Clinical Case Reports International

Case Study
Published: 30 May, 2022

A Palmitoylethanolamide (PEA) and Magnesium Based Product (PEAMag) Reduces the Pain and Improves Quality of Life in Patients Affected by Acute and Chronic Pelvic Pain

Marco Rinaldi[1,2], Sebastiano Di Lena[1], Deborah Luccarelli[3] and Carlo Bettocchi[4,5]*

[1]Department of Urology, Western Hospital Unit "San Pio", Italy

[2]Department of Urology, University of Bari, Italy

[3]Department of Pharmacy, University of Bari, Italy

[4]Department of Urology, University of Foggia, Italy

[5]European Society for Sexual Medicine (ESSM), Italy

Abstract

Aims: To assess the analgesic efficacy of a Palmitoylethanolamide and Magnesium based product (PEAMag) on acute and chronic pelvic pain due to different causes, such as CPPS, acute and chronic prostatitis, acute and recurrent cystitis and bladder stones.

Methods: A pilot, open-label, prospective, monocentric study was carried out involving 32 patients treated with PEAMag sticks administered orally sublingual for a period of 3 months. Pelvic pain was evaluated using the Visual Analogue Scale (VAS score) and Quality of Life (QoL) associated with pelvic pain using number 9 domain (Quality of Life) of the Italian version of the NIH-CPSI scale.

Results: A significant and progressive reduction in pain intensity after 1 month of treatment with PEAMag ($p<0.001$) and after 3 months of treatment ($p<0.001$) and a significant improvement in Quality of Life after 1 month of treatment ($p<0.0001$) and after 3 months of treatment ($p<0.001$) was observed. The results show also improvements from one month after treatment to 3 months after treatment.

Conclusion: These data highlight the potential benefit of PEAMag in patients with varying nature and intensity acute and chronic pelvic pain and confirm the good safety profile of PEA and magnesium based product.

Keywords: Pelvic pain; PEA; Magnesium; Acute prostatitis; Chronic prostatitis; Cystitis; CPPS

OPEN ACCESS

Correspondence:
Marco Rinaldi, Department of Urology, Western Hospital Unit "San Pio", Castellaneta, Italy,
E-mail: marrin91@yahoo.it

Received Date: *05 May 2022*
Accepted Date: *23 May 2022*
Published Date: *30 May 2022*

Citation:
Rinaldi M, Di Lena S, Luccarelli D, Bettocchi C. A Palmitoylethanolamide (PEA) and Magnesium Based Product (PEAMag) Reduces the Pain and Improves Quality of Life in Patients Affected by Acute and Chronic Pelvic Pain. Clin Case Rep Int. 2022; 6: 1337.

Introduction

Pelvic pain is a condition that can appear as acute or chronic, characterized by painful symptomatology in pelvic and/or perineal region and depends on different pathology both man and woman [1-6].

Therapeutic approach on pelvic pain can be managed in different way. About medical approach there are many drug compounds, including food supplements. About these last, they already proved the efficacy in pain reduction PEA based compounds [7] for analgesic and anti-inflammatory activity [8]. In addition Magnesium showed positive analgesic effects in general, mainly for antagonistic action against NMDA receptors [9].

PEAMag is a compound consisting of Palmitoylethanolamide (PEA) and magnesium, administered sublingual [10].

Palmitoylethanolamide (PEA) is an endogenous cannabinoid with anti-inflammatory (reducing the release of inflammatory mediators) and analgesic properties, also acting on the processes of neuropathic pain [11].

In terms of antinociceptive mechanism of action, magnesium acts as an antagonist of the NMDA receptor, which prevents central sensitization and attenuates hypersensitivity to pain [9].

Table 1: Values and data are expressed as means ± standard deviation.

	MEAN ± SD	%
Age	54.8 ± 19.2	
Sex		
M		50%
F		50%
Acute prostatitis		6.50%
Acute cystitits		22%
CPPS		9%
Bladderstones		6.50%
Chronicprostatitis		28%
Recurrentcystitis		28%
VAS score before treatment	7.2 ± 1.3	
VAS score after 1 month treatment	2.1 ± 1.3	
VAS score after 3 months treatment	0.8 ± 0.9	
QoLbefore treatment	4.1 ± 0.8	
QoLafter 1 month treatment	1.2 ± 0.9	
QoLafter 3 months treatment	0.3 ± 0.5	

This clinical investigation was carried out to assess the efficacy of a PEA and Magnesium Based Product (PEAMag) on acute and chronic pelvic pain.

Methods

Study design and patient population

This clinical trial was performed at "San Pio" Hospital, Castellaneta, Italy. Both female and male patients aged from 21 to 87 years with a diagnosis of acute or chronic pelvic pain from multiple pathological causes (Acute and Chronic prostatitis, Acute and Chronic Cystitis, CPPS, Bladder stones) were enrolled.

Eligible patients had to meet following criteria: Presence of suprapubic and/or perineal pelvic pain.

A baseline visit was carried out before treatment start.

The first patient was enrolled on 2021 January, and the last patient completed the study on 2022 January.

