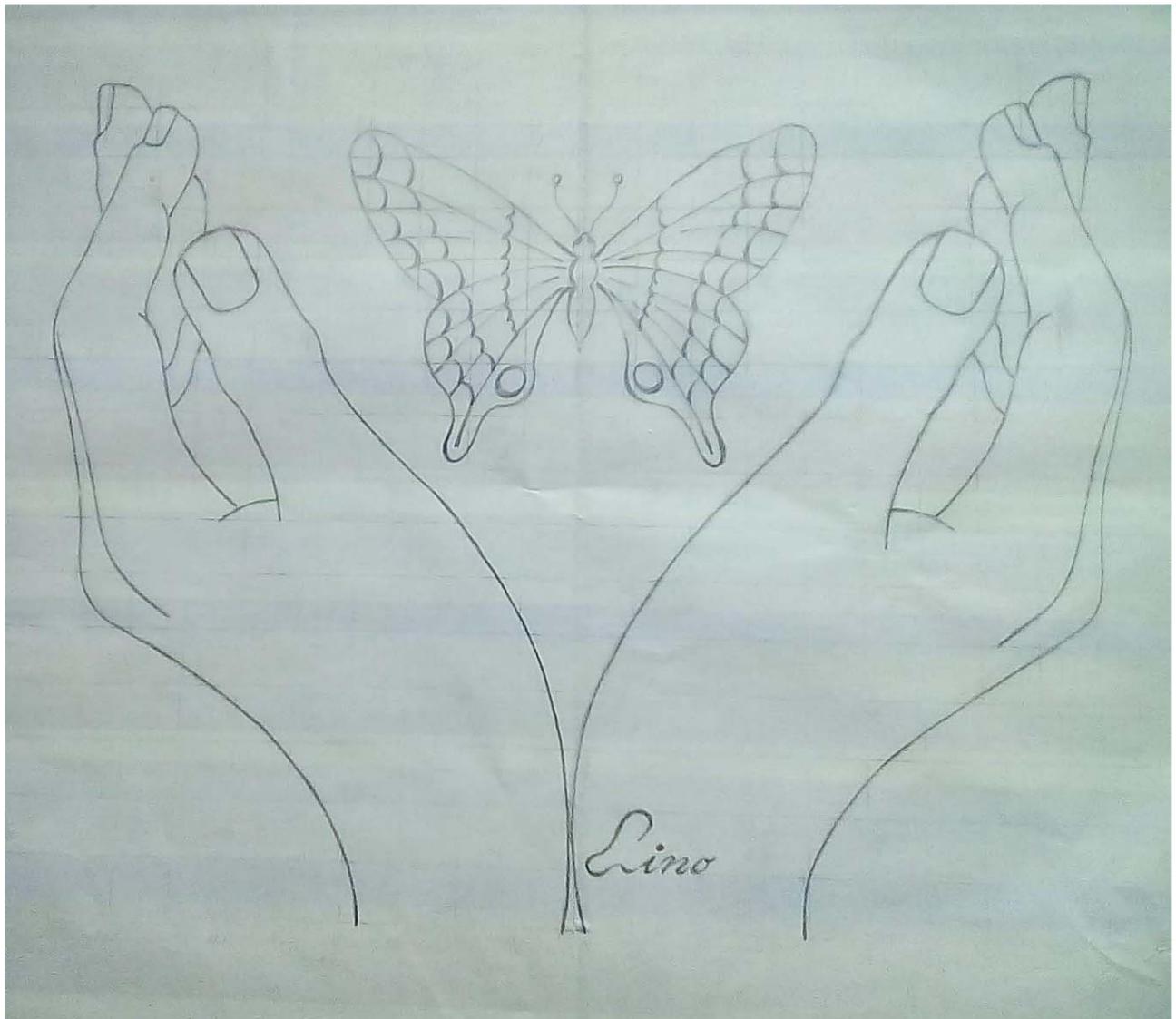


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Home therapy of the Sars-Cov-19 Omicron variant: our experience.

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KEYWORDS: Sars-Cov-19, Omicron, Pandemic.

