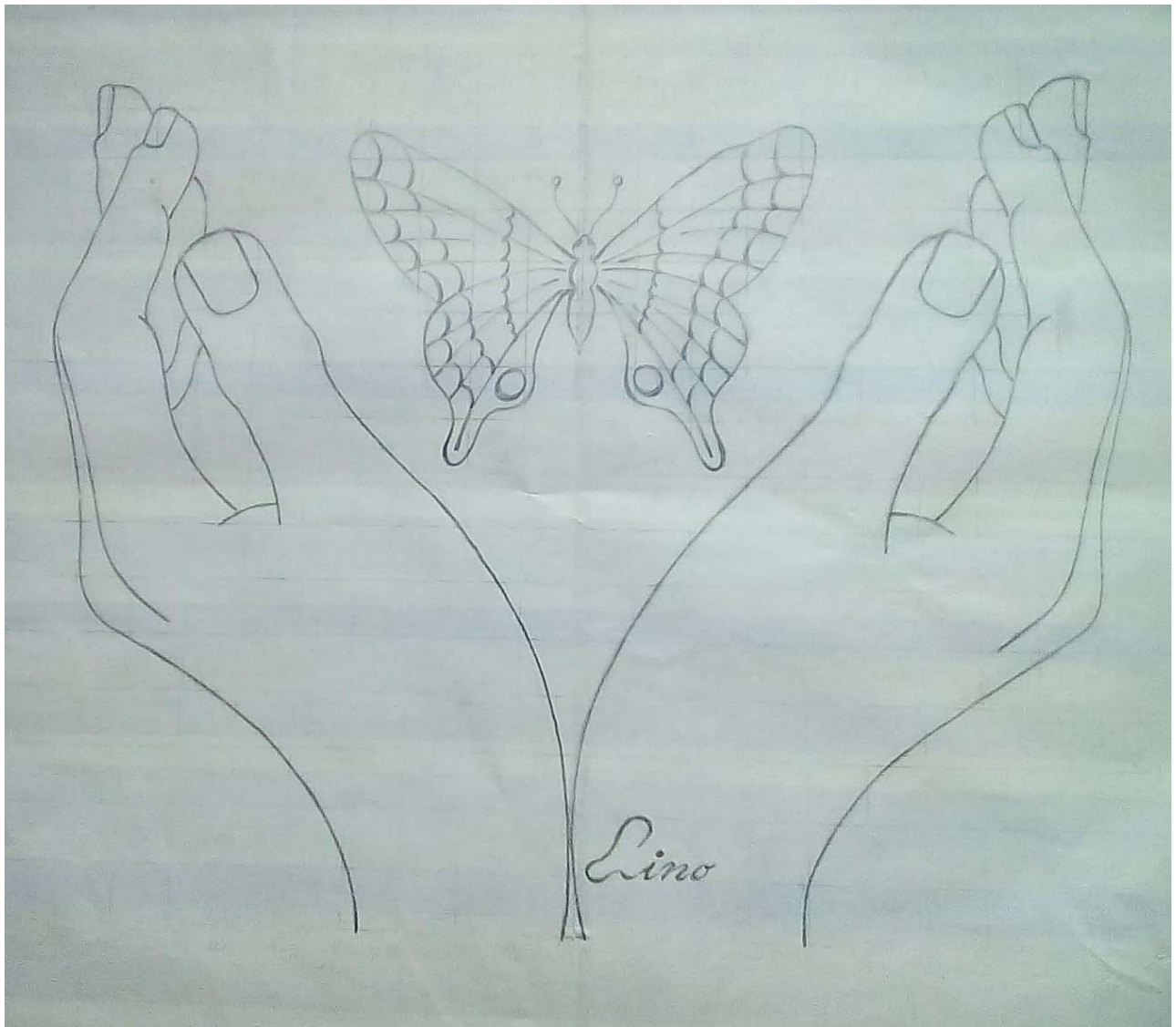


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Effect and Safety of Choline Alfoscerate (Gliatilin^R) in elderly patients.

