

Rehabilitative treatment of patients with COVID-19 infection: the P.A.R.M.A. evidence based clinical practice protocol

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Summary. *Background:* The impact of the SARS-CoV-2 on the National Health System (NHS) required a reorganization of the various levels of care, which also involved the rehabilitation reality. *Aim of the work:* A clinical practice review of the literature was conducted to provide operational-rehabilitation guidelines adapted to the local reality and to the recent corporate reorganization in the context of the COVID-19 emergency. *Methods:* A practice review of the available scientific evidence was regularly conducted from the start of the COVID-19 pandemic to periodically update the clinical practice guidelines. Articles that met the following inclusion criteria were included: studies conducted on human adult subjects with COVID-19 infection, undergoing rehabilitation in any hospitalization setting. *Results:* The results of this clinical practice update were periodically discussed with colleagues and collaborators in a multi-professional team, in order to guarantee a good clinical practice protocol, named P.A.R.M.A. *Conclusions:* The P.A.R.M.A. protocol is the result of a periodic review literature update, which has allowed us to take charge of patients affected by COVID-19 according to the most up-to-date clinical evidences, guaranteeing a shared and uniform treatment within a local reality in an era of health emergency. (www.actabiomedica.it)

Key words: covid-19, coronavirus, rehabilitation, clinical protocol.

Background

The impact of the SARS-CoV-2 on the National Health System (NHS) required a reorganization of the various levels of care, which also involved the rehabilitation realities (1). In the city of Parma (Italy) and its Province, the rapid increase of COVID-19 patients, both with mild and moderate to severe

symptoms (2-3), in need of hospital interventions, has determined a series of events that inevitably required a reorganization of the health governance. The first factor addressed was the need to differentiate health care pathways for COVID-19 and non-COVID-19 patients (4). This represented a massive stress for the healthcare system forcing health authorities to take urgent measures to manage the flow of

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COVID-19 patients (5). Intensive Care Units (ICU) had to transfer more stable patients to other Units with decreasing treatment intensity (step-down) in order to hospitalize new acute COVID-19 positive patients, while continuity of care for other should be maintained.

In this new condition, the difficulties in the organization of the rehabilitation wards and the safety of patients and operators quickly led to a new organizational proposal, and re-adapting care strategies, as requested to many other national and international units and immediately witnessed by scientific societies and international organizations in the rehabilitation section (6-9). Those strategies were oriented towards an early discharge, where possible, of COVID-19 negative patients from the rehabilitation units (10) or, in case of need to continue the rehabilitation treatment, in non-COVID-19 wards (11). Furthermore, the measures of social distancing and restriction of movement, decided by national and local authorities in attempt to limit contagion, had negative impact on the management of rehabilitative patients in need of outpatient and home treatment (11). Consequently, the Rehabilitative Medicine Unit of Parma has been reorganized several times until today (12). In addition to the previous transversal rehabilitation needs of non-COVID-19 patients hospitalized in the different departments of the Hospital, new activities for patients affected by COVID-19 had to be implemented. These comprehended: the rehabilitative care of non-COVID-19 patients maintenance (rehabilitation consults in clean wards for adults and children and outpatient activities, even introducing telemedicine (13) when possible); taking care of COVID-19 patients at different levels of care, integrating their treatment with the latest literature on the subject (14); creating a network with territorial rehabilitation and accredited rehabilitation facilities (for COVID-19 and non-COVID-19 patients).

In order to provide operational-rehabilitation guidelines adapted to the local reality and to the recent corporate reorganization in the context of the COVID-19 emergency, a continuous clinical update using the latest literature was conducted.

Methods

Evidence Acquisition: A literature review was conducted monthly from January 1st, 2020 to July 31st, 2020 in order to guarantee updated clinical practice guidelines based on available evidences. The result of this review was a clinical protocol named P.A.R.M.A.

“P” stands for “Pandemic”, as on March 11th 2020, the World Health Organization declared the outbreak of COVID-19 a pandemic (15-16).

“A” stands for “Adults”. Overall, 69% of cases, 55% of hospitalizations, 47% of hospitalizations in ICU and 20% of deaths associated with COVID-19 are adults under 65 years of age (15,17).

