverse events, with a very good efficacy profile in the preliminary results.

All these nonoral routes alternatives of administration offer a useful alternative delivery system for patients who have difficulty swallowing conventional tablets and for patients whose nausea and/or vomiting impede swallowing tablets and/or make the likelihood of complete absorption unpredictable. These different formulations offer migraineurs the possibility of using abortive treatment at the onset of migraine attacks without the need of liquids, anytime and anywhere.

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