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KEYWORDS: Dementia, MMSE, Choline Alfoscerate, CV RISK.

ABSTRACT

Background: Numerous clinical and epidemiological studies have underlined the positive effect of Choline Alfoscerate (Gliatilin) in patients suffering from cognitive impairment. Choline Alfoscerate represents an optimal combination therapeutic treatment for delaying cognitive decline. A systematic literature review showed that the drug's benefits outweigh any possible side effects.

Aim: This study aims to evaluate, through the HRV analysis, the safety of Gliatilin behind the autonomic nervous system evaluation using HRV analysis. **Materials and Methods:** In the Geriatric Department of the San Giovanni di Dio Hospital we have enrolled 30 patients. Due to the advanced age of the patients, and the difficulties in connecting with the hospital structure caused by the Covid-19 pandemic, the study was carried out on a subgroup of 20 patients (7 males and 13 females with mean age $81. \pm 6.9$ years old.) who completed the follow-up. All the enrolled patients were affected by cognitive impairment, and test underlined MMSE mean $18,7/30 \pm 3,9$. **Protocol:** After 10 rest minutes we recorded a digital EKG (cardiolab xai-medica) for 5 minutes. We have repeated the digital EKG recorded after 1 month of Gliatilin treatments. All data were analyzed with a specific software for HRV linear analysis. Statistical analysis was performed with SigmaStat 3.5 software for Windows. Paired T-test for quantitative variables were used to compare basal conditions vs effect of the treatment in the same patients. Statistical significance was fixed at $P < 0.05$. **Results:** We observed no significant differences in R-R interval, in Tpeak-to Tend index and Qtc in the treated group. The absence of any statistically significant variations confirms the safety of Gliatilin in elderly patients. The results are express as mean \pm SD. **Discussion and Conclusions:** The analysis of the data allows us to affirm that treatment with Gliatilin does not cause a statistically significant change in the main arrhythmic indices. The treatment with Gliatilin determines a reduction of the orthosympathetic tone and a simultaneous hyperactivity of the parasympathetic tone with a cardioprotective effect.

Background: Numerous clinical and epidemiological studies have underlined the positive effect of Choline Alfoscerate (Gliatilin) in patients suffering from cognitive impairment.

Choline Alfoscerate represents an optimal combination therapeutic treatment for delaying cognitive decline. A systematic literature review

showed that the drug's benefits outweigh any possible side effects.

Aim: This study aims to evaluate, through the HRV analysis, the safety of Gliatilin behind the autonomic nervous system evaluation using HRV analysis.

Materials and Methods: The study group is represented by patients belonging to the Medical and Geriatric Unit of the San Giovanni di Dio Hospital in Fondi.

The inclusion criterion required for enrolment is represented by a MMSE value $> 24/30$, in patients with Mild Cognitive Impairment.

The exclusion criteria are attributable to the HRV analysis technique which does not allow the study of patients with rhythm abnormalities or atrial fibrillation, and patients with pacemakers or other implantable electronic devices.

The enrolment for the study was voluntary. Patients and caregivers were given informed consent explaining in detail the rationale for the study, how it was conducted and the possibility of withdrawing at any time. Sensitive data have been processed in accordance with the privacy law.

In July 2021, at the Medical and Geriatric Units of the San Giovanni di Dio Hospital in Fondi, Latina (Italy), we began a training experience. During the training period it was also possible to examine the medical records of patients admitted for Mild cognitive Impairment.