“R” stands for “Respiratory”. The main signs and symptoms of patients hospitalized with COVID-19 are associated with respiratory infection with fever, cough, dyspnoea, myalgia or fatigue and high respiratory rate (>24 acts per minute) (15,18).

“M” stands for “Multi-organ”. The majority of patients admitted to ICU (19) have multi-organ failure, including clinical manifestations similar to Acute Respiratory Distress Syndrome (ARDS-like, 67%), acute kidney damage (29%), cardiac damage (23%) and liver dysfunction (29%) (20).

“A” stands for “Asymptomatic” (or Paucisymptomatic). Approximately 80% of patients with a confirmed laboratory diagnosis presented mild to moderate disease with or without pneumonia (21).

Database and search strategy: We searched all papers published from January 1st, 2020 until July 31st, 2020 in all principals databases: PubMed, SCOPUS, Embase, WOS, Pedro. Documents from official organizations were also evaluated. The search query included COVID-19 patients and rehabilitation as intervention using the Boolean operator AND. All types of rehabilitation interventions founded were compared with any other intervention proposed. Every kind of clinical outcome was considered especially at first, considering the poor knowledge of the condition, of its progression and its sequelae and the apparently multifaceted clinical presentation (22-38). Moreover, given the lack of uniformity in the terminology and the scarcity of articles in the first weeks, it was decided to use generic terms in the search string.

Selection criteria: We included articles that met the following inclusion criteria: studies conducted on human adults' subjects with COVID-19, undergoing rehabilitation in any hospitalization setting.

Data extraction: Articles were initially screened by title and abstract, those who were unclear were reviewed according the selection criteria through full text. Two MD independently extracted data from the studies that met the inclusion criteria and they were blinded to each other's. In case of disagreement, a third opinion was sought and the results were periodically discussed with colleagues and other rehabilitation professionals (physical therapists, speech therapists, occupational therapists, nurses and MD of other specializations). Given the practical objective of this literature revision, the number of articles excluded was not marked during each update process. The following screened articles were included:

- from January 1st, 2020 until March 15th, 2020: 9 new scientifically peer reviewed articles, including two guidelines on rehabilitation of COVID-19 patients (39-40) that were used as a basis of our activity;
- from March 16th, 2020 until April 15th, 2020: 50 new peer reviewed articles, including new guidelines on COVID-19 rehabilitation (41) and on the management of COVID-19 patients at different levels of care (42). Reports from national scientific societies (7,14) and from international organizations in the rehabilitation sector (8,43) were also taken into account;
- from April 16th, 2020 until May 15th, 2020: 160 new peer reviewed articles;
- from May 16th, 2020 until June 15th, 2020: 186 new peer reviewed articles;
- from June 16th, 2020 until July 31st, 2020: 275 new peer reviewed articles, including a systematic review on current evidence about rehabilitation of COVID-19 patients (44).

During the editing of the review, especially in the very early stage, systematic reviews with meta-analysis were not available or possible to do because of the lack of randomized clinical trial studies, except for two evidences (45-46).

Results

The contents of the Rehabilitation Protocol COVID-19 P.A.R.M.A. at different levels of care will be detailed as follows. The drafting of the protocol consisted of 2 phases.

Preparatory phase: personal protective equipment (PPE) proper fitting and removal guidelines were acquired and shared with fellow specialists and multidisciplinary teams (47). Staff safety was a priority as well as avoidance of PPE waste. The rehabilitative care of the patient affected by COVID-19 was generally activated after Psychiatrist consult that was requested by the care manager of the patient affected by COVID-19, and was performed according to criteria agreed with the Health Management and the individual Operative Units.

Operational phase: A flow-chart (Supplementary Material 1) aimed at quickly identifying patient's rehabilitation needs was used. The organization of rehabilitation interventions, articulated differently in relation to the level of care (48) of the COVID-19 patient (see below), included: ICU, post-intensive therapy, inpatient wards as described below. Moreover, a network with other local Hospitals was created in order to facilitate the taking charge in the peripheral districts (e.g. sharing of the tools produced as flow-chart, mentioned above and patients and operators brochures –Supplementary Material 2 and 3-, planning of transfers to other rehabilitation facilities, collaboration with the peripheral rehabilitation services, detection and reporting to the ward Physician of any residual rehabilitation needs of discharged patients).

