April 30, 2021

PharmacologyOnLine

Archives • 2021 • vol.1 • 214-223

THE MONITORING MODEL FOR COVID-19 PATIENTS IN THE CONTEXT OF TERRITORIAL MEDICINE: THE EXPERIENCE OF THE COVID SPECIAL UNIT (USCO) OF POTENZA

Giuzio, F.[1,3]*; Bonomo, M.G.[2]*; Armenante, G.[1]; Barra, G.[1]; Casolaro, G.[1]; Di Ludovico, C.[1]; Galasso, L.[1]; Giacco, D.[1]; Grassi, F.[1]; Lardo, D.A.[1]; Monnè, M.L.[2]; Padula, L.M.[1], Paterna, A.[1]; Salzano, G.[2]; Sangregorio, M.[1]; Saponara, A.[1]; Saturnino, C.[2]; Vargas, M.S.[1]; Testa, Y.[1]; Tripodi, F.[1]; D'Angola, L.[1]; Molinari, S.M.[1]

[1] USCO (Unità Speciali Covid), Distretto della Salute di Potenza-ASP, Via del Gallitello 100, Potenza, Italy
[2] Dipartimento di Scienze, Università degli Studi della Basilicata, viale dell'ateneo Lucano, Potenza, Italy
[3] International PhD Programme 'Sciences', Dipartimento di Scienze, Università degli Studi della Basilicata, Potenza, Italy

* federica.giuzio@unibas.it
* mariagrazia.bonomo@unibas.it

Abstract

The purpose of this work is to describe the organization and the experience gained by the COVID Special Unit of Potenza (Basilicata Region, Italy) in the months of activity in the Covid-19 emergency. It also describes how the use of IT tools has considerably simplified the territorial management of suspected and confirmed Covid19 cases.

"Home hospitalization" has become the new model of assistance for the Potenza Unit, with a significant and modern use of telemedicine, self-monitoring and home medical-nursing assistance. Creating new perspectives within a reform of the National Health System for the future territorial management of non-critical Covid-9 patients is, therefore, the key message of our work.

Keywords: *Covid-19, USCO, IT tools, telemedicine, home hospitalization, future territorial medicine management*

Introduction

Coronavirus disease 2019 (COVID-19), responsible for the pandemic that started in China in late 2019, is caused by the beta-coronavirus SARS-CoV-2, a highly contagious single-stranded RNA virus (1). Transmission occurs mainly by air and is mediated by the binding of the viral protein Spike (S) to the highly expressed angiotensin converter 2 enzyme (ACE2) in the lung; therefore the infection usually presents with respiratory symptoms. Blood dissemination and the presence of ACE2 to a lesser extent also in the endothelium of blood vessels, in the epithelial cells of the intestine and in neurons is responsible respectively for systemic, intestinal, anosmia and ageusia symptoms. (1,2) Several variants of SARS-CoV-2 have currently been identified: variant B.1.1.7, widely spread in the US, B.1.351 initially identified in South Africa and B.1.1.28, found in four travelers from Brazil during routine screening investigations at Haneda Airport (Tokyo). All of them have accumulated, among the many mutations that characterize them, mutations in protein S, acquiring the selective advantage of greater transmissibility; the 69–70 mutation of the commonly called "English" variant also produces a negative result on the 3 targets available for the diagnostic test based on RT-PCR, creating new concerns about strategies to overcome the pandemic. (3). Studies carried out in China during 2019-2020 show that in more than 80% of cases, patients have mild symptoms or are asymptomatic, but about 5% have respiratory failure, septic shock and multi-organ dysfunction, with fatality in 50% of such cases. (2) In the initial stage the symptoms are nonspecific and flu-like. In most patients, the disease ends at this stage with the need for symptomatic therapy only. In the second stage we have viral replication and lung inflammation with bilateral interstitial pneumonia often accompanied by hypoxia and the need for mechanical ventilation. In the third stage of systemic hyper-inflammation, due to Acute Respiratory Distress Syndrome (ARDS), fluid collects inside the bronchioles with interruption of the protective surfactant surfactant coating and collapse of the alveolus, accompanied by an uncontrolled inflammatory response with massive release of cytokines, platelet activation and coagulopathy (1). Given the heterogeneity of manifestations, it is essential to identify high-risk patients based on age, previous pathologies (hypertension, obesity, cancer, congestive heart failure, COPD, etc.) and the stage of the disease, for a territorial management of prevention of complications and the evolution of the disease and prompt hospitalization when necessary. On 11 March 2020, the World Health Organization (WHO) declared the international outbreak of the SARS-CoV-2 coronavirus infection as a pandemic. The COVID-19 epidemic in Italy was divided into several phases which led to a subdivision into different areas based on the risk level of the infection and with different restrictive measures. With the Legislative Decree 14/2020 of 9/03/2020, the Special Continuity Care Units (USCA) are established in the territory to strengthen the welfare system in order to face the new pandemic needs on the peninsula. Article 8 of Legislative Decree 14/2020 in fact provides for the establishment and activation of the USCA by March 20, 2020 in all regions: a team for every 50,000 inhabitants, made up of doctors and subsequently also of nurses, thus ensuring continuity of care, even during the day, to patients who do not require hospitalization. The special unit is active 7 days a week, from 8.00 to 20.00 and is activated by the General Practitioner (GP), the Pediatrician of Free Choice (PLS) or the Continuity Care Doctor (MCA) who communicate to the USCA the name and address of the patient allowing the taking in charge, the isolation and quarantine of close contacts, the clinical evaluation, the therapeutic planning, the daily monitoring and the delivery of any necessary material (pulse oximeters, devices for telematic monitoring, drugs etc ..).

