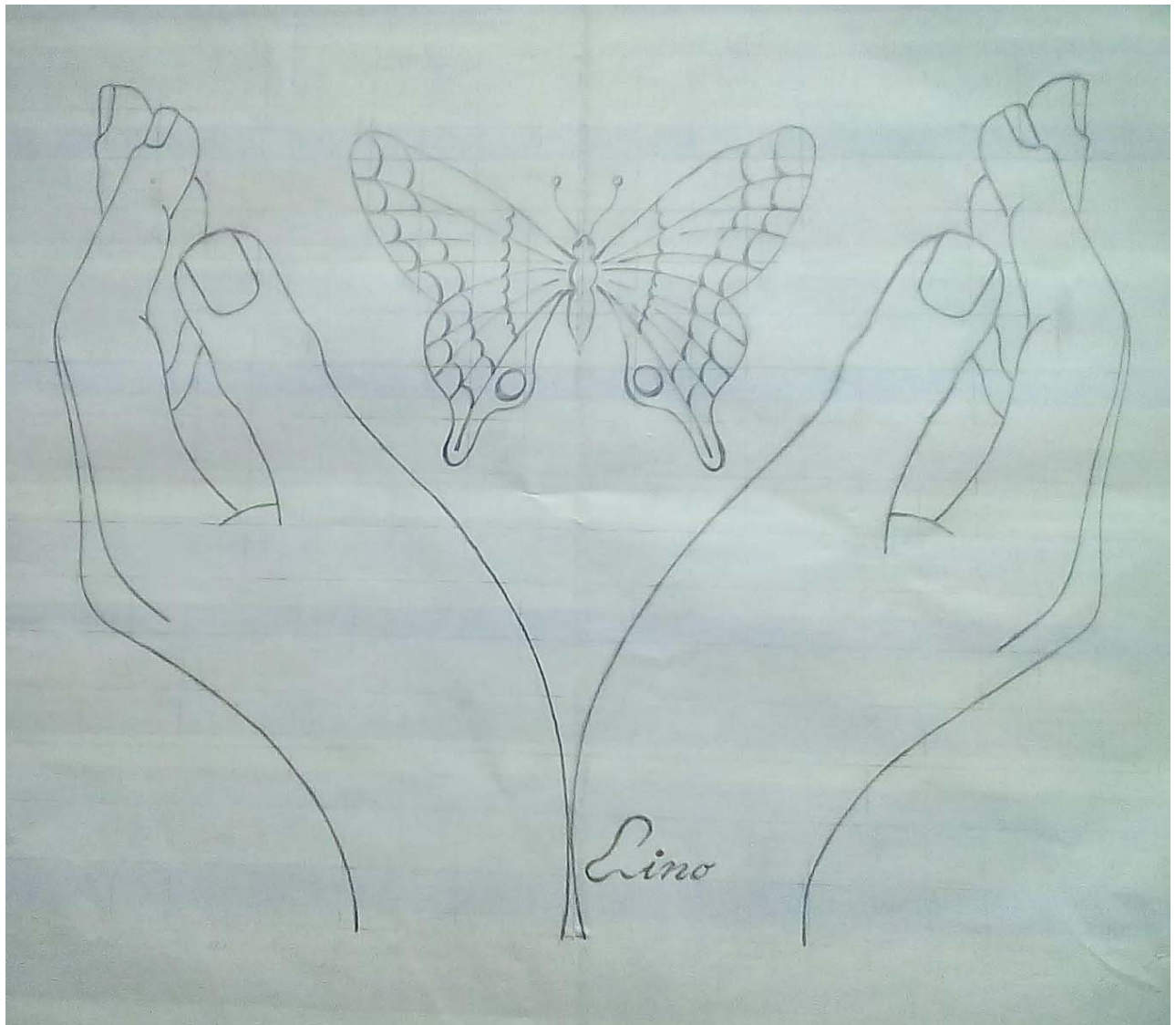


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SAFETY AND EFFICACY OF VIVIVEN IN PATIENTS WITH VENOUS INSUFFICIENCY AND STASIS EDEMA: MEDICAL AND NURSING ASPECTS.

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KEY-WORDS: VENOUS INSUFFICIENCY, BIA, BCM, ECM.

