

A particular case of facial paraesthesias due to a meningioma

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Background: Meningiomas are the most frequently diagnosed primary brain tumors (about 30% of all primary brain and central nervous system tumors). Although most are benign, their intracranial location may lead to severe and even potentially lethal consequences. Most meningiomas are asymptomatic, some may cause seizures and others may lead to focal signs. Here, we aim to show a particular case of facial paraesthesias due to the uncommon cause of a meningioma.

Methods: A 63-year-old woman came to our outpatient neurological clinic for the gradual onset of paraesthesias to the left half of the superior lip in three months. Her complaint started as a tingling sensation and became progressively more and more intense until turning into a burning and swelling sensation. The sensations were constant, worsened by speaking and reduced during the night. We first prescribed a medical therapy (pregabalin and a supplement drug containing vitamins B1, B6, E and α -lipoic acid). After, the patient underwent a massive facial MR and, later, a brain contrast enhanced (CE) MR. Finally, she underwent a neurosurgical and a radiotherapy consultation and cyberknife intervention.

Results: Neurological examination was irrelevant, symptoms decreased just a little after medical therapy. The basic massive facial MR showed only an intrasellar arachnoidocele. The following brain CEMR showed an extracranial vascularised formation at the level of left cerebellopontine angle (coronal diameter 13x12mm, axial one 16.7x16.4mm), with marked dural contrast enhancement and associated to compression of the origin of left trigeminal nerve and Gasser's ganglion. Such formation was referable to a meningioma. Neurosurgeon suggested to consult a radiotherapist, who set two options: watchful waiting or performing cyberknife intervention; our patient chose the latter option (25Gy in 5 fractions) with a reduction of symptoms (no more swelling sensation and no speech worsening), but persistence of paraesthesias.

Conclusions: Cerebellopontine angle tumors may cause trigeminal neuralgia, but such painful condition is usually brief, intense and electric shock-like. In our case, the meningioma is probably the cause of such particular clinical presentation and cyberknife intervention may have reduced tumor dimensions, soothing symptoms. Since the patient did not recover fully, other approaches are still needed.

The prevention of migraine without aura with KUZIK®. An open-label observational trial

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Background: Kudzu (*Pueraria lobata*) is a wild climbing plant native to Central Asia belonging to the Fabaceae family, with a root having a high content of isoflavones. This open-label observational study evaluated the efficacy and tolerability of kudzu (K) developed with an innovative programmed release technology (Kuzik® by GAM FARMA) in a sample of 60 consecutive patients with migraine without aura (MWOA), who needed prophylaxis treatment (diagnosis and prophylaxis according to ICDH-II)

Methods: Sixty patients (F/M = 13/47, age: 37.9±11.4) with MWOA received K at a dose of 1 cps UID for 120 days. The efficacy of the

treatment was evaluated considering the days of headache per month (primary endpoint), pain intensity according to the NRS scale and NSAID consumption per month (secondary endpoints), at T0, T1 and T2 (after 60 and 120 days of therapy), with the help of the patient's headache diary.

Results: **Frequency:** At T0, was 10.1±3.2. At T1, the average frequency was 6.8±3.2 (min: 0 max: 15) resulting in a statistically significant mean reduction of 3.3 attacks (I.C. 95%: 2.6 - 3.9; p<0.001). At T2 the value was 5.7 ± 2.8 with an average reduction, compared to T0, of 4.4 (95% CI: 3.6 - 5.2; p<0.001). The percentage of patients who observed a reduction equal to or greater than 50% in the frequency was 16.7% at T1 and 31.7% at T2. **NRS:** The mean value on NRS on T0 was 8.3±3.2. At T1, a statistically significant reduction of 2.0 points was observed (I.C. 95%: 1.5 - 2.5%; p<0.001). At T2, the mean reduction from baseline was 2.7 points (I.C. 95%: 2.0 - 3.4%; p<0.001). **NSAID Consumption:** At T0 the average consumption of NSAID was 9.5±4.7 units. At T1 the consumption was reduced by 3.6 units (95% CI: 2.5 - 4.7, p<0.001), this reduction was substantially confirmed at T2 (4.5, 95% CI: 3.2 - 5.7, p<0.001) with NSAID consumption 5.0±3.1 units.

Conclusions: The prophylactic use of Kudzu resulted in a reduction equal to or greater than 50% of the frequency in 31.7% of patients, a significant reduction in the average consumption of NSAID and in the NRS score. No side effects were reported during therapy. These data demonstrate the efficacy of Kudzu as prophylaxis treatment for migraine without aura, associated with good tolerability.

Efficacy of fremanezumab in patients with chronic migraine with or without concomitant use of preventive medication

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Background: Some patients with CM may take more than one preventive medication. Fremanezumab (TEV-48125), a fully humanized monoclonal antibody targeting calcitonin gene-related peptide (CGRP), has demonstrated efficacy in migraine prevention.

Methods: In this Phase III, randomized, double-blind, placebo-controlled, parallel-group study, eligible patients with prospectively confirmed CM (≥15 headache days and ≥8 migraine days per month) were randomized 1:1:1 to receive subcutaneous injections of fremanezumab quarterly (675 mg at baseline; placebo at Weeks 4 and 8), fremanezumab monthly (675 mg at baseline; 225 mg at Weeks 4 and 8) or placebo at each time point over a 12-week treatment period. Changes from baseline were assessed in the monthly average number of headache days of at least moderate severity, and in migraine days in patients with or without concomitant preventive medication.