For any direct intervention on COVID-19 patient, the whole team of the rehabilitation unit was primarily trained (49) to ensure the necessary knowledge of the disease and safety operating procedures and the different operational protocols shared. A follow-up by the Psychiatrist consultant was also activated when necessary, i.e. for the evaluation of complex cases or for the evaluation and monitoring of specific needs and for the identification, reporting and organization of the transfer to other settings.

COVID-19 P.A.R.M.A. Protocol in ICU: The Rehabilitative Medicine Unit and the ICU, as



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FLOW-CHART TO REQUIRE REHAB CONSULTATION

QUICK IDENTIFICATION OF REHABILITATION NEEDS
IN COVID-19 IN-PATIENTS,
TO MAINTAIN AND/OR RECOVERY
RESIDUAL ABILITIES

DOCUMENT FOR OPERATORS

ADRESSED TO COVID-19 WARDS

IMPORTANT:

- ⇒ **The Flow-Chart suggests the identification of possible rehabilitation needs** during hospitalization and suggests Rehabilitation Strategies for **hospitalization period** and **discharge** in COVID-19 patients.
- ⇒ **La Flow-Chart** aims to preserve the **Personal Protective Equipment** encouraging only appropriate consultations
- ⇒ **The use of this Flow-Chart facilitates Rehab Service intervention in COVID-19 ward**

indicated in the literature (50-51), have always collaborated in promoting early rehabilitation whenever indicated (52). Early physiotherapy in ICU patients seems to be associated to significantly mortality and morbidity reduction as well as duration of mechanical ventilation or delirium (53). Literature studies also clearly reported complications related to prolonged hospitalization in ICU, on which early rehabilitation intervention is indicated to prevent the Post Intensive Care Syndrome (PICS) (54). PICS is characterized by cognitive, physical and psychic impairment (33,42,55-56). This treatment could be carried out upon direct referral by the ICU MD to the Physical Therapists working in ICU and was based on inclusion/exclusion criteria previously agreed with Rehab unit.

Inclusion criteria for rehabilitative treatment in COVID-19 ICU patients were: pronation time of less than 12 hours; cardio-vascular stability, although norepinephrine in low-speed pump; no Deep Vein Thrombosis (DVT), in case of DVT only the unaffected limb was treated, until de-clotting was reached. Deep sedation did not exclude the treatment.

Criteria for rehabilitation interruption were: fluctuations in body temperature (≥ 38); increased respiratory symptoms, fatigue and no relief after rest; onset of symptoms like chest tightness, chest pain, difficulty breathing, severe cough, dizziness, headache, blurred vision, palpitations, sweating, instability and other symptoms (41), in patients able to report it. Physical Therapists had to monitor oxygen saturation (SpO₂) (e.g. blood oxygen saturation $\leq 90\%$ or more than 4% lower than the baseline value caused exercises interruption), blood pressure and heart rate, respiratory frequency (only for patients not in controlled mode), state of agitation and appearance of neurological signs or pain during treatment (57).

Any intervention was tailored on the COVID-19 patient in ICU. The rehabilitation intervention in this setting should be led by specialists in multidisciplinary teams (49) with a wide range of supporting skills (42). It should start early in the course of hospital treatment (58) and it should consider the clinical stability of the patient (as inclusion/exclusion criteria defined above

PRACTICAL INDICATIONS OF PHYSIOTHERAPY SUPPORT

TO PROMOTE BREATHING AND THE MAINTENANCE AND/OR RECOVERY OF
ENDURANCE, MUSCLE STRENGTH, TO REDUCE THE FATIGUE OF THE PATIENT
AFFECTED BY COVID-19 IN THE ACUTE PHASE

USER-ORIENTED DOCUMENT

TO BE IMPLEMENTED DURING
HOSPITALIZATION FOR COVID-19 AND ONLY
IF ALLOWED BY CLINICAL CONDITIONS

FOR SPECIAL REHABILITATION NEEDS, MED. REHAB. CONSULTATION IS NECESSARY.