Basilicata region responded to the appeal by setting up 6 COvid-19 Special Units (USCO) in the province of Potenza. The USCO of Potenza is divided into three stations for monitoring patients and families and one other station entirely aimed at the management of positive patients in nursing homes for the elderly and RSA.

The regional guidelines state that non-critical patients must be reported by GPs, doctors employed in contact tracing, continuity doctors and pediatricians of free choice, to USCO units, where enrollment is decided and doctors organize home monitoring. Telemedicine was considered the fundamental monitoring strategy, after all devices

(such as pulse oximeters, sphygmomanometers and tablets) and drugs (such as corticosteroids, antibiotics, low molecular weight heparin, oxygen, hydroxychloroquine etc ...), (7- 8) were provided to assisted patients. The management of the diagnostic swab, after the request by a family doctor or a doctor from the hygiene office, was also entrusted to the USCO, together with a team of nurses and drivers specifically appointed for their execution.
To USCO19 are reported (9):

- Positive patient with mild symptoms and with at least one risk factor

- Patient with Covid19 who does not need hospitalization or discharged with a diagnosis of Covid19 who presents mild symptoms

- Patient with even modest respiratory symptoms but with fever lasting beyond the 4th day or patient positive and/or with well-founded suspicion of Covid19 desease presenting dyspnoea

The reported patient is contacted by telephone by the USCO doctor who submits a questionnaire (10) documenting on age, sex, epidemiological status, past medical history, ongoing immunosuppressive therapy, performed vaccination, therapy in progress, basal spO2, spO2 after walking test, breath frequency, heart rate, temperature, clinical symptoms related to SARS-Cov-2 infection.
The monitoring frequency is decided considering the patient's clinical history, age, comorbidities and severity of the disease, from one to three times a day in the initial period and subsequently more spaced (up to only three times in a week) in the recovery and asymptomatic phases.
The "Modified Early Warning Score" (MEWS) scale is used in the assessment of the patient, which considers body temperature, peripheral oxygen saturation, systolic blood pressure and respiratory and heart rate, (11) as well as the characteristic symptoms of Covid-19 infection (cough, dyspnoea, diarrhea, expectoration, asthenia, headache, vomiting, nausea, and changes in consciousness) and their changes in the progressive evaluations. (12) This helps the physician decide whether to initiate a home clinical evaluation or send the patient to the hospital.

