

# Disentangling the impact of COVID-19 infection on clinical outcomes and preventive strategies in older persons: an Italian perspective

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Italy was one of the first western countries to embrace the first wave of COVID-19 and undergo detrimental outcomes in older adults in different clinical settings, especially in those with comorbidity and frailty. In addition, older nursing home (NH) residents had significantly higher mortality rates most likely due to the increased susceptibility of infection due to combined physical vulnerability and risks linked to the NH living environment itself.

Different reports throughout Italy have rapidly highlighted selected outcomes related to COVID-19 in older patients being treated in acute and long-term care (LTC) settings. However, the majority of these studies are single center studies. Thus, it remains fundamental to collect large data from prospective based-population studies in order to identify preventive and therapeutic COVID-19 risk/protective factors correlated with COVID-19 health status outcomes.

In this commentary paper, we will discuss different Italian reports according to clinical settings and highlight the importance of GeroCovid Observational and GeroCovid Vax, two large population based prospective studies in Italy.

**Key words:** COVID-19, Italy, vaccines in long term care, elderly, depression

## INTRODUCTION

The Coronavirus disease 2019 (COVID-19) pandemic caused by severe acute respiratory syndrome coronavirus (SARS-CoV-2) has caused high rates of morbidity and mortality on a worldwide scale. Italy was one of the first countries to embrace the impact of the first wave of COVID-19 in older adults with negative outcomes, especially in frail elders. During the first wave of the pandemic, older Italians especially with frailty<sup>1</sup>, showed to be the extremely vulnerable to mortality with overall fatality rates reaching 26% in acute care<sup>2</sup> and 33% in long-term care settings<sup>3</sup>.

During the month of March 2020, case fatality rates were 20.2% in those over 80 years with a greater vulnerability in men<sup>4</sup>. Similar patterns quickly followed across different countries worldwide. For example, one US report found that in 5700 COVID-19 cases, case fatality rates were over 40% in those over the age of 80 years during hospitalization, raising concerns on very old vulnerable people<sup>5</sup>. Even though it remains unclear the role played by common comorbidities, older age continues to be the highest lethality risk factor since the beginning of the pandemic.

The extremely high mortality rates linked to COVID-19 in those living in Nursing Homes (NH) caused a severe worldwide crisis in NH organization and functioning. The combinations of vulnerable older persons (with frailty syndrome and comorbidities) along with NH living environment (group gatherings, more than one person per room, limited personal protection equipment, etc.) underline the so-called “Perfect Storm” for COVID-19 transmission<sup>6</sup>. In Italy, fatality rates reached 33% in long-term care settings<sup>3</sup>. Worldwide data in approximately 50 studies found that long-term care residents had an attack rate of 45% for COVID-19 and a death rate of 23%<sup>7</sup>. Indeed, the urgent need for answers related to COVID-19 prognosis in aging elders has prompted researchers to aim at identifying related risk factors and innovative therapeutic measures.

One Italian report underlined that specific combinations of comorbidities during COVID-19 infection were associated with in-hospital mortality in older persons (mean age 79 years)<sup>8</sup>. These authors underlined that the following combinations: i) ischemic heart disease and atrial fibrillation; ii) atrial fibrillation and heart failure; iii) atrial fibrillation and stroke; iv) heart failure and COPD; v) stroke and dementia, and vi) type 2 diabetes and obesity occurred more frequently than expected in those dying with COVID-19, thus, indicating a potential role of these clinical profiles in the chain of events that led to death in those who contracted SARS-CoV-2. At the moment, large prospective longitudinal studies in older persons can successfully provide important indicators

needed to better understand this unraveling coronavirus.

In this commentary, we will discuss diverse Italian findings related to COVID in older persons. We will highlight the importance of prospective population based studies that are currently providing evidence for potential risk factors associated with COVID-19. The first study is the GeroCovid Observational Study, a multicenter and multi-setting study that is currently disentangling questions in both acute and long-term care (LTC), as well as in outpatient care. The second study is the GeroCovid Vax study dedicated to identifying the safety and efficacy of COVID-19 vaccinations in older persons living in NHs. The actual inclusion of older persons in the initial clinical trials for evaluating vaccine safety and efficacy were not representative enough of the geriatric population<sup>9</sup>; thus, understanding their role in older vulnerable individuals will provide important knowledge to the available literature.