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ABSTRACT

Background: The SARS-Cov-2 pandemic began in Italy with the Delta variant in 2019. Even today, with the Omicron variant, the SARS-Cov-2 pandemic represents the main health emergency in the country. This variant is less virulent than the Delta variant but, at the same time, is more contagious. The higher contagiousness of the Omicron variant, compared to the Delta variant, once again puts a strain on the Hospital and Territorial health system. **Aim:** The aim of our study is to highlight the effect of the home therapy called Protocol-Lino. This therapeutic scheme involves the oral administration of drugs and, only in case of strict necessity, requires the drugs to be administered subcutaneously (Tab. 1). **Materials and Methods:** On January 17, 2022, we began the drafting of this scientific study: 69 patients were enrolled in our project but only 30 subjects have currently completed the protocol and sent the Covid-19 molecular test results, which proved to be negative. Therefore, our study discloses only the data concerning this limited group of 30 patients enrolled in the protocol (16 men and 14 women) affected by SARS-Cov-2 variant Omicron. The enrolled subjects had a mean age of 44 + 21 years (with a minimum age of 10 years and a maximum age of 92 years). All the subjects enrolled in the study provided their informed consent to the therapy, clinical telemonitoring and remote assistance, which is essential to ensure continuity of hospital care for Non-Covid patients. All the enrolled subjects continued their pharmacological treatments for chronic diseases in progress in compliance with professional ethics. At the time of enrolment, patients underwent an anamnestic investigation in order to exclude any drug allergies or possible adverse reactions. The sample of 30 enrolled subjects was divided, during the statistical processing of the data, into three different groups. The treatment protocol has been summarized in table number 1 (Tab.1). The clinical parameters and anamnestic data of the enrolled subjects were statistically processed using the SigmaStat 3.5 software for Windows. The paired T-test was used to analyze the different variables measured before and after the treatment envisaged in the Protocol-Lino in order to confirm the efficacy of the therapeutical scheme. Statistical significance was set at $P < 0.05$. **Results:** The results of our study allowed us to highlight a statistically significant improvement in heart rate and oxygen saturation values as a result of the continued administration of the treatment, which was carried on up to the negativization of the Covid-19 molecular test in all the 30 enrolled patients. As a matter of fact, we noted a statistically significant reduction in heart rate in all the enrolled subjects – more precisely, in both the two subgroups

of patients created by differentiating subjects over 60 and subjects under 60 years of age. In the same way, the data showed an increase in the value of oxygen saturation, as a result of the treatment administrated up till the negative result of the Covid-19 molecular test, both in the two subgroups obtained by discriminating on the basis of age above or below 60 years. **Discussion:** The persistent SARS-Cov pandemic in its various variants still puts a strain on hospital and territorial medical nursing activities today. The treatment envisaged in our Protocol-Lino is based on the experience carried out during the first Delta variant pandemic; it was developed with appropriate modifications linked to the lower virulence of the variant associated with its greater diffusibility compared to the previous variants in circulation in Italy. The treatment that we propose allows to treat the inflammatory pulmonary component by means of antibiotic therapy with macrolide, and avoids the overlap of opportunistic bacterial infections. The treatment with N-Acetyl-Cysteine was added in order to guarantee a fluidifying therapy of the pulmonary secretions as well as an adequate protection of the organism from the oxidative stress induced by the infection. The treatment with Ferachel forte was introduced in order to guarantee an adequate supply of iron and essential microelements as cofactors of the main enzymatic activities of the organism. The Squdo Nutraceutical has been included in the protocol in order to support and enhance the immune defenses through the action of lactoferrin and the trace elements present in the compound. **Conclusion:** The data presented in our study allow us to highlight the significant improvement in oxygen saturation in patients undergoing treatment with Protocol-Lino. The identification of two subgroups of patients, who were split into two broad age groups with a range of below and above 60 years of age, has allowed us to confirm the efficacy of the treatment in all population groups and confirm the safety of the treatment even in elderly patients.