The data about our study are related to 20 patients (7 men and 13 women) affected by Dementia (with MMSE $18,7/30 \pm 3,9$) and with mean age of $81 \pm 6,9$ years old. All patients enrolled in the study provided their informed consent to the observational study. All patients continued home pharmacological treatments in respect with the ethical guidelines. As regards to the use of scale, it has been standardized to the international reference system for laboratory tests and instrumental tests. Screening eligibility requirements included the age of at least 18 years old. All patients provided written informed consent. The exclusion criteria included treatment with anti-arrhythmic drugs for the assessment of heart rate variability, in patients affected with heart disease, in order to avoid distortions in the heart rate variability. At the time of enrolment, a run-in period allowed us to subject all the enrolled patients to a non-invasive 12-lead digital electrocardiographic recording in order to evaluate the effect of Choline Alfoscerate on cardiovascular risk explored by the analysis of QT, Qtc and Tpeak to T end Index (Tp/Te). The three different cardiovascular risk indices were evaluated by electrocardiographic trace in the basal condition and after 30 days of treatment with Choline Alfoscerate (Gliatilin). The treatment was performed using 600 mg caps in two daily administrations, for 1 month. Data was measured using cardiolab Xai-medica software, and analyzed with SigmaStat 3.5 software for Windows XP. We used the Paired T test to analyze the numerical data deriving from pre and

post treatment recordings in the same subjects enrolled in the study. The Paired T test allows you to perform comparative statistical analyzes on small groups. (Tab. 1). Statistical significance was fixed at $P < 0.05$.

Results: The results of our pilot study conducted on 20 patients allowed us to highlight a statistically significant improvement in Mini Mental State Examination without a statistically significant modification of the Arrhythmic index (QT, Qtc and Tp/Te). The absence of any statistically significant modification of the QT, Qtc and Tp/Te index is a significant clinical advantage because it led us to exclude a correlation with arrhythmic risk. All enrolled patients have an elevated cardiovascular risk profile and have a normal blood pressure (with their home pharmacological treatment). From July 2021 a total of 20 patients entered the run-in period. All patients data respect the criteria for the study. No patients were randomized in error or were enrolled in violations of good clinical practice. Most patients received recommended drug therapy for chronic Hypertension.

Conflict of Interest: none declared

The treatment was well tolerated in routine clinical practice. All patients started the drug's study and no subjects were excluded after the patients run-in period due to the absence of transient adverse events.

Discussion and Conclusion: Our study was designed to provide evidence to support the efficacy of Choline Alphoscerate (Gliatilin) treatment in managing of Dementia in elderly patients. The data collected from the study show that the treatment statistically improves the Mini Mental State Examination test. No significant modifications are noted about cardiovascular risk evaluation (Table 1). There is no statistically significant change in Arrhythmic risk evaluated exploring Qt, Qtc and Tpeak to T end index. This experience has led us to use Choline Alphoscerate in elderly patients with Dementia.

LIMITATIONS OF THE STUDY:

Our data gives comfortable results, but further evaluation is needed to have conclusive results for the entire population.

Acknowledgement:

TABLES

	CONTROL \pm SD	EFFECT \pm SD	Probability (P)
MMSE (0-30)	18,692 \pm 3,881	21,077 \pm 4,010	0,001*
QT (msec)	387,700 + 33,545	398,350 + 31,423	0,132
QTc BAZZET (sec)	0,430 + 0,021	0,447 + 0,048	0,105
QTc FREDERICIA (sec)	0,415 + 0,019	0,433 + 0,046	0,094
QTc FRAMINGHAM (sec)	0,415 + 0,018	0,428 + 0,030	0,079
QTc HODGES (sec)	0,415 + 0,018	0,428 + 0,034	0,141
Tpeak to Tend (msec)	94,800 + 14,877	94,150 + 12,877	0,824
Tpeak to Tend/QT	0,24	0,23	Ns

Table 1: Descriptive Statistics about Mini Mental State Examination and Arrhythmic index.