Methods

Informatic management of patients and tampons: the SISIR platform and the Tracing Center

The SISIR platform, which can only be consulted by USCO doctors, the referring GP / pediatrician and the continuity of care doctor, is the tool used for the management of the positive or, in some cases, suspected Covid patient. The platform allows programming of the molecular swab for the search for SARS-COV2 for the citizen reported as close contact of a subject tested positive, definition of the duration of the quarantine for the citizen waiting for a molecular swab, opening the territorial monitoring file, identification of any cohabitants / connected cases by the tracing center, communications between Task Force and patient, acquisition of the outcome of the molecular swab transmitted by the analysis laboratory.
The task of the USCO of Potenza is to take care of critically ill patients (positive for Covid-19) in the acute phase of the disease or of citizens waiting for a swab who have symptoms compatible with Sars-Cov2 infection. Once the criticality report has been received, the USCO doctor activates the telephone monitoring procedure after filling in a form and the data collected are then transferred in computer mode to the territorial record in order to start the monitoring that consists in the acquisition, through telephone contact and direct conversation with the patient, information on any variation (exacerbation or improvement) of the symptoms; patient's daily parameters acquired by the same independently; therapy in progress, any side effects and suspension of the same. Based on the available data, the USCO doctor establishes the update frequency (12, 24, 48 or 72 hours) and schedules the home visit based on the severity of the clinical picture to prepare for any hospitalization or continuation of home management. From the start of the activity of the USCO in Potenza until January 2021, the total number of positive patients monitored was 426 in the Potenza district alone. As regards the management of molecular swabs, after the expiry of

the quarantine the doctor of Public Health and Hygiene Office orders to collect and execute the swab at the patient's home or at the spepoint set up at the San Carlo Hospital in Potenza.

The USCO home visit and intervention criteria

The USCO home visit is performed after an initial telephone evaluation with the patient during which the doctor identifies some criteria worthy of clinical study which are: clinical picture with a tendency to worsen compared to previous days; increase in body temperature, failure to respond to paracetamol or to therapies established in the previous days; malaise suggested by the patient as the onset of dyspnea.
At the moment of the visit, each patient is notified by telephone of the arrival of a USCO team consisting of a driver, one or two doctors and, if necessary, also the figure of a nurse. After appropriate dressing, performed according to ISS regulations, the operators visit the patient. The visit consists (14) of a general physical examination of the patient; the detection of specific parameters, such as body temperature (CT), blood pressure (BP), heart rate (HR), respiratory rate (RR), 02 saturation (SPO2%) in ambient air and/or with oxygen therapy both at rest and after walking for 6 minutes (WT); a thoracic physical examination with auscultation. and if possible an ultrasound examination of the chest.
The doctor takes care of the following parameters:

- positive gait test (to be performed in patients with SpO2> 94% in ambient air and at rest);
- chest pain related to breathing;
- progressive worsening of symptoms;
- deterioration of general conditions with progressive impairment of the ability to hydrate and feed;
- tachypnea and / or orthopnea;
- persistent heartbeat;
- cyanosis;
- hemoptysis.

With the aim of avoiding improper overloading of the 118 service, red flags have been identified useful for activating the ambulance with subsequent transfer of the patient to the hospital of reference: dyspnea; alteration of the state of consciousness; syncope or P.A. systolic <100mmHg not otherwise explainable; SpO2 <92% in ambient air (or <90% in ambient air in the COPD patient); focal or multifocal confluent B lines assessable on ultrasound examination.
In the USCO home visit, the chest ultrasound has proved to be a useful tool for integrating the physical examination of the chest, when this is altered (therefore in the presence of pathological lung sounds on auscultation or alterations in the tactile vocal thrill and percussion). However, it is a sensitive method only on pleural and subpleural changes and allows the previously detected pulmonary changes to be observed over time, monitoring their progress during home therapy. In fact, it must be remembered that it should not be used as a diagnostic tool for COVID-19 due to the low specificity of the artifacts generated by viral infection in the subpleural area (15, 24).