## METHODS

### STUDY POPULATION

GeroCovid Observational included persons  $\geq 60$  years of age with or at risk of COVID-19 willing to participate in the study. Data were collected retrospectively and prospectively from March 1, 2020 to December 31, 2020. The study has been described elsewhere<sup>10</sup>. The Italian Society of Gerontology and Geriatrics (SIGG), in collaboration with the Norwegian Geriatrics Society founded the GeroCovid Observational Study, a multicenter and multi-setting study that is currently providing evidence for risk factors in both acute and long-term care (LTC), as well as in outpatient care settings. GeroCovid Observational is also investigating clinical presentation of infection and clinical outcomes, including changes in health status, hospitalizations, and death. GeroCovid Vax Study began in January 2021. The Italian National Institute of Health (Istituto Superiore di Sanità, ISS; Rome, Italy) and the Italian Society of Gerontology and Geriatric Medicine (SIGG; Florence, Italy) formed the GeroCovid Vax study group to investigate the safety and efficacy of COVID-19 vaccination in older adults living in NHs throughout Italy. In a subpopulation, both humoral and immune cellular responses are being tested to identify an adequate level of vaccine protection. Enrollment period was from January to June 30th, 2021. There are planned follow-up periods to test for changes in clinical and biochemical data. Timed follow up visits are planned at specific intervals for a 12-month follow up observational period. Information regarding any adverse events from COVID-19 vaccinations are

reported, as well as any changes in cognitive, functional and routine blood parameters are registered (Tab. I). The data collection for both studies use the same platform provided by BlueCompanion (United Kingdom, France) <sup>11</sup>. In particular, the GeroCovid e-Registry was developed by adapting a proprietary electronic platform (e-Trajectories). In March 2020, in conjunction with the COVID-19 pandemic, BlueCompanion provided their health data collection system for the GeroCovid initiative. E-Trajectories and GeroCovid adaptation are based on the CleanWeb engine produced by Telemedicine Technologies (Boulogne-Billancourt, France), embedded in a dedicated web platform designed for integrating data from different sources. All data are recorded on web servers located in the EU (France and Poland). ICT operations are compliant with the European General Data Protection Regulation (GDPR) and with the relevant international standards for clinical trials (ISO 9001 certification and FDA CFR 21 part 11). Bluecompanion continuously provides training sessions for investigators from each investigational site, as well

as technical support. Data collection is under constant quality control and investigators are required, when necessary to verify data entry. All individual clinical data were anonymized before data entry.

#### ETHICAL ASPECTS

The Campus Bio-Medico University Ethical Committee approved the overarching protocol of the GeroCovid Observational study in April 2020. All participating investigational sites gained approval from their local Ethical Committee review board. Informed consent was necessary to participate in the study.

## RESULTS AND ONGOING INVESTIGATIONS

#### GEROCVID OBSERVATIONAL STUDY

3396 participants were included per protocol by 86 Italian investigational sites, (plus 148 from 3 sites in Norway). Recent reports from different settings have

**Table I.** General characteristics of GeroCovid Observational and GeroCovid Vax Studies.

	<b>GeroCovid Observational</b>	<b>GeroCovid Vax</b>
Age	≥ 60 years of age	≥ 60 years of age
	- with COVID-19 - no COVID-19	- no COVID-19
Study Aims	<ul style="list-style-type: none"> <li>• assess changes in COVID risk profile</li> </ul>	<ul style="list-style-type: none"> <li>• assess the safety of COVID-19 vaccines</li> </ul>
	<ul style="list-style-type: none"> <li>• assess the impact on physical, cognitive, psychological &amp; behavioral status in non COVID-19 participants</li> </ul>	<ul style="list-style-type: none"> <li>• assess adverse side effects following vaccine inoculation</li> </ul>
	<ul style="list-style-type: none"> <li>• assess clinical &amp; functional outcomes following COVID-19 hospitalization</li> </ul>	<ul style="list-style-type: none"> <li>• assess clinical &amp; functional changes over time following vaccination</li> </ul>
	<ul style="list-style-type: none"> <li>• identify significant measures in homecare &amp; outpatient services</li> </ul>	<ul style="list-style-type: none"> <li>• assess COVID-19 following vaccination</li> </ul>
	<ul style="list-style-type: none"> <li>• identify measures in LTC to prevent &amp; protect against COVID-19</li> </ul>	<ul style="list-style-type: none"> <li>• assess efficacy (monitor immune response)</li> </ul>
Settings	Acute wards, outpatient clinics (memory, post hospitalization from COVID-19), Homecare assistance, LTC (assisted living, retirement homes, NHs)	LTC (NH, Retirement home)
Functional, cognitive, comorbidity parameters	ADL, IADL, CIRS, MMSE, GDS, physical activity	ADL, IADL, CIRS, MMSE, GDS, physical activity
Frailty anamnestic parameters	Frailty criteria <sup>20-21</sup>	Frailty criteria <sup>20-21</sup>
Biochemical parameters	Blood/urine analyses	Blood samples
Drug use monitoring	ATC classification	ATC classification
Outcome	Type of outcome <sup>10</sup> ( <i>infection, death, hospitalization, changes in clinical, cognitive &amp; functional parameters</i> )	Adverse events ( <i>infection, death, hospitalization, other</i> ) immune response
Data entry method	E-registry (BlueCompanion, France) <sup>11</sup>	E-registry (BlueCompanion, France) <sup>11</sup>