PEAMag treatment

Eligible patients received a single stick containing 1200 mg PEA plus 140 mg Magnesium (PEAMag 1200) once daily for 28 days followed by a single stick containing 600 mg PEA plus 70 mg Magnesium (PEAMag 600) once daily for 56 days.

Clinical assessments

An initial screening visit was performed to determine patient eligibility and diagnosis of type of pelvic pain and the pathological causes.

The primary endpoint was reduction in pelvic pain intensity, evaluated by the Visual Analogue Scale (VAS) at baseline, after one-month of treatment and after three-month treatment (after, 1 and 3 months from beginning). The patients were asked to indicate pain intensity on the scale from 0 "no pain" to 10 "the most painful sensation imaginable".

The Secondary endpoint was improvement from baseline in quality of life associated with pelvic pain, recorded using number 9 domains (Quality of life) of the Italian version of the NIH-CPSI scale [4]. The patients were asked to indicate QoL on the scale from 0 (Delighted) to 6 (Terrible). The assessment of safety included the registration of all investigator-assessed adverse events. All study visits were carried out by a clinician.

Statistical analysis

The results obtained by evaluating VAS (Visual Analogue Scale) pain intensity score and associate pelvic pain Quality of Life (QoL) were analyzed using the domain number 9 of the Italian version of the NIH-CPSI scale in order to evaluate mean changes across time [4-6]. Windows Excel for Mac-OS calculator was used to calculate means values obtained by VAS pain intensity score and the QoL at the end of 1-month and 3-month PEAMag treatment *vs.* mean values obtained before starting PEAMag treatment; Windows Excel for MacOS was used to conduct other statistical analyses such as standard deviation and p values.

Data and values are expressed as mean ± Standard Deviation (SD), if not otherwise stated. Results are considered significant for p values less than 0.05.

Results

Patients characteristics

Thirty-two patients of both sexes with age of 54.8 ± 19.2 (four patients aged from 21 to 30 years; 4 from 31 to 40 years; 5 from 41 to 50 years; 4 from 51 to 60 years; 7 from 61 to 70 years; 5 from 71 to 80 years; three patients over 80 years) between 21 and 87 years were enrolled in the study. Females accounted for 50% (16/32) of enrolled patients and males the remainder 50% (16/32).

The associate medical condition causing pain includes 6.5% acute prostatitis; 22% acute cystitis; 9% CPPS; 6.5% bladder stones; 28% recurrent cystitis; 28% chronic prostatitis.

Patient demographic and baseline clinical characteristics are reported in Table 1.

PEAMag effect on pain intensity

During PEAMag treatment, the average pain intensity score evaluated by VAS decreased from 7.2 ± 1.3 at baseline to 2.1 ± 1.3 to 1-month after treatment in patients. This reduction in mean score was significant ($p<0.001$) (Figure 1). The results improve with a further significant decrease at 3 months. The VAS score decreased from 7.2 ± 1.3 at baseline to 0.8 ± 0.9 to 3 months after treatment. This reduction in mean score was significant ($p<0.001$) (Figure 2).

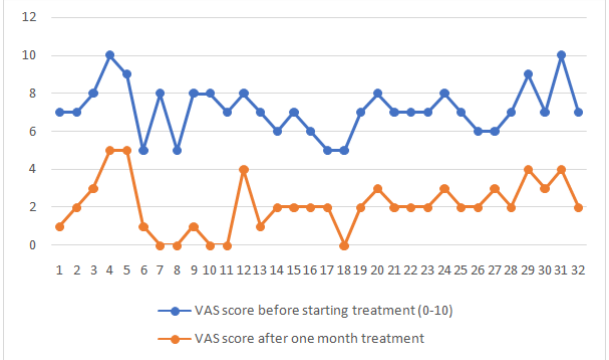

Figure 1: Effect of PEAMag on pain intensity scores after 1 month of treatment.

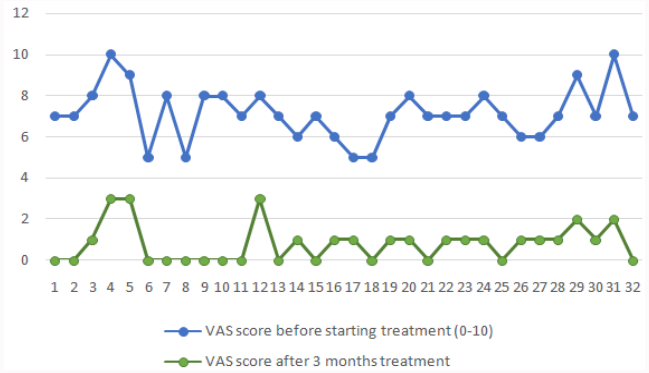

Figure 2: Effect of PEAMag on pain intensity scores after 3 months of treatment.