SOS Covid-19 web platform and App

In order to face the fast increase of infected people and to manage those who find themselves isolated or in need of support, on the 7th of April 2020 Basilicata Region made available to the population the " SOS Covid-19" App, developed by Apperò s.r.l. The company has contacted all patients with a positive covid PCR-swab proposing them to be monitored with the new application SOS Covid-19. According to those accepting to use this app, a list of patients is made and sent to the USCO, who evaluates them and, if needed, begin the telemonitoring. Thanks to the app the patient can update more than once in a day his SpO2% and body temperature, and contact them through video chat or phone his GP or USCO's doctor. USCO doctors evaluate patients' daily updates on the app and decide who needs to be contacted and potentially be part of the telemonitoring on the platform SISIR, or to visit them at home. The app besides highlights the patients showing altered vital signs (BT > 37°C, SpO2% < 92%), alerting the doctors about possibly clinical worsening of covid positive patients. The application is available for free for Android, and the logins are guaranteed by an activation code provided from Basilicata Health system (Azienda sanitaria provincial-ASP). In case no android device is available (smartphone or tablet), ASP has

provided tablet Samsung Galaxy TAB A to the positive patients until their recovery from covid disease.

Results

We noticed some differences in patient Monitoring and enrollment between the first Monti of activity and the end of the year when the Basilicata region registered a big increase in the number of infected people. From April to May 2020 the total number of monitored patients was 132 of which only 35 of them resulted positive to Covid-19. From June to August we had 40 patients monitored only in Potenza of which only 10 resulted positive. From September and During the autumn the number of infected people raised enormously with 34 positive patients in September, 84 positive patients in October, 110 positive patients in November, 88 positive patients in December, and 72 positive patients in January 2021. The total amount of covid-19 positive patients monitored from the beginning of USCO activity in the district of Potenza, until January 2021, is 433: 197 males and 229 women (table 1). Figure 1 shows males and females monitored patients percentage divided by age groups. Figures 2-4 show the number of patients monitored, divided by age groups, who presented risk factors, symptoms, and the therapy to which they were subjected. Overall, 38 of these patients were hospitalized while about 15 underwent home lung ultrasound, a solution in case of necessary hospitalization. No patient demonstrated signs of toxicity during our monitoring and required discontinuation of therapy.

USCO activity concerned also fragile people living in nursing homes or prisons. In particular, in November 2020 we registered 81 Covid-19 infected fragile patients of which 19 were hospitalized and 5 died. In December there were 23 more cases of which 16 were hospitalized and 12 died. In January 2021 the total amount were 115 Covid-19 positive patients in the nursing homes of which 15 were hospitalized and 10 died. In each nursing home lungs, ultrasounds were done to every Covid-19 positive patient and were fundamental in the decision-making process to hospitalize.

Discussion

The Potenza USCO service, from its institution (march 2020) until now, had to modulate periodically its internal organization and its resources due to the pandemic progression and the need to make the service more efficient, placing himself as a link between the territorial health service and the hospital ones. Indeed the USCO integrated with all the territorial services of the network involved in the emergency management(hygiene and public health department, general practitioners and territory pediatricians, emergency, community care, citizens).

Our results prove that USCO service took care of a heterogeneous range of people for age(15-90 yo), clinical conditions (low symptomatic and symptomatic), clinical profiles (healthy patients, patients with comorbidity and fragile), often managing entire families. Data show that elders, fragile patients, and those with morbidities need stricter monitoring and an early and personalized treatment due to their higher risk of Sars-cov2 complications and hospitalization.

Telephone monitoring shows to be useful only with collaborative patients or with those supported by a caregiver in the use of pulse-oximeter and blood pressure monitor. Has been demonstrated that pulse-oximetry is the most important and predictive sign for respiratory failure and severe covid-19 pneumonia in-home monitored patients, also in those who don't suffer from dyspnea (so-called silent hypoxemia). Although its ease of use and low costs make it a very interesting option to identify early phase problems, only a few independent scientific studies have evaluated pocket pulse-oximeter and smartphone-based performances. The lack of data makes us doubt their accuracy, especially when O2 saturation goes below 90% (16).
Home visiting mostly showed to be a fundamental tool to manage fragile or unstable patients: physical examination, direct vital signs monitoring, lung ultrasound, and the Knowledge of patient social context were essential to make therapeutical and management decisions.
In our experience lung, ultrasound was useful for that little part of patients with borderline pulse-oximeter values or morbidities that could confuse

the medical case. As shown in literature(17) lung ultrasound can be useful for monitoring patients with an early Sars-cov2 infection because in the early stages, although it is less sensitive than the lung TC in the detection of early subpleural lesions, is more sensitive than Xray. Thus if lung ultrasound shows pleural thickening, subpleural lesions, increase in B-lines (ring-down), or pleural effusion, it's surely linked to a certain grade of lung involvement. That doesn't mean Sars-cov2 related pneumonia but it means that further diagnostic is needed in that positive covid-19 patient.