Background: The SARS-Cov-2 pandemic began in Italy with the Delta variant in 2019. Even today, with the omicron variant, the Sars-Cov-2 pandemic represents the main health emergency in the country. This variant is less virulent than the Delta variant but, at the same time, is more contagious. The higher contagiousness of the Omicron variant, compared to the Delta variant, once again puts a strain on the Hospital and Territorial health system.

Aim: The aim of our study is to highlight the effect of the home therapy called Protocol-Lino.

This therapeutic scheme involves the oral administration of drugs and, only in case of strict necessity, requires the drugs to be administered subcutaneously (Table 1).

Materials and Methods: In January 2022 our research group was contacted by the relatives of geriatric patients followed in the Geriatric Department of the San Giovanni di Dio hospital in Fondi (Latina), for the positivity to Sars-Cov-2 of the family unit. In order to ensure continuity of care for geriatric patients, we introduced a protocol for remote surveillance and remote

assistance of the patients and their relatives. On January 17, 2022, we began the drafting of this scientific study and 69 patients were enrolled in our project but only 30 subjects have currently completed the protocol and sent the Covid-19 molecular test results, which proved to be negative. Therefore, our study discloses only the data concerning this limited group of 30 patients enrolled in the protocol (16 men and 14 women) affected by Sars-Cov2 variant Omicron. The subjects enrolled had a mean age of 44 + 21 years old (with a minimum age of 10 years old and a maximum age of 92 years old). All the subjects enrolled in the study provided their informed consent to the therapy, clinical telemonitoring and remote assistance, which is essential to ensure continuity of hospital care for Non-Covid patients. All the subjects enrolled continued the pharmacological treatments for their chronic diseases in progress in compliance with professional ethics. At the time of enrolment, patients underwent an anamnestic investigation in order to exclude any drug allergies or possible adverse reactions. The sample of the 30 enrolled subjects was divided, during the statistical processing of the data, into three different groups. The treatment protocol has been summarized in table number 1 (Tab.1). Azithromycin was included in the protocol 1 tab once a day for three days in order to avoid possible bacterial superinfections (1), to reduce the production of pro-inflammatory cytokines such as IL-8, IL-6, TNF alpha, reduce oxidative stress, and modulate T-helper functions (2). N-Acetyl-cysteine (NAC) is a precursor of reduced

glutathione (GSH). It has been included in the protocol three times a day for its antioxidant role at the systemic level, and its anti-inflammatory and immune-modulating characteristics that may prove beneficial in the treatment and prevention of SARS-Cov-2.(3) At very high doses, NAC is also used as an antidote against paracetamol intoxication. Thiols block the angiotensin-converting enzyme 2 thereby hampering penetration of SARS-CoV-2 into cells. (4) The Nutraceutical Squdo^(R) (AQMA Italia S.p.A., Milan, Italy) was included in the protocol, for the immunostimulating properties of Lactoferrin. Lactoferrin (Lf) was included, 1 tab once a day, for its antiviral efficacy against a wide range of viruses, including SARS-CoV, a closely related coronavirus to SARS-CoV-2. Furthermore, Lf possesses unique immunomodulatory and anti-inflammatory effects that may be especially relevant to the pathophysiology of severe COVID-19 cases.(5-6) The Nutraceutical Ferachel Forte^(R) (AQMA Italia S.p.A., Milan, Italy) was inserted, in order to supplement iron, folic acid and other trace elements (7-8) to support the hematopoietic system in the production of haemoglobin and in the improvement of arterial saturation. The acetylsalicylic acid was included in the protocol for its antiplatelet effect in order to prevent thrombotic phenomena.

The administration of the treatment started as soon as the Covid-19 test carried out by means of a molecular swab resulted positive. In the case of symptoms associated with fever manifested over the weekend, the treatment was started on

Monday, after confirmation of the positive molecular test for Covid-19. The clinical parameters and anamnestic data of the enrolled subjects were statistically processed using the SigmaStat 3.5 software for Windows. The paired T-test was used to analyze the different variables measured before and after the treatment envisaged in the Protocol-Lino in order to confirm the efficacy of the therapeutical scheme. Statistical significance was set at $P < 0.05$.