ADL: Activities of Daily Living; IADL: Instrumental Activities of Daily Living; GDS: Geriatric Depression Scale; LTC: Long-Term Care; MMSE: Mini-Mental State Examination

been published using data from the electronic registry. One study from the acute care setting, showed approximately 22% of COVID-19 patients had an Atrial Fibrillation (AF) and in-hospital mortality was significantly higher in the AF group (36.9 vs 27.5%,  $p = 0.015$ )<sup>12</sup>. The authors also found that i) the use of preadmission and in-hospital oral anticoagulation in older patients with AF was correlated with improved survival; ii) in-hospital low-molecular-weight heparin therapy, when following oral anticoagulation at home, was associated with reduced mortality in older patients with AF and COVID-19; iii) a better preadmission functional profile is related to higher survival in older adults with AF and COVID-19.

Another report sampled 90 patients in outpatient and homecare services setting and tested for the role of preserving health status through telephone and video calls during lockdown<sup>13</sup>. They concluded that Activities of Daily Living (ADL), cognitive functioning using the Mini Mental State Examination (MMSE) and quality of life using the European Quality of Life scale (EuroQoL) scores (ADL:  $2.27 \pm 1.65$  vs  $1.98 \pm 1.72$ ,  $p = 0.001$ ; MMSE:  $15.59 \pm 7.83$  vs  $14.49 \pm 7.96$ ,  $p < 0.001$ ; EuroQoL:  $42.22 \pm 11.88$  vs  $40.0 \pm 12.45$ ,  $p = 0.005$ ) significantly worsened over time from T0 (March 2020) and T1 (May 2020), while no significant changes were found in Instrumental activities of daily living (IADL), Geriatric Depression Scale (GDS) and Cumulative Illness Rating Scale (CIRS) scores<sup>13</sup>. Even though the majority of patients were clinically stable over time, behavioral changes were found in 24.4% of patients and anxiety and insomnia in 17.7% of patients<sup>13</sup>.

A new preliminary report (*in press*), carried-out on 168 patients afferent to 10 different Italian Centers for cognitive decline and dementia (CD/D), investigated the impact of lockdown on psychological well-being of individuals with cognitive deterioration. Symptoms of anxiety (28.8%), depression (48%), and psychological stress (24.8%) were observed in these patients who were found to experience psycho-affective disorders according to their pre-quarantine cognitive functioning. In particular, during the first lockdown, individuals cognitively more impaired showed more severe depressive and anxious symptoms, compared to those with better cognitive functioning<sup>14</sup>.

Four additional studies currently are under evaluation, related to the age-related changes in clinical presentation, the chest tomography pattern of COVID-19 in the very old, impact of the lockdown on the health status of demented patients and the clinical and epidemiological features of COVID-19 in NHs. All investigations testify the focus of GeroCovid Observational on the frail population directly or indirectly suffering from COVID-19.

## GEROCOVID VAX STUDY

The Ethical Committee of the Spallanzani Hospital approved the GeroCovid Vax study protocol. Informed consent was also necessary to participate. The study began in January 2021 and ended enrollment as of June 30, 2021. Currently, per protocol inclusion data are available in 3014 participants from 76 Nursing homes all over Italy. Of these, 685 participants have undergone blood testing for humoral and cellular immunity testing which are necessary to understand the efficacy of the immune response in old age. As of August 12, 2021 the clinical follow-up is still ongoing, however enrollment has ceased. Clinical data collections are being performed (7 days prior to the first vaccine dose, 7 days following the second dose, 2-, 6-, and 12-months following the first dose). The study will be concluded in the second quarter of 2022.