Furthermore, it can be carried out by any doctors with the right competence; it's a bedside exam, safe(biological risk not significant), repeatable and low cost. The ultrasound machine is a manageable, portable diagnostic tool that avoids patient relocation and can be disinfected(18,19).

Ultrasound is affected by several limits: physical (air in the lung or thorax bones), anatomical (thoracic wall structures), and technical/executive (operator's expertise); it can study only 70% of pleural lines and permits visualize only pleural and sub-pleural lesions; if it is negative ,that doesn't exclude deep lung lesions; ultrasound findings in a covid-19 patient are not always related to the infection (because of pathological findings are common to other interstitial lung disease and lung disease) (20,21) and ultrasound findings don't correlate to disease extension and its anatomopathological severity (no panoramic exam). Thus for its interpretation, it is necessary a good clinical orientation and for constant use in the domestic management of covid-19 patients it is necessary to invest in operator's training and integration of ultrasound with laboratory (also at home) and clinical data .

Care setting has been for all patients their homes, totally or partially, during pre or post-hospitalization ,and from the month of November 2020 when infections raised, part of the service dedicated to patients in care residence. Due to these reasons and gradually workload rise it was necessary to hire more operators ,doctors, nurses, drivers, opening two more workplaces (from two to four) and it was necessary to renovate work model organization in terms of technological support, diagnostic and monitoring instruments and job tasks (e.g. more shifts to cover PCR and rapid tests execution needs).

For the entire emergency management system, the periodic expansion of the SISIR platform proved fundamental and, in particular for the USCO service, the updating of the "territorial record" for enrolled patients, with the implementation of epidemiological, health and strictly clinical data have speeded up and made monitoring and data collection more efficient.

The introduction of an App for telemonitoring has also favored the surveillance of patients who could have available a smartphone at home and made it easier to contact the population of younger patients, who, however, had to manually upload their parameters to the App. (blood pressure, transcutaneous oximetry and body temperature). An increase in the use of typical technologies of digital health could be hoped for, to expand and make teleconsultation and telemonitoring more accessible and above all to optimize the measurement of the parameters at home, with a data truthfulness control systems, as also demonstrated by the literature (22).

In conclusion, our study shows that the USCO Service, for the purposes with which it was born, cannot be a "static" service and has had and will need to be remodeled until the health emergency, linked to the pandemic of COVID-19 , Will come to an end. In light of the results of patient care, it cannot be excluded that, even after the health emergency, the USCO may take on an innovative important role in territorial care as an evolution of the existing home care service, both in terms of versatility and effectiveness of patient care and management, alongside existing general medicine and home care services.

The pandemic has in fact highlighted the dramatic delay of an updated approach to a third age medicine that requires a strong integration between local services and a multidimensional approach to the elderly patient.

For the near future we hope to consolidate the integration between the various nodes of territorial assistance, through shared operational protocols, a professionalizing, targeted and uniform training of the involved healthcare professionals, a greater

investment in IT infrastructures (23) and digital health and a service evaluation system.