IMPORTANT:

- ⇒ Because of Covid-19 infection, **breathing is difficult**, you can have the feeling of air lacking, you can feel in constant breathlessness. This, together with fever and coughing, in addition to staying in bed for a long time, may cause a **muscular weakening**. Doing any movement, even breathing and eating, can become increasingly **tiring**.
- ⇒ **Your help is important to STAY BETTER. HERE WHAT YOU CAN DO, together with Physical Therapists!**

PRACTICAL INDICATIONS OF PHYSIOTHERAPY SUPPORT

TO ALLOW PULMONARY RE-EXPANSION, SAFE MOBILITY AND
MAINTENANCE OF THE RESIDUAL ABILITIES OF COVID-19 PATIENT IN
ACUTE AND POST-ACUTE PHASE

DOCUMENT FOR OPERATORS

TO BE IMPLEMENTED IN COVID-19 HOSPITAL WARDS

IMPORTANT:

- ⇒ The Covid-19 patient should be stimulated to move respecting Dyspnea and Fatigue
- ⇒ Monitoring of Respiratory Frequency (RF), Blood Oxygen Saturation and Heart Rate (HR).
- ⇒ **Do not give devices for pulmonary rehabilitation, except after specialist advice** (Pneumologist or Physiatrist).
- ⇒ It should be remembered that **for special rehabilitation needs patients must be evaluated by the Medical Specialist and by an experienced Physical Therapist.**



and shared with the multidisciplinary team of the various units) (59-60).

Moreover, the rehabilitation treatment had to take into account the main issues of the patient in this hospitalization setting:

- Weaknesses acquired in ICU (ICUAW) (61), a very common feature following respiratory distress, with estimates between 25-100% and with possible predisposing factors such as immobility, suboptimal glycaemic control and iatrogenic use of steroids and neuromuscular blocking agents. The ICUAW is an important determinant of poor long-term functional performance and requires expensive rehabilitation and treatment.
- Critical illness polyneuropathy and critical illness myopathy (62-63), appearing in 25-46% and 48-96% of patients respectively (64). The stress response of the acute event induces a negative protein balance and an anabolism resistance signalling, this reaction, together with physical inactivity (immobility) leads to proteolysis and loss of muscle mass (63,65).
- Prolonged immobility and its sequelae (66), e.g. cardiorespiratory deconditioning, postural instability, DVT, muscle shortening, pressure injuries.
- Oedemas (67) or increased joint stiffness (68), frequently seen in patients with ICU. Oedemas were especially in the upper extremities, probably due to protein deficits (69) or to fixing methods of ventilation devices (70).

Protocol COVID-19 P.A.R.M.A. in post-intensive care unit: The literature showed that the patient in a post-intensive ward had high rates of myopathy and neuropathy and therefore needs early rehabilitation (52). A strength-recovery oriented treatment of both peripheral and respiratory muscles, where possible, had a positive influence on the duration of ventilation (53). The rehabilitation activities in Parma hospital took place within a newly established post-intensive care respiratory unit. The constant presence of a consultant specialist in Physical Medicine and Rehabilitation within the ward team was foreseen (71-72). The rehabilitative care

took place after daily collegial discussions with colleagues Pulmonologists and Anaesthesiologists (50). The definition of the rehabilitation program was based on the multidisciplinary approach which included daily evaluation of the possibility of respiratory weaning from the ventilator and/or tracheostomy tube and definition of other rehabilitative goals (e.g. need of speech therapy) (53,73). Speech therapy was targeted on evaluation of the swallowing of patients with tracheotomy tube (74), disconnected from mechanical ventilation and close to trach tube removal (after fibrobronchoscopy performed by specialists in the field and possible specialist Otorhinolaryngology's evaluation for selected patients). Dysphagia evaluation in patient with tracheotomy tube was provided with Blue Dye Test, Daniels Test and Bedside Swallow Assessment (75-76). Those tests aimed to assess dysphagia resulting from oropharyngeal and/or laryngeal trauma, attributable to both the invasive procedure and the possible direct additional effect of SARS-CoV-2, capable of causing laryngeal inflammation in some patients, neuromuscular weakness, reduction of laryngeal sensitivity, alterations in the state of consciousness, gastroesophageal reflux disease or incoordination between breathing and swallowing (77-78). The underlying pathological mechanism of post-intubation dysphagia was believed to determine its duration (79) and its identification and treatment were the key to promoting patient recovery (80). Management of the rehabilitation treatment was based on the same criteria of treatment of the COVID-19 patient admitted to ICU (see above).

