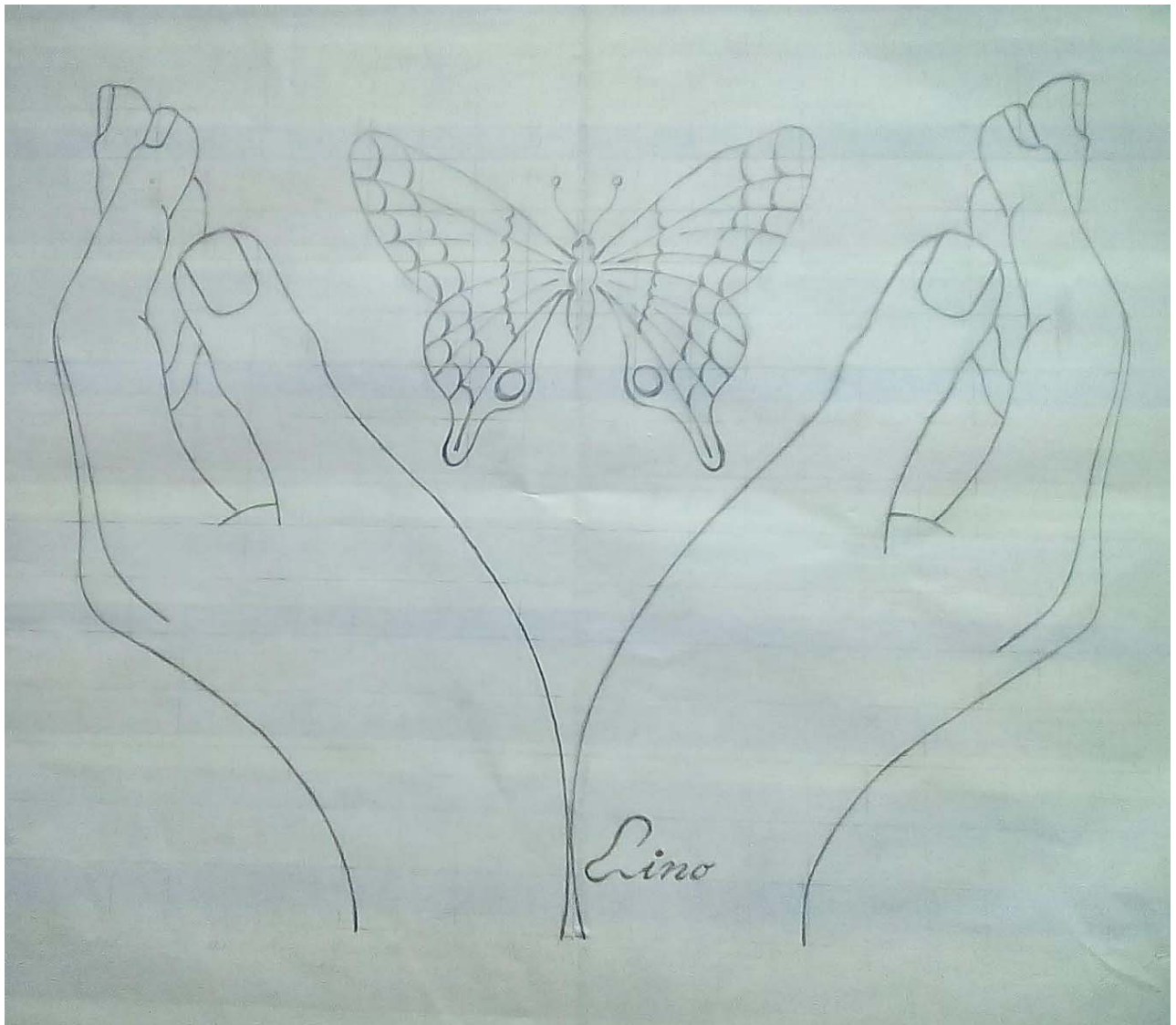


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Safety of palmitoylethanolamide in elderly patients with comorbidities: medical and nursing aspects.

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KEYWORDS: Comorbidity, QTc; QT, CV RISK.

Background: comorbidities represent increasingly present clinical conditions in relation to the lengthening of the average life of the population. The analysis of the current Lexis pyramids allows us to extrapolate the modification characterized by the narrowing of the base linked to the low birth rate and by the transformation of the pyramid into a trapezoidal figure. The QT, Qtc and Tpeak to Tend indices are proposed indices for arrhythmic risk stratification. **Aim:** The aim of this study is to evaluate, through the HRV analysis, the safety of the nutraceutical formulation with palmitoylethanolamide explored by Qt, Qtc and Tpeak to T end index. **Materials and Methods:** In our study we enrolled 26 patients (16 men and 10 women) with a mean age of 81 + 6.9 years. All patients enrolled in the study gave their informed consent to the observational study. All patients continued their pharmacological treatments in compliance with professional ethics. at the time of enrolment, patients will undergo non-invasive electrocardiographic recording to evaluate the effect of treatment on cardiovascular risk explored by the analysis of QT, Qtc and Tpeak to Tend Index (Tp/Te). The three different cardiovascular risk indices were evaluated by electrocardiographic tracing at the baseline state and after 30 days of treatment. Data were measured with xai-medica cardiolab software and analyzed using SigmaStat 3.5 software for Windows. The paired T-test was used to analyze the different variables and to compare the treatment effect. Statistical significance was set at $P < 0.05$. **Results:** our pilot study conducted on 26 patients allowed us to highlight that the nutraceutical reduces heart rate and the arrhythmic index QT, even if not significantly, it is irrelevant on the arrhythmic risk and can be administered safely even in elderly patients (QT, Qtc and Tp/Te). The absence of any statistically significant change in QT, Qtc and Tp/Te index is a significant clinical advantage since it excludes correction with arrhythmic risk. **Discussion and Conclusions:** The data of the present study underline that the nutraceutical reduces the heart rate and the QT, even if significantly and has no influence on the arrhythmic risk, therefore it can be administered safely even in elderly patients. However, further studies are needed to validate the data across all population groups. **Limitations of the study:** due to the poor compliance of the patients, there are no definitive data on the anti-inflammatory role (VES, CRP, white blood cells) of palmitoylethanolamide in the patients undergoing the study.

References:

1) Marcucci M, Germini F, Coerezza A, Andreinetti L, Bellintani L, Nobili A, Rossi PD, Mari D. Efficacy of ultra-micronized palmitoylethanolamide (um-PEA) in geriatric patients with chronic pain: study protocol for a series of N-of-1 randomized trials. *Trials*. 2016 Jul 29;17:369.

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