References

1. Machhi, J. (2020). The Natural History, Pathobiology, and Clinical Manifestations of SARS-CoV-2 Infections. *Journal of Neuroimmune Pharmacology*, 1–28.
2. Hasan, K., & Siddiqi, M.R.M. (2020). COVID-19 illness in native and immunosuppressed states: A clinical–therapeutic staging proposal. *The Journal of Heart and Lung Transplantation*, 39(5), 405-40.
3. Galloway, S.E. (2021). Emergence of SARS-CoV-2 B.1.1.7 Lineage — United States. *Morbidity and Mortality Weekly Report*, 70(3), 95-99.
4. https://www.regione.basilicata.it/giuntacma/files/docs/DOCUMENT_FILE_3070926.pdf
5. https://lab24.ilsole24ore.com/coronavirus/
6. https://opendatadpc.maps.arcgis.com/apps/opsdashboard/index.html#/b0c68bce2cce478eaac82fe38d4138b1
7. Principi, N., & Esposito, S. (2020). Chloroquine or hydroxychloroquine for prophylaxis of COVID-19. *The Lancet Infectious Diseases*, 20 (10), 1118.
8. Şimşek, S. Ünal S. (2020). Antiviral treatment of COVID-19. *Turkish Journal of Medical Sciences*, 50(SI-1), 611-9.
9. Procedura operativa per la gestione di casi sospetti di infezione da COVID-19 in Basilicata- Versione 8 del 19 novembre 2020.
10. Allegato 1 (scheda di monitoraggio domiciliare).
11. Hu, H., Yao, N., & Qiu, Y. (2020). Comparing Rapid Scoring Systems in Mortality Prediction of Critically Ill Patients With Novel Coronavirus Disease. *Academic Emergency Medicine*, 27 (6), 461-468.
12. Li, L.Q., Huang ,T., & Wang, Y.Q. (2020). COVID-19 patients' clinical characteristics, discharge rate, and fatality rate of meta-analysis. *Journal of Medical Virology*, 92 (6), 577-583.
13. Ferner, R.E., & Aronson, J.K. (2020). Chloroquine and hydroxychloroquine in covid-19. *British Medical Journal*, 369, 1432.
14. Procedura operativa per la gestione di casi sospetti di infezione da Covid-19 in Basilicata Dipartimento Politiche della Persona Task Force Coronavirus SARS-CoV-2.
15. Moore, S., & Gardiner, E. (2020). Point of care and intensive care lung ultrasound: A reference guide for practitioners during COVID-19. *Radiography*, 26(4), e297-e302.
16. Luks, A.M., & Swenson, E.R. (2020). Pulse Oximetry for Monitoring Patients with COVID-19 at Home. Potential Pitfalls and Practical Guidance. *Annals of the American Thoracic Society*, 17(9), 1040-1046.
17. Joseph, Tinku. (2020). International Pulmonologist's consensus on COVID-19. International Pulmonologist's Consensus On Covid-19. Chief Editors.
18. Peng, Q.Y. (2020). Findings of lung ultrasonography of novel Coronavirus pneumonia during the 2019– 2020 epidemic Intensive Care Med. *Intensive Care Medicine*, 46 (5), 849-850.
19. Buonsenso, D. (2020). Point-of-Care Lung Ultrasound findings in novel Coronavirus Disease-19 pneumoniae: a case report and potential applications during COVID-19 outbreak. *European Review for Medical and Pharmacological Sciences*, 24 (5), 2776-2780.
20. Trovato, G.M., & Sperandeo, M. (2013). Sounds, ultrasounds, and artifacts: which clinical role for lung imaging? *American Journal of Respiratory and Critical Care Medicine*, 187 (7), 780-1.
21. Sperandeo, M., Varriale, A., Sperandeo, G., Polverino, E., Feragalli, B., Piattelli, M.L., Maggi, M.M., Palmieri, V.O., Terracciano, F., De Sio, I., Villella, M., Copetti, M., Pellegrini, F., Vendemiale, G., & Cipriani, C. (2012). Assessment of ultrasound acoustic artifacts in patients with acute dyspnea: a multicenter study. *Acta Radiologica*, 53 (8), 885-892.
22. Quarato, C.M.I., Venuti, M., Lacedonia, D., Simeone, A., Dimitri, L.M.C., Rea, G., Ferragalli, B. & Sperandeo, M. (2020). The Role of Transthoracic Ultrasound in the

novel Coronavirus Disease (COVID-19): A Reappraisal. Information and Disinformation: Is There Still Place for a Scientific Debate? *Frontiers in Medicine*, May 27;7:271

23. Xu, H., Huang, S., Qiu, C., Liu, S., Deng, J., Jiao, B., Tan, X., Ai, L., Xiao, Y., Belliato, M., & Yan, L. (2020). Monitoring and Management of Home-Quarantined Patients With COVID-19 Using a WeChat-Based Telemedicine System: Retrospective Cohort Study. *Journal of Medical Internet Research*, 22(7).
24. Asadzadeh, A., Pakkhoo, S., Saeidabad, M.M., Khezri, H., & Ferdousi, R. (2020). Information technology in emergency management of COVID-19 outbreak. *Informatics in Medicine Unlocked*, 21, 100475.