Results: The results of our study allowed us to highlight a statistically significant improvement in heart rate and oxygen saturation values as a result of the continued administration of the treatment, which was carried on up to the negativization of the Covid-19 molecular test in all the 30 enrolled patients. More in detail, we noted a statistically significant reduction in heart rate both in the total of subjects enrolled ($P < 0,001^*$) and in the subgroups created by differentiating subjects under 60 years old ($P < 0,005^*$) (Tab. 1). The absence of statistical significance of the heart rate value measured only in the over 60 group ($P = 0.083\%$) can be explained by the presence of beta-blockers or other antiarrhythmics (Class III) as home treatment for comorbidities due to the high frequency of hypertensive heart disease, chronic heart failure, supraventricular tachycardia, atrial fibrillation and atrial flutter in people over 60 years old. In the same way, the data showed a statistical significant increase in the value of oxygen saturation after continued treatment until the Covid-19 molecular test was negative both in the entire enrolled group ($P < 0,001^*$) and in the

two subgroups obtained by discriminating on the basis of age above 60 years old ($P = 0,009^*$) or below 60 years old ($P < 0,001^*$).

Discussion: The persistent SARS-Cov pandemic in its various variants still puts a strain on hospital and territorial medical nursing activities today. The treatment envisaged in our Protocol-Lino is based on the experience carried out during the first Delta variant pandemic; it was developed with appropriate modifications linked to the lower virulence of the variant associated with its greater diffusibility compared to the previous variants in circulation in Italy. The treatment that we propose allows to treat the inflammatory pulmonary component by means of antibiotic therapy with macrolide and avoid the overlap of opportunistic bacterial infections. The treatment with N-Acetyl-Cysteine was added in order to guarantee at the same time fluidifying therapy of the pulmonary secretions and adequate protection of the organism from the oxidative stress induced by the infection. The treatment with Ferachel forte was introduced in order to guarantee an adequate supply of iron and essential microelements as cofactors of the main enzymatic activities of the organism. The Squdo Nutraceutical has been included in the protocol in order to support and enhance the immune defences through the action of lactoferrin and the trace elements present in the compound. In accordance with the professional ethics and hospital protocols of the AUSL of Latina, we included in the study design the protocol of Monoclonal therapies sent to us by the staff of Monoclonal therapies of the Santa

Maria Goretti hospital in Latina. Accordingly, we included the possibility of administering Monoclonal therapy (SOTRAVIMAB) - which is also active against the Omicron variant - and 3 antivirals: Molnupinavir or LAGEVRIO, that can also be administered to patients with Chronic Kidney Failure but not to dialized patients; PAXLOVID, that can be administered to patients who do not receive polypharmacotherapy (given the possibility of drug interactions); and lastly VEKLURY, that can be administered to all kinds of patients as long as it is dispensed within 7 days of the onset of symptoms. The absence of statistical significance of the heart rate value measured only in the over 60 group ($P = 0.083$) can be explained by the presence of beta-blockers or other antiarrhythmics (Class III), in

Conflict of Interest: none declared

the home treatment of comorbidities due to the high frequency of hypertensive heart disease, heart failure, supraventricular tachycardia, atrial fibrillation and atrial flutter in people over 60.

Conclusion: The data presented in our study allow us to highlight the significant improvement in oxygen saturation in patients undergoing treatment with Protocol-Lino. The distinction of the subjects enrolled in two subgroups based on the age below or above 60 years has allowed us to confirm the efficacy of the treatment in all population groups and confirm the safety of the treatment even in elderly patients.

LIMITATIONS OF THE STUDY: Our data gives comfortable results for the Italian people, but further evaluation is needed to have conclusive results for the entire population.

TABLES

Time 0		Azitromicine +	
Symptoms and	=> Start Protocol-Lino	Squdo + Ferachel +	=>
Sars-Cov Test (+)		Fluimucil + ASA	Absent Syntoms and
			Sars-Cov Test (-)

Table 1: Detail of the study design and relative treatment algorithm (*).