## DISCUSSION

The COVID-19 pandemic has stimulated numerous research protocols in geriatric medicine in order to identify and to improve health outcomes from COVID-19 infection, as well as to understand the benefits related to vaccine use. Older and in particular, frail older adults have continuously demonstrated to be at a significantly higher risk for negative health outcomes. A meta-analysis regarding mortality in older Italians with a COVID-19 infection found that dementia, diabetes, chronic kidney disease and hypertension were the main comorbidities associated with death in study sizes ranging from 18 to 1591 individuals<sup>15</sup>. These authors underlined that at the time of admission, clinical frail severity, as well as the presence of > 3 comorbidities, were significantly associated with an increased overall death rate. In comparison to the GeroCovid Observational data regarding in-hospital mortality, a newly published report based in Italy confirmed the importance of clinical functional characteristics at admission on outcomes in older persons<sup>16</sup>. Both GeroCovid Observational and GeroCovid Vax specifically include physical and cognitive functioning parameters, as well as frailty markers.

At the moment, GeroCovid Observational study holds a particular role on identifying risk factors related to outcomes from COVID-19 due to study design. GeroCovid Observational is continuously monitoring and updating the health status of study participants prospectively in order to gain knowledge regarding outcomes in diverse clinical settings, while GeroCovid Vax is providing an important basis for the use and safety of COVID-19 vaccinations in vulnerable elders living in NHs.

Lockdown measures held an overall negative impact on socialization in older persons. As previously mentioned



findings from GeroCovid Observational show a significant increase in anxiety and insomnia using telemedicine techniques to check and follow-up patient health status<sup>13</sup>. Interestingly, another Italian study testing the impact of social distancing during the first wave quarantine/self-isolation ( $31 \pm 5$  mean days) in 334 participants, using an online survey, found that a higher anger score was significantly and negatively related to age, and scores on the Brief Resilience Score and Coping Scale, whereas a significant and positive relationship was found with the fear of getting infected and female gender<sup>17</sup>. The negative impact on social status related to COVID-19 is raising serious concern for long-term effects on health status. GeroCovid Observational may provide the necessary answers.

Additional strengths of GeroCovid Observational include the involvement of multiple clinical settings with the e-registry platform that ensures for a high-quality data entry from each setting. In older persons, GeroCovid Observational has provided and will continue to provide data regarding: i) disease infection onset symptoms; ii) factors related to clinical course of COVID-19; iii) effects on health status of older persons at risk of COVID-19. Since the implementation of anti-COVID-19 vaccines in December 2020, aggregated public data have shown decreases in the incidence of cases of SARS-CoV-2 infection and related deaths<sup>18</sup>. However, lower incident cases might also reflect improved NH organization reducing virus transmission spread. Indeed, by understanding vaccine effectiveness in NH residents, who were not included in clinical trials and who often have reduced immune responses, the GeroCovid Vax study will disentangle numerous doubts of vaccine efficacy and safety<sup>19</sup>.

In conclusion, GeroCovid and GeroCovid Vax represent an example of real life research applied to the most vulnerable fraction of the population exposed to COVID-19. Interestingly, they rely upon a sophisticated and high quality methodological approach to achieve in a standardized way the relevant information from different clinical settings. By standardizing the assessment instruments, they make possible to identify setting specific features of the pandemic. Eventually, the integrated clinical and laboratory approach to the immunization policy will gain insight into the immunologic response of the most frail and multimorbid people.

### Ethical consideration

The Campus Bio-Medico University Ethical Committee approved the overarching protocol of the GeroCovid Observational study in April 2020. All participating investigational sites gained approval from their local Ethical Committee review board. Informed consent was necessary to participate in the study.

The Ethical Committee of the Spallanzani Hospital approved the GeroCovid Vax study protocol. Informed consent was necessary to participate.

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### Conflict of interest

The Authors declare no conflict of interest.

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## SUPPLEMENTARY MATERIAL

### MEMBERS OF THE GEROCOVID OBSERVATIONAL WORKING GROUP <sup>16</sup> (IN ALPHABETICAL ORDER)

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