Table 1. Total number of monitored patients

Age groups	Patients	Female	Male
0-20	26	17	9
21-40	94	51	43
41-60	159	75	84
61-100	147	86	61
Total	426	229	197

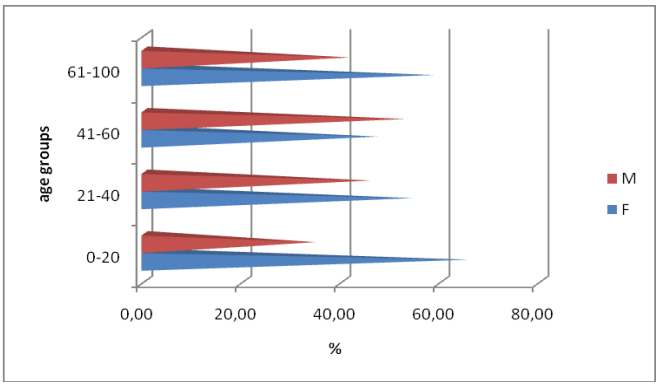

Figure 1. percentage of males and females monitored patients divided by age groups.

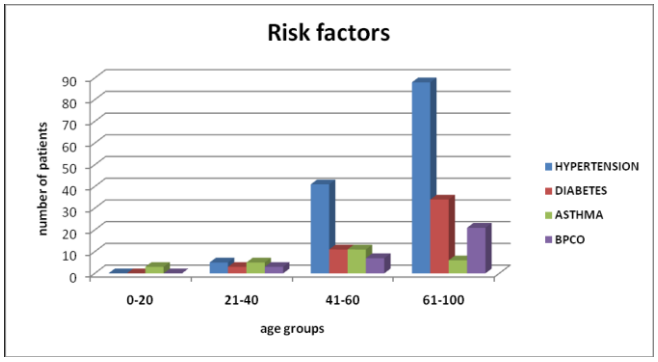

Figure 2. Number of monitored patients presenting risk factors.

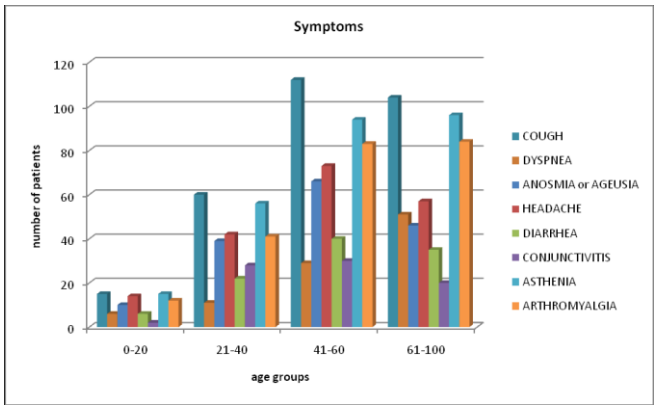

Figure 3. Number of monitored patients presenting symptoms.

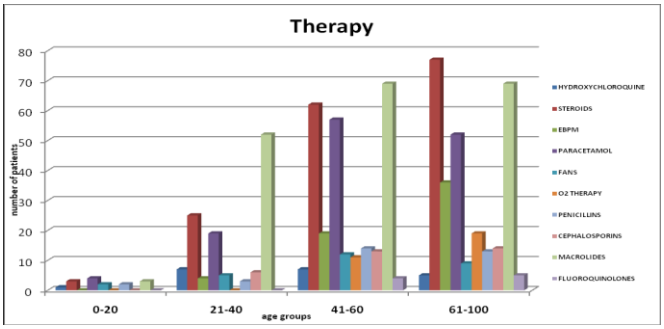

Figure 4. Number of monitored patients treated