UNWIND THE PAIN

PALMIGES

(A Patent Applied Product)

Background:

- Neuropathic pain is as defined by International Association for the Study of Pain (IASP), "pain caused by a lesion or disease of the somatosensory nervous system" and affects 7–10% of the general population.
- Multiple causes of neuropathic pain have been described and its incidence is likely to increase owing to the ageing global population, increased incidence of diabetes mellitus and improved survival from cancer after chemotherapy.

Prevalence:

- In primary medical care settings, the prevalence has been reported to be between 2 and 11%.[1]
- By Neuropathy Symptom Score (NSS) and Neuropathy Disability Score (NDS) criteria, the prevalence of DPN was 29.2%.[1]
- Cancer patients indicate a prevalence of 19 %.[1]
- Prevalence estimates of neuropathic pain in low back-related leg pain (LBLP) patients varied from 19% to 80%.[2]

Current treatment modalities and their Drawbacks:

- Current treatment drugs such as gabapentin, pregabalin and duloxetine etc have annoying side effects such as drowsiness, dizziness, blurred vision, somnolence, peripheral edema etc.
- Moreover using these drugs on long term causes desensitisation of neuro receptors. Therefore, there is increase in the dose of these drugs to elicit the desired response and that leads to more number of side effects. In addition, some require dosage adjustments in renal impairment.
- Hence, the currents treatment paradigm have some gaps and require some new arsenal to fight against Neuropathic Pain.

PALMIGES

Clinical Evidence:

"Palmitoylethanolamide, A Special Food For Medical Purposes, In The Treatment Of Chronic Pain: A Pooled Data Meta-analysis"*

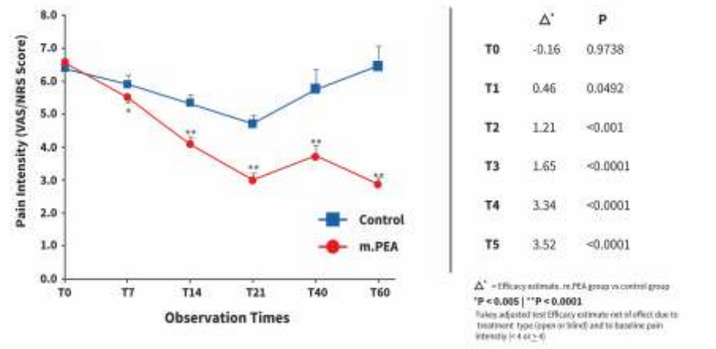
Source of Pain	Study Design	n°	Regimen of m.PEA or u.m.PEA	Published Studies & Proceedings	Unpublished Studies
Lumbosciatica	Double blind, two doses, randomized, controlled m.PEA vs placebo + NSAIDs when needed	636	1st arm 300mg/day m.PEA x 21 days 2nd arm 600mg/die m.PEA x 21 days +NSAIDs when needed	Guida G et al. 2010 (42)	
Carpal tunnel syndrome in diabetic patients	Open controlled randomized m.PEA vs no treatment	40	1200mg/day m.PEA x 60 days	Assini A et al. 2010 (68)	
Carpal tunnel course pre-and post-operative	Open controlled randomized m.PEA vs no treatment	50	1200mg/day m.PEA x 60 days		Evangelista M. 2015 a
Carpal tunnel syndrome	Double blind, randomized, controlled u.m.PEA vs placebo + NSAIDs when needed	48	1200mg/day u.m.PEA x30 days + NSAIDs when needed		Zanette G 2015b
Radiculopathy (331) Osteoarthritis (54) Herpes Zoster (44) Diab. Neuropaty (32) Failed back surgery (76) Oncologic (22) Other diseases (51)	Open-label	610	1200mg/day u.m.PEA x 21 days followed by 600mg/ day u.m.PEA x 30 days (+anticonvulsant, opioid and rescue drugs except 90 patients)	Gatti A et al. 2012 (69)	
Low back pain	Open-label	20	1200mg/day u.m.PEA + Oxyicodone x 30 days	Desio P.. 2011 (70)	
Diabetic neuropathy (11) Postherpetic neuralgia (19)	Open-label	30	1200mg/day u.m.PEA +Pregabalin x 45 days	Desio P.. 2010 (71)	
Diabetic neuropathy (23) Postherpetic neuralgia (7)	Open-label	30	1200mg/day u.m.PEA x 40 days	Cocito D et al. 2014 (72)	
Post stroke	Open controlled, randomized, u.m.PEA + Physiotherapy vs only Physiotherapy	20	1200mg /day u.m.PEA x 60 days followed by 600mg/ day u.m.PEA x 30 days	Parabita M et al. 2011 (73)	
Neuropathic pain induced by chemotherapy	Open label	10	1200mg /day u.m.PEA x 60 days		Spada S. 2015c
Multiple Sclerosis	Double blind, randomized, controlled u.m.PEA vs placebo	27	1200mg /day u.m.PEA x 365 days	Montella S et al., 2014 (74)	
Charcot Marie Tooth	Open label	12	1200mg /day u.m.PEA x 80 days	Montella S et al., 2014 (74)	Putzu GA. 2015d.

