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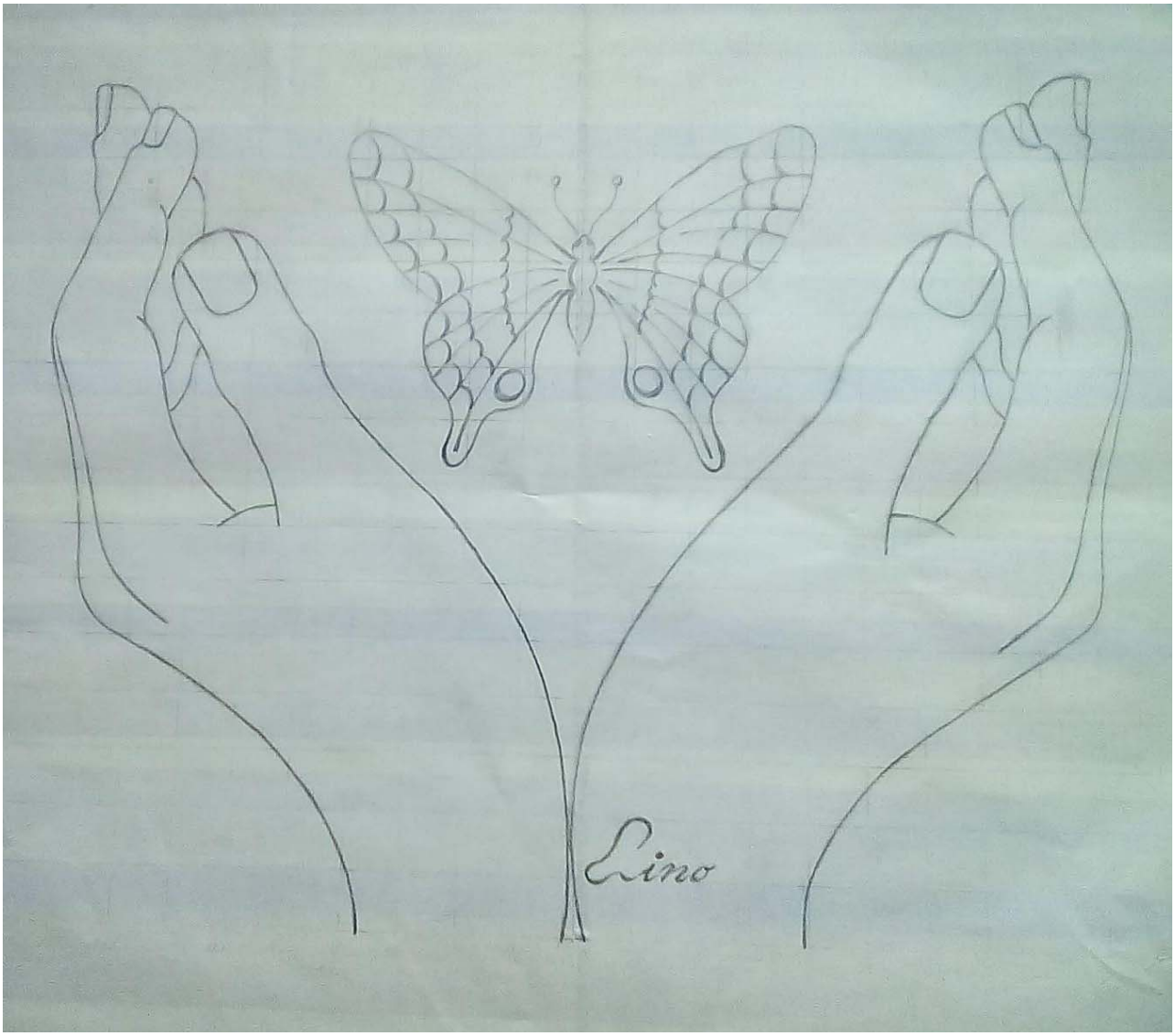

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EFFICACY OF FORXIGA IN PATIENTS SUFFERING FROM HEART FAILURE WITH LOW EF% AND TYPE II DIABETES MELLITUS: MEDICAL AND MEDICAL ASPECTS.

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KEYWORDS: CHF, Diabetes, QTc; QT, CV RISK.