Protocol COVID-19 P.A.R.M.A. in the wards of the Hospital: The rehabilitative care in the COVID-19 Hospital wards created during the emergency (81) took place following a Physiatrist consult requested by the physician who was in charge of the patient, by means of the specially designed flow-chart and followed the indications (82) mentioned above. The Individual Rehabilitation Project (83) was drawn up on the basis of the patient's residual disability and/or any previous disabilities. The objective of the rehabilitation intervention was the recovery of the greatest possible degree of patient autonomy also in order to facilitate the discharge. Any residual rehabilitation needs after discharge was assessed and reported through the discharge letter to the General Practitioner. General

Practitioners, playing an important role in mediating information on the health status of the family unit, participated in the patient's care path by promoting the continuity of care in rehabilitation services of Local Health Authority. Prescription of orthosis and aids took place according to Local Health Authority rules, which also included telematics modalities. The Rehabilitative Medicine Unit produced an informative brochure based on available literature evidence (Supplementary Material 2), with the aim of providing the patient with an exercise plan to be autonomously performed, where possible, after discharge. For patients already bedridden before the acute event or whose precarious clinical conditions did not allow to arrange a targeted rehabilitation treatment, an informative brochure for Operators was provided (Supplementary Material 3), with a few simple rehabilitative indications for the correct manual handling of patients and to facilitate care procedures. The contents of the brochure were in continuity with the project of education to the correct handling of loads for staff safety, already previously activated by Physical and Rehabilitation Unit in collaboration with the Hospital Prevention and Protection Service.

Criteria for exclusion from rehabilitative care in wards were body temperature $\geq 38.0^\circ\text{C}$, initial diagnosis time ≤ 7 days, time from onset to dyspnea ≤ 3 days, progress of chest imaging within 24–48 hours $> 50\%$, blood pressure $< 90/60\text{mmHg}$ or $> 140/90\text{mmHg}$ (14,41). Criteria for rehabilitation interruption were described above (see Protocol COVID-19 P.A.R.M.A. in ICU).

Intervention (84): According to the Guidelines for Clinical Practice on Physiotherapeutic Management for COVID-19 patients in acute setting (85), Physical Therapists performed their activity as follows:

- They accessed hospital wards on COVID-19 patients after specialist evaluation or according to protocols agreed upon with the different units;
- They provided mobilization, exercise and rehabilitation interventions, e.g. in patients with comorbidities leading to significant functional decline and/or in ICUAW;
- They perform treatments only in the presence of rehabilitative indications given by the

Physiatrist, so as to minimize PPE wasting and staff exposure to SARS-CoV-2;

- Their activity included constant collaboration with MD and nurses to determine the inclusion/exclusion criteria for physical therapy and for screening according to established/agreed guidelines.

First indications available in literature (39,85–86) planned the physiotherapeutic involvement according to clinical severity of COVID-19 patients, with possible interventions of physical activity and motor and/or neuromotor rehabilitation in case of worsening of previous disability and in the presence of significant functional limitations, such as ICUAW, frailty, multiple comorbidity and advanced age, according to the patient's clinical trend. Moreover, general recommendations for respiratory physiotherapy interventions were defined (14,39,76,85). These were applicable not only to COVID-19 patients, but also to patients undergoing treatment for other pathologies in outpatient care or in the non-COVID-19 inpatient ward, for whom the rules of staff and patient and operators protection should always be maintained (47).

Considering that many respiratory physiotherapy interventions are potential aerosol generators, there was a risk of creating airborne transmission of SARS-CoV-2 during treatments. Physical therapists should assess the risk against the benefit in completing these interventions and use airborne contact precautions. PEEP-bottle was not recommended for patients with COVID-19 for the risk of hemodynamic worsening particularly in patients with normal lung compliance (3) and also because of uncertainty about the potential of aerosol diffusion (87). In any case, understanding the correct pathophysiology is critical to establishing the basis for appropriate treatment and the use of PEEP-bottle has to be agreed with the multidisciplinary team for special cases. Sputum inductions should not be performed. Physical therapists can continue to advise on patient positioning requirements.