ABSTRACT

Aim: The aim of our study is to evaluate the efficacy of Viviven^(R) in the treatment of water-salt retention in venous insufficiency associated with stasis oedema by means of bioimpedance evaluation. **Materials e Methods:** In our study, 18 subjects (10 men and 8 women) with an average age of 80 years (minimum age 64 years and maximum age 90 years) affected by venous insufficiency associated with stasis oedema were enrolled. All subjects enrolled, aged over 65 years, voluntarily agreed to undergo bioimpedance assessment and outpatient follow-up using a non-invasive method based on the measurement of resistance to the flow of transcutaneous electrical current. All patients were asked for informed consent to perform the screening procedure and to the processing of personal data. After the blood bioimpedance assessment, the patients enrolled in the study were treated with Viviven for 1 month and subsequently re-evaluated in the outpatient setting. **Results:** Data analysis showed a statistically significant change in the value of extracellular fluids (ECM) after 1 month of therapy with Viviven, confirming the efficacy of the therapy. No adverse events were reported during treatment. No statistically significant changes in the parameters relating to intracellular fluids (BCM) were measured. **Discussion:** From the data in the table it emerges that 1 month of therapy with Viviven determines a statistically significant reduction in the values of extracellular fluids (ECM), indicative of a correction of stasis oedema associated with chronic venous disease. No statistically significant changes in intracellular fluids were found after treatment (BCM). **Conclusions:** The pilot study we conducted allowed us to confirm, through instrumental bioimpedance

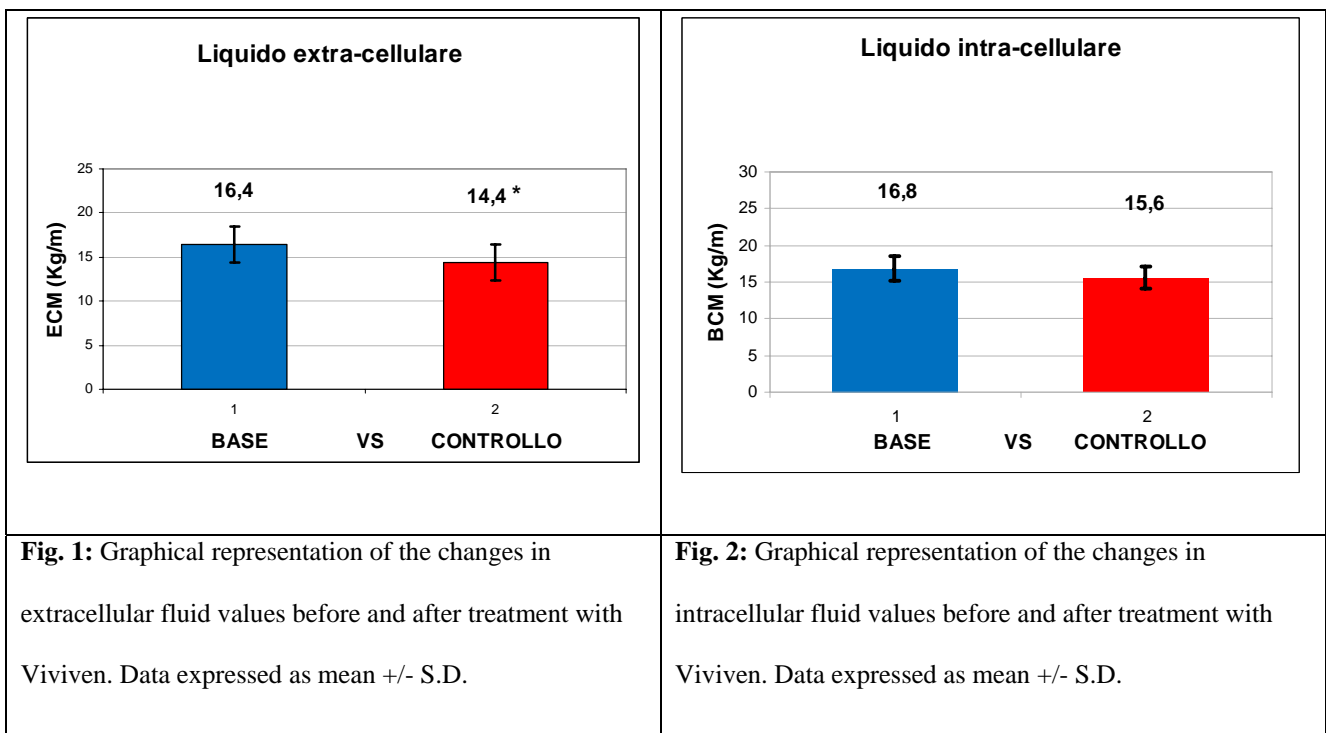
examination, the efficacy of treatment with Viviven in subjects affected by venous insufficiency associated with stasis oedema. Unexpectedly, no statistically significant variation was recorded in intracellular fluids assessed by skin bioimpedance. Currently, the size of the sample under examination and the average age of the patients enrolled do not allow us to extend the results of the study to the entire population.

Tables

| | BASE \pm DS | CONTROL \pm DS | Probability (P) |
|------------|---------------------------------|------------------------------------|------------------------|
| BCM | 16,828 + 4,707 | 15,639 + 2,744 | 0,180 |
| ECM | 16,467 + 3,016 | 14,472+ 1,929 | 0,007 * |

Tab. 1: Descriptive analysis of data from the Bioimpedance study and intra and extracellular fluid values in patients with venous insufficiency associated with stasis oedema before and after treatment with Viviven. The probability is considered significant only if $P < 0.050$.

Figures



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