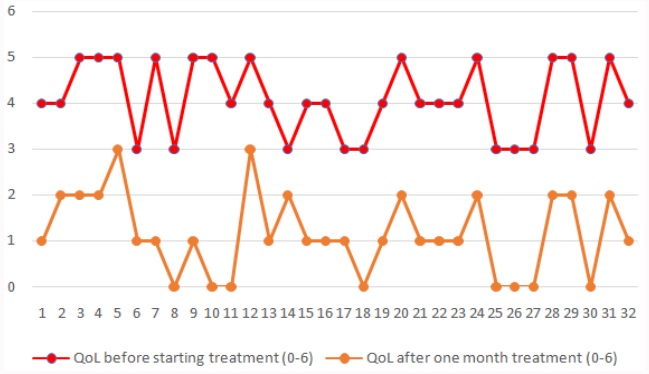

Figure 3: Effect of PEAMag on QoL after1month of treatment.

PEAMag Effect on Quality of Life (QoL) score of the domain number 9 of the Italian version of NIH-CPSI

During PEAMag treatment, the average QoL score evaluated by domain number 9 of Italian version of NIH-CPSI decreased from 4.1 ± 0.8 at baseline to 1.2 ± 0.9 to 1-month after treatment. This reduction in mean score was highly significant ($p<0.0001$) (Figure 3). The QoL score decreased from 4.1 ± 0.8 at baseline to 0.3 ± 0.5 to 3 months after treatment. This reduction in mean score was significant ($p<0,001$) (Figure 4).

Discussion

The main goals of pelvic pain treatment are commonly based on maximizing symptomatic control of pain and quality of life while avoiding adverse events and treatment complications [5]. The present results show that 1 month of PEAMag treatment leads to a significant reduction in acute and chronic pelvic pain in patients with pelvic pain associated with many pathologies and these results improve after 3 months of treatment.

Patients did not report any adverse events during and after PEAMag treatment, with the exception of one episode of mild diarrhea after three months of treatment in a patient also being treated with nitrofurantoin (long term low dose therapy) therefore not univocally associated with PEAMag.

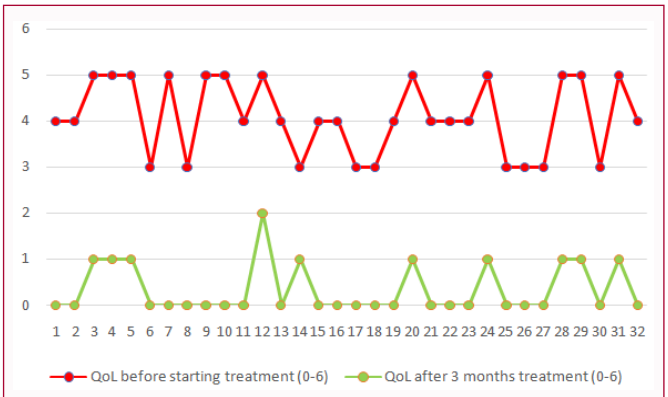

Figure 4: Effect of PEAMag on QoL after 3 months of treatment.

These results, although obtained in an open-label pilot survey and on a limited number of patients, highlight the potential benefit of PEAMag in patients with acute or chronic pelvic pain and confirm the good safety profile of this product. The present data need to be confirmed in a larger multisite placebo-controlled, double-blind clinical study.

References

1. Yu Maksimova M, Sharov MN, Zaitsev AV, Prokofyeva YS, Rachin AP, Rachin SA. Chronic pelvic pain syndrome in women: Diagnostic and therapeutic aspects. Urologiia. 2020;(6):156-61.
2. Vi NH, Anthony JS. Acute and chronic prostatitis. Med Clin North Am. 2004;88(2):483-94.
3. Jonathan CG. Cystitis and pelvic pain management: Guidelines versus real-world practice. Urologia. 2017;84(Suppl 1):1-4.
4. Gianluca G, Nicola M, Alfonso C, Andrea R, Giuseppe L, Fabrizio T, et al. The Italian version of the National Institutes of health chronic prostatitis symptom index. Eur Urol. 2005;47(6):805-11.
5. Maria BP, Vincenzo P, Pasquale S, Caterina A, Lorenzo DN, Maria CP. Chronic pelvic pain: Assessment, evaluation, and objectivation. Pain Res Treat. 2017;2017:9472925.
6. Propert KJ, Litwin MS, Wang Y, Alexander RB, Calhoun E, Nickel JC, et al. Responsiveness of the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI). Qual Life Res. 2006;15(2):299-305.
7. Cervigni M, Nasta L, Schievano C, Lampropoulou N, Ostardo E. Micronized Palmitoylethanolamide-Polydatin reduces the painful symptomatology in patients with interstitial cystitis/bladder pain syndrome. Biomed Res Int. 2019;2019:9828397.
8. Passavanti MB, Alfieri A, Pace MC, Pota V, Sansone P, Piccinno G, et al. Clinical applications of palmitoylethanolamide in pain management: Protocol for a scoping review. Syst Rev. 2019;8(1):9.
9. Shin HJ, Hyo-Seok N, Do SH. Magnesium and Pain. Nutrients. 2020;12(8):2184.
10. Tarun G, Bhaskara J, Li X. Sublingual drug delivery. Crit Rev Ther Drug Carrier Syst. 2008;25(5):449-84.
11. Linda R, Christopher JF. The basal pharmacology of palmitoylethanolamide. Int J Mol Sci. 2020;21(21):7942.