For clinical practice goal of this protocol, authors paid special attention to the recommendations for mobilization and exercise. Mobilization and

exercise prescription should involve careful consideration of the patient's condition (e.g. stable clinical presentation with stable breathing and hemodynamic function) (88). As suggested in literature (85,89), mobilization of the patients was encouraged in the early stages of the disease course. When safe to do so at an early age, patients should also be encouraged to maintain daily life activities and the residual functioning in their rooms (e.g. sitting on the bed, performing simple exercises independently, aerobic low load exercises with low intensity <3,0 METS were suggested, based on subjective symptoms). Where available, it was advisable to hand in a brochure (see Supplementary Materials 2 and 3).

Indications on equipment have also been defined: The use of the larger equipment (e.g. mobility aids, ergometers and tables) must be carefully considered and discussed with the department staff to reduce their contamination. Stuff must be easily sanitized or dedicated to the unit (85). The use of specialized equipment must be avoided, if not necessary, for basic functional tasks. Wherever possible, the movement of equipment between infectious and non-infectious areas must be restricted. The minimum number of personnel necessary to carry out the activity safely must be defined (88).

Clean rehabilitation ward: The Rehabilitation Ward of Parma Hospital had to reorganize its structure during the emergency of COVID-19 pandemic (12). Experts opinions and expert literature interpretations regarding management and activity planning of a clean rehabilitation ward in anticipation of a future reopening were reviewed (8,90). In the reorganization of health services, which became necessary in the face of the health emergency of COVID-19, it must be borne in mind that other diseases have continued to occur and, among the diseases defined as "time-dependent" because they must be treated as quickly as possible, we paid utmost attention to acute cerebrovascular events (91). Moreover, outpatient activities have continued through telemedicine, considering the indications of company documents and expert opinions (13,92-95).

Discussion

This clinical protocol was the result of a periodic review of the literature, which has allowed us to take charge of patients affected by COVID-19 according to the most up-to-date clinical evidence, guaranteeing a shared and uniform treatment within local reality in an era of health emergency. The COVID-19 P.A.R.M.A. Protocol, developed by a team of rehabilitation operators (MD rehabilitation specialists, physical therapists, speech therapists, nurses, MD of other specializations) was adapted to the local reality in which the team operates. It was the result of the integration of what was indicated in the existing medical guidelines, reported in the most recent literature on the subject, and many years of professional experience of the operators involved. This work was initially necessary in absence of scientific evidences, clinical guidelines or opinion based on the experience of other rehabilitative team. Moreover, the speed of spread of the virus and the geographic trend of the pandemic that swiftly hit Northern Italy immediately after China, made it difficult to find evidence in the literature at first. It was necessary to collect more information on the virus and to better understand its mechanism of action in order to adapt the rehabilitation interventions to the clinical condition of the COVID-19 patients. For these reasons and for the mainly practical objective we set ourselves that it was not possible to carry out the work purely as a systematic review. This evidence-based protocol supported rehabilitation defined as a multidisciplinary intervention based on personalized evaluation and treatment (96). To reach this level of knowledge, the continuous collaboration and constant comparison with the various professional roles involved in the care managing of COVID-19 patients was fundamental. In parallel to the ever increasing number of hospitalizations and the simultaneous recruitment of new support staff, it was useful to train staff and patients undergoing rehabilitation with Physical Therapist on possible good practice even in emergency conditions. The systematic study of the literature together with the consolidated clinical experience of the professionals involved, allowed to apply rehabilitation even in a context in which many rehabilitation departments had to significantly changed their activity, converting rehabilitative

beds in COVID-19 beds (1,5,97), and in which global medical interest focused primarily on internist aspects, especially in the early stages of the emergency. Further studies on the clinical behavior of SARS-CoV2 and follow-up on COVID-19 patients undergoing rehabilitation treatment will be necessary to evaluate the presence of eventual further rehabilitation needs, facing a long-term course of disease still unknown.

Conclusions

The emerging and rapidly evolving situation of COVID-19 pandemic has stimulated the clinical world to share information, making it essential to follow the evidences. The initial lack of literature stimulated the sharing of skills between the various professional figures, allowing the definition of practical clinical protocols such as the example described in this work.

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