(*). In accordance with the professional ethics and hospital protocols of the AUSL of Latina, we included in the study design the protocol of Monoclonal therapies sent to us by the staff of Monoclonal therapies of the Santa Maria Goretti hospital in Latina. Accordingly, we included the possibility of administering Monoclonal therapy (SOTRAVIMAB) - which is also active against the Omicron variant - and 3 antivirals: Molnupinavir or LAGEVRIO, that can also be administered to patients with Chronic Kidney Failure but not to dialized patients; PAXLOVID, that can be administered to patients who do not receive polypharmacotherapy (given the possibility of drug interactions); and lastly VEKLURY, that can be administered to all kinds of patients as long as it is dispensed within 7 days of the onset of symptoms.

All enrolled patients	CONTROL \pm SD	EFFECT \pm SD	Probability (P)
HR (bpm)	82,267 \pm 13,470	74,667 \pm 8,845	< 0,001*
SO2 (%)	96,400 \pm 1,694	98,367 \pm 0,765	< 0,001*
Under 60 years old	CONTROL \pm SD	EFFECT \pm SD	Probability (P)
HR (bpm)	82,292 \pm 13,281	75,292 \pm 7,910	0,005*
SO2 (%)	96,750 \pm 1,152	98,417 \pm 0,776	< 0,001*
Over 60 years old	CONTROL \pm SD	EFFECT \pm SD	Probability (P)
HR (bpm)	79,000 \pm 14,432	72,375 \pm 10,596	< 0,083§
SO2 (%)	95,625 \pm 2,615	98,250 \pm 0,707	< 0,009*

Table 2: Descriptive Statistics about Heart Rate and Oxygen Saturation index.

Data are express as mean \pm Standard Deviation (SD)

FIGURES

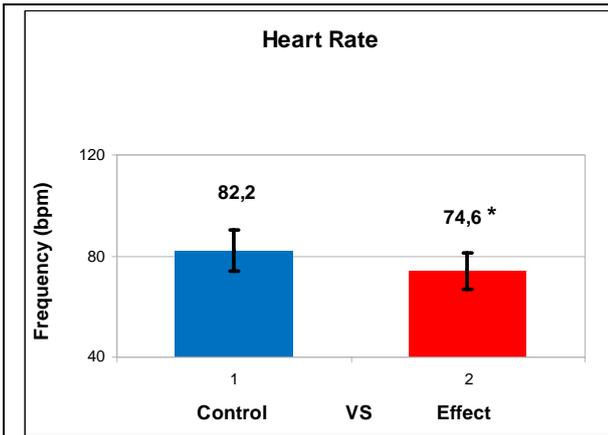


Fig. 1: Descriptive statistic about Heart Rate (beats per minutes) variation in all the enrolled subjects. Data are expressed as mean \pm S.D.

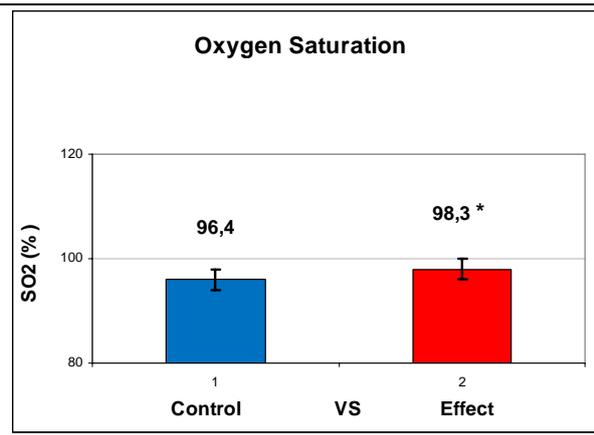


Fig. 2: Descriptive statistic about blood Oxygen saturation (%) variation in all the enrolled subjects. Data are expressed as mean \pm S.D.