Results: Analyses included 239 patients receiving one concomitant preventive medication (quarterly, N=77; monthly, N=85; placebo, N=77) and 882 patients receiving none (quarterly, N=298; monthly, N=290; placebo, N=294). During the 12-week treatment period, fremanezumab reduced from baseline the mean number of monthly headache days of at least moderate severity versus placebo in patients receiving concomitant preventive medication (quarterly: -3.8±0.61; monthly: -4.5±0.57; placebo: -2.5±0.61), reaching significance with monthly dosing (P=0.003). Reductions were also significant for fremanezumab quarterly and monthly in those not receiving concomitant preventive medication (quarterly: -4.6±0.33; monthly: -4.9±0.33; placebo: -2.7±0.33; both, P<0.0001). These reductions were observed as early as 4 weeks after initiation of fremanezumab monthly in patients receiving concomitant preventive

THE PREVENTION OF MIGRAINE WITHOUT AURA WITH KUZIK® AN OPEN-LABEL OBSERVATIONAL TRIAL

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INTRODUCTION

Kudzu (*pueraria lobata*) is a wild climbing plant native to Central Asia belonging to the Fabaceae family, with a root having a high content of isoflavones. This open-label observational study evaluates the efficacy and tolerability of kudzu (K) developed with an innovative programmed release technology (Kuzik® by GAM FARMA: Kudzu d.e. 200 mg: Isoflavons 80 mg - Puerarin 60 mg, Cucumber d.e. 60 mg, MSM 150 mg) in a sample of 60 consecutive patients with migraine without aura (MWOA), who need prophylaxis treatment (diagnosis and prophylaxis according to ICDH-II)

MATERIALS AND METHODS

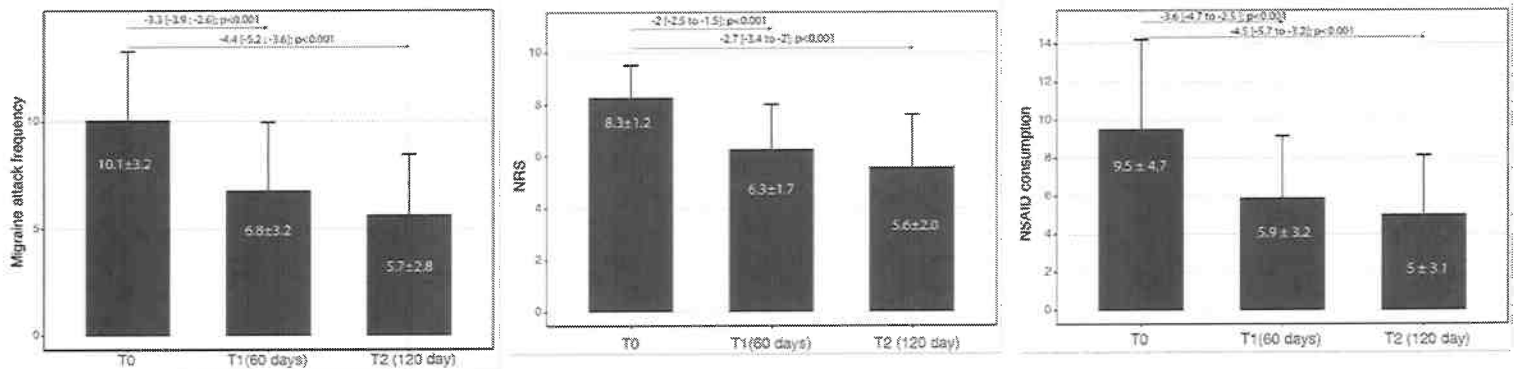
Sixty (60) patients (F / M = 13/47, age: 37.9 ± 11.4) with MWOA received K at a dose of 1 cps UID for 120 days. The efficacy of the treatment was evaluated considering the days of headache per month (primary endpoint), pain intensity according to the NRS scale and NSAID consumption per month (secondary endpoints), at T0, T1 and T2 (after 60 and 120 days of therapy), with the help of the patient's headache diary.

RESULTS

- **Frequency:** At T0, was 10.1 ± 3.2 . At T1, the average frequency was 6.8 ± 3.2 (min: 0 max: 15) resulting in a statistically significant mean reduction of 3.3 attacks (I.C. 95%: 2.6 - 3.9; $p < 0.001$). At T2 the value was 5.7 ± 2.8 with an average reduction, compared to T0, of 4.4 (95% CI: 3.6 - 5.2; $p < 0.001$). The percentage of patients who observed a reduction equal to or greater than 50% in the frequency was 16.7% at T1 and 31.7% at T2.

- **NRS:** The mean value on NRS on T0 was 8.3 ± 3.2 . At T1, a statistically significant reduction of 2.0 points was observed (I.C. 95% 1.5 - 2.5%, $p < 0.001$). At T2, the mean reduction from baseline was 2.7 points (I.C. 95% 2.0 - 3.4%, $p < 0.001$).

- **NSAID Consumption:** At T0 the average consumption of NSAID was 9.5 ± 4.7 units. At T1 the consumption was reduced by 3.6 units (95% CI: 2.5 - 4.7, $p < 0.001$), this reduction was substantially confirmed at T2 (4.5, 95% CI: 3.2 - 5.7, $p < 0.001$) with NSAID consumption 5.0 ± 3.1 units.



DISCUSSION AND CONCLUSIONS

The prophylactic use of Kudzu gave a reduction equal to or greater than 50% of the frequency in 31.7% of patients, a significant reduction in the average consumption of NSAID and in the NRS score. No side effects were reported during therapy. These data demonstrate the efficacy of Kudzu as prophylaxis treatment for migraine without aura, associated with good tolerability.

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