FIGURES

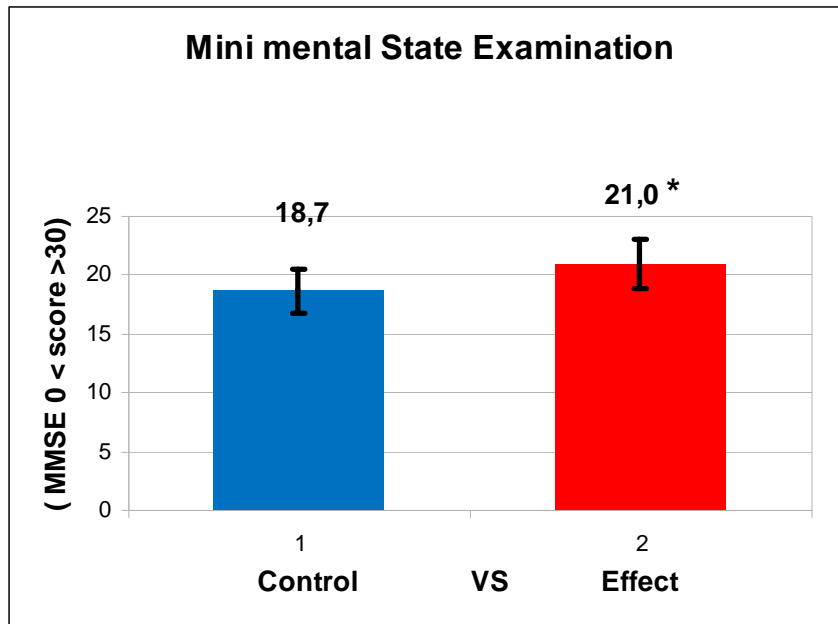


Fig. 1: Descriptive statistic about Mini Mental State Examination test (MMSE) modification before and after treatment period with Choline Alfoscerate. Data are expressed as mean \pm S.D.

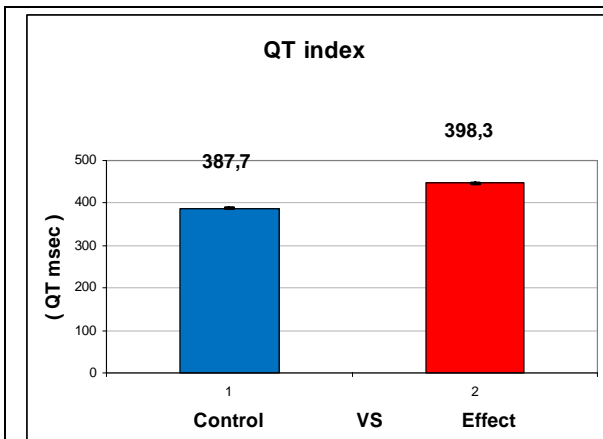


Fig. 2: Descriptive statistic about QT index modification before and after treatment period with Choline Alfoscerate.

Data are expressed as mean \pm Standard Deviation.

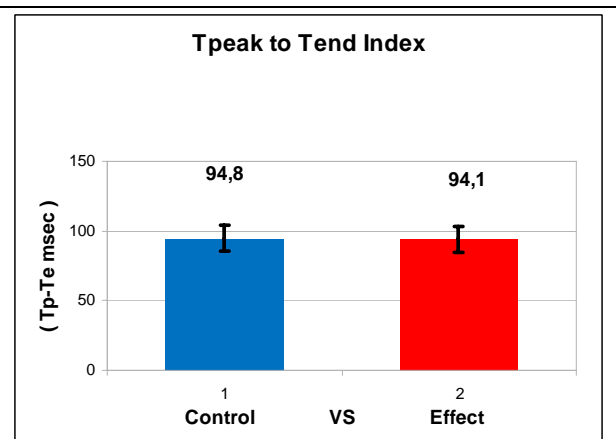


Fig. 3: Descriptive statistic about Tpeak to Tend index modification before and after treatment period with Choline Alfoscerate.

Data are expressed as mean \pm Standard Deviation.

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