ABSTRACT:

Aim: the aim of our study is to evaluate the effectiveness of FORXIGA in the treatment of heart failure with low EF% in patients with type II diabetes. **Materials and Methods:** Our pilot study enrolled 5 subjects (4 men and 1 woman) with an average age of 75 years (minimum age of 71 years and maximum age of 79 years) suffering from heart failure with low ejection fraction (EF < 40 %). All enrolled subjects, over the age of 65. All patients, voluntarily undergo to anamestic evaluation of the number of heart failure relapses during treatment with FORXIGA. The enrolled subjects were followed in follow-up to re-evaluate relapses and compliance with treatment. All patients provided informed consent to the anamnesis, cardiological tests during hospitalization and to the processing of personal data. Following the anamnestic evaluation, the patients enrolled in the study underwent cardiological and echocardiographic evaluation to evaluate the EF% (examination in the last 3 months after hospitalization). **Results:** the analysis of the data underline a statistically significant reduction in the value of relapses approximately 3 months after the treatment with FORXIGA (10 mg once a day as an additional therapy to the treatment for heart failure). No adverse events were reported during treatment and no hypoglycemic episodes were reported during the treatment period (3 months). **Discussion:** From the data in the table it emerges that therapy with Forxiga as an add-on therapy in diabetic patients suffering from heart failure with low EF% determines a statistically significant reduction in the values of heart failure relapses. The data analysis confirmed the pharmacological safety of Forxiga at a dosage of 10 mg per day in diabetic patients since

despite the statistically significant reduction in glycemic values after 3 months of treatment. No hypoglycemic episodes occurred. The size of the sample does not allow us to present definitive data but it will be necessary to increase the number of patients enrolled and continue the follow-up at 6-9-12 months. The data extrapolated after 3 months of treatment with Forxiga at a dosage of 10 mg did not highlight a statistically significant change in compliance with therapy due, probably, to the prescribability of the drug with exemption for pathology through a specialist therapeutic plan in note 100. **Conclusions:** The pilot study data allowed us to confirm the safety of the pharmacological treatment given the absence of hypoglycemia and other significant side effects. The size of the sample under examination does not allow us to present definitive data applicable to all patients suffering from diabetes mellitus and heart failure with low EF%. The data relating to compliance do not highlight a statistically significant change in adherence to treatment due, probably, to the prescribability of the treatment with ticket exemption for pathology (diabetes) with specialist therapeutic plan in "note 100".

TABLE

	BASE + DS	**CONTROL + DS**	**Probability (P)**
RECIDIVE (1-5)	1,200 ± 0,447	0,200 ± 0,147	<0,001*
COMPLIANCE (0-10)	7,600 + 0,894	7,400 + 0,894	0,374
GLICEMIA (mg/dl)	123,400 + 19,034	110,400 + 18,902	0,043*

Tab. 1 Descriptive analysis of data relating to treatment with Forxiga IN PATIENTS WITH HEART FAILURE WITH LOW FE% affected by type II diabetes mellitus. The probability is considered significant only if $P < 0.050$.

FIGURES

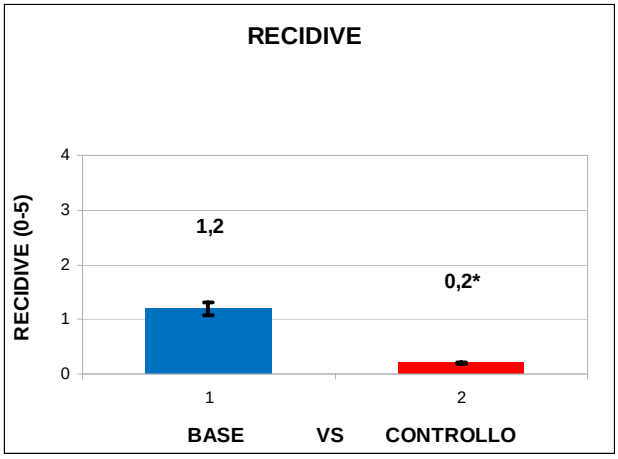

Fig. 1 Graphic representation of the changes in the number of relapses before and after treatment with Forxiga 10 mg re-evaluated after approximately 3 months. Data expressed as mean +/- S.D.

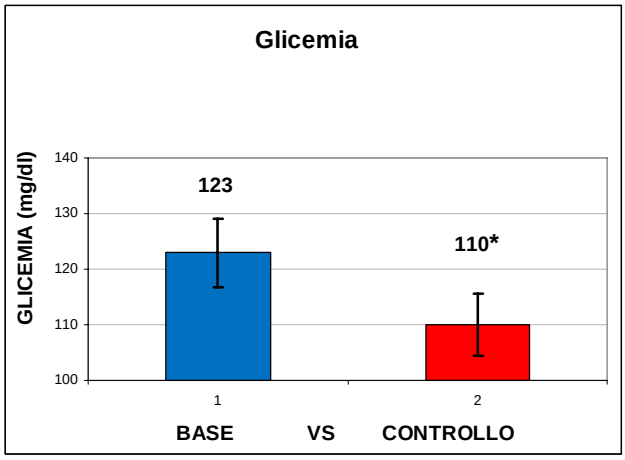

Fig. 2 Graphic representation of changes in compliance with treatment with Forxiga 10 mg re-evaluated at approximately 3 months. Data expressed as mean +/- S.D.

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