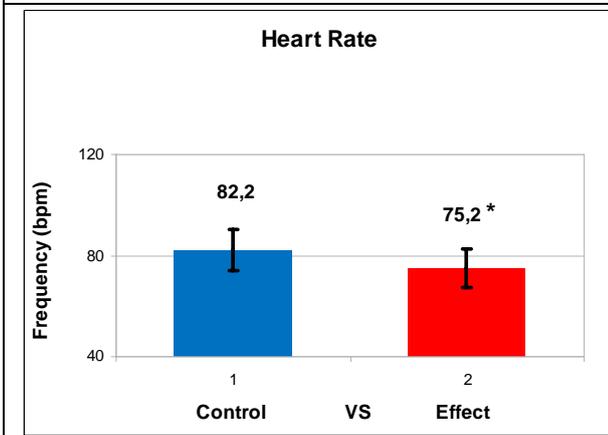


Fig. 3: Descriptive statistic about Heart Rate (beats per minutes) variation in the subgroup of enrolled subjects under 60 years old. Data are expressed as mean \pm S.D.

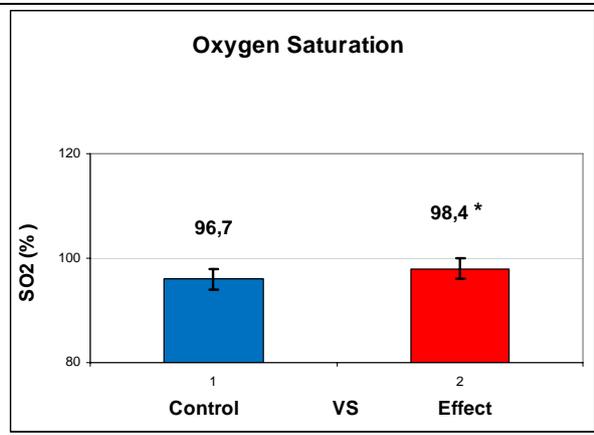


Fig. 4: Descriptive statistic about Heart Rate (beats per minutes) variation in the subgroup of enrolled subjects under 60 years old. Data are expressed as mean \pm S.D.

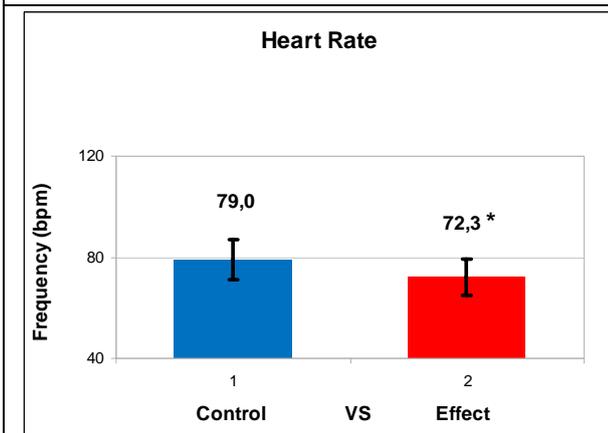


Fig. 5: Descriptive statistic about Heart Rate (beats per minutes) variation in the subgroup of enrolled subjects over 60 years old. Data are expressed as mean \pm S.D.

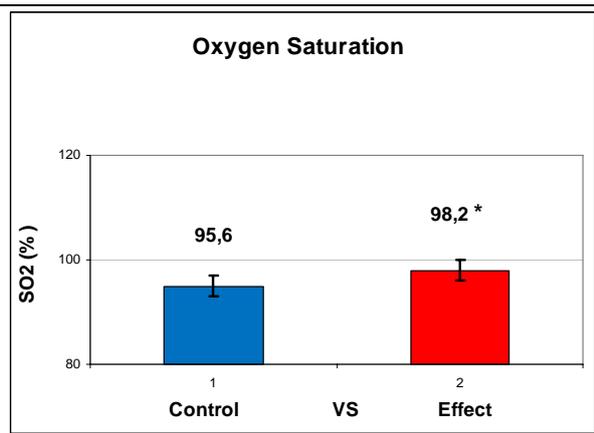


Fig. 6: Descriptive statistic about Heart Rate (beats per minutes) variation in the subgroup of enrolled subjects over 60 years old. Data are expressed as mean \pm S.D.

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