Clinical trials selected for pooled meta-analysis.

a. Department of Anesthesia and Intensive Care, Catholic University, Roma, Italy. Manuscript in preparation. b. Researcher affiliation: Section of Neurology, Pederzoli Hospital, Peschiera del Garda Verona, Italy. Manuscript in preparation. c. Division of medical oncology. Hospital "Rizzo," Siracusa, Italy. Manuscript submitted to Pain Medicine. d. Neurology and Clinical Neurophysiology, Casa di Cura Polispecialistica Sant'Elena, Cagliari, Italy. Manuscript submitted to Journal of Pain Management. *rescue drugs = Paracetamol + Tramadol

Distribution of patients according to pain Etiology.

	Etiopathogenesis			
	Degenerative	Neuropathic	Mixed	Miscellaneous
Patient number	1174 (79.1%)	170 (11.5%)	82 (5.5%)	58 (3.9%)



Changes in pain intensity in patients treated with PEA and control groups at different observation times. Values are expressed as mean + SEM

- All observations on the intensity of pain (4,435) relating to 1,484 patients were analyzed by repeated measures GLMM, using as descriptive variables: study type, baseline pain intensity, time, and treatment.
- Pain reduction was more evident in the group treated with PEA compared to controls.

Conclusion

- PEA induced pain relief is progressive, age and gender independent, and not related to etio-pathogenesis of chronic pain.
- PEA controls mechanisms common to different conditions where chronic pain or neuropathic pain is associated, e.g. Neuroinflammation.

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Description :

- PALMIGES counters the condition of Inflammation in Neuropathic Pain resulting in lowering/ alleviating the symptoms of chronic Pain.
- PALMIGES is a composed of PEA, Genistein and Daidzein manufactured in accordance with MPFAITECH technology.
- RITALA is the proprietary blend & is manufactured in Technical Collaboration with ENAVANT Research LLC, USA.
- RITALA and MPFAITECH are the Registered Trademarks of Enavant Research LLC. USA.

Indications :

- Chronic Pain
- Neuropathic Pain
- Diabetic Neuropathy
- Sciatic Pain & Nerve compression pain
- Fibromyalgia
- Trigeminal Neuralgia
- Migraine

PALMIGES contains the following components :

Palmitoylethanolamide (PEA)	• Palmitoylethanolamide (PEA) is considered an endogenous PPAR- agonist or activator, interacting with this receptor to inhibit inflammatory pathways & oxidative stress. • During chronic pain, PEA can modulate the PPAR pathway that is able to attenuate NFκB induced inflammatory factors (IL-1, or TNF), inhibit infiltration and activation of MC, reduce mesangial matrix proliferation induced by reactive oxidative stress (ROS) which then resulted in albuminuria.
Genistein	• Genistein, is an FAAH Inhibitor that prevents the degradation of PEA from FAAH enzyme in the body & also exert synergistic effect with PEA to reduce oxidative stress in the over-inflamed neuronal cells.
Daidzein	• Daidzein belongs to the class of isoflavones and serves as a potent FAAH Inhibitor in conjunction with Genistein. It works as a competitive binder to FAAH disallowing it to degrade the externally supplemented PEA.
MPFAITECH	• A Technology to ensure the proprietary blend is presented in a form that could be easily absorbed in the human body.

Dosage :

- Standard recommended daily dose of Palmiges is 1- 2 capsules preferably divided over the day
- Or as prescribed by Medical Practitioner

References :
1. J Indian Prosthodont Soc. 2016 Apr-Jun; 16(2): 114–115
2. The journal of Pain.,june 2017.

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