





Telemedicine in children with medical complexity on home ventilation during the COVID-19 pandemic

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Abstract

Children with medical complexity (CMC) are patients with one or more complex chronic conditions dependent on medical technologies. In our unit (Pediatric Pulmonology and Respiratory Intermediate Care Unit, Department of Pediatrics, "Bambino Gesù" Children's Hospital and Research Institute), we regularly follow-up CMC patients, particularly children on long-term, invasive (IMV) or noninvasive (NIV), ventilation. Children suffering from chronic diseases and with medical complexity have lost the possibility to go to the hospital during the COVID-19 pandemic. The aim of this article is to describe our experience with telemedicine (teleconsultation [TC] and telemonitoring of ventilator [TM]) in CMC on ventilation. We presented 21 children on long-term ventilation (NIV or IMV) whose planned hospital admission was postponed due to lockdown. A total of 12 healthcare problems were detected during scheduled TCs. Only one problem was not solved by our remote intervention. Specifically, TM has allowed us to change the ventilator parameters and to monitor patients on ventilation remotely. In conclusion, the use of telemedicine in CMC ventilated patients resulted in a feasible tool to avoid in-person visits during the pandemic.

KEYWORDS

mechanical ventilation, noninvasive ventilation, respiratory technology, telemedicine, telemonitoring

1 | INTRODUCTION

Children with medical complexity (CMC) are defined as children with one or more complex chronic conditions that are often multisystem and severe. They are functionally limited and often dependent on medical technologies. CMC are often affected by medical comorbidities, they are frequently hospitalized and supported by different health providers (nurses, physiotherapists, etc.).^{1,2}

Technological improvements have driven the rapid evolution of telemedicine, which is an expanding field of medicine that uses telecommunication and information technology. Telehealth has the

important benefit of increasing patients' access to care by delivering assistance when and where they need it. However, despite the indubitable advantages of using telemedicine to manage CMC patients, this practice is not extensively spread.³ With the increasing use of telecommunications for the exchange of clinical information, together with the considerable technological progress in this field, the scope of telemedicine was defined as: "the use of information and electronic communication technologies to provide and support health care when participants are distant."³ Exponential technological advances have driven the rapid evolution of telemedicine. The development of Internet and Web connection has increased social

networking, interoperability, collaboration, and communication.⁴ It has been used successfully in neonatology, in pediatric intensive care, in ophthalmology for screening retinopathy of prematurity, for chronic diseases such as asthma and diabetes, in psychology, for outpatient care, in dermatology, and in education.⁵

Telehealth could facilitate management of CMC patients by reducing their movements to hospitals. Thus, the possibility of using telemedicine in the field of home ventilation is a promising developing field of application. With the development of telehealth tools, variables that were previously exclusively recorded in hospitals can be monitored at patient's homes. Several studies have shown good acceptance of telemedicine tools by patients and families, as well as by paramedical and medical teams.⁶

On December 31st, 2019, the Wuhan Municipal Health Commission (China) reported a cluster of pneumonia cases of unknown etiology in the city of Wuhan, in the Chinese province of Hubei, to the World Health Organization. The first two cases of coronavirus 2019 (COVID-19) in Italy, a couple of Chinese tourists, were confirmed on January 30th, 2020, while the first case of secondary transmission occurred in Codogno, a Lombardy town in the province of Lodi, on February 18th. On March 10th, 2020, due to the spread of the virus across Italy, all Italian citizens were forbidden to move from home, except for proven work needs, absolute urgencies or health reasons.⁷

On the one hand, hospitals had to convert spaces and move staff to deal with the emergency; on the other hand, they were forced to suspend elective procedures, postpone nonessential in-person meetings and reduce hospital staff. Moreover, patients gave up hospital appointments and admissions due to the COVID-19 pandemic.

In our unit (Pediatric Pulmonology and Respiratory Intermediate Care Unit, Department of Pediatrics, "Bambino Gesù" Children's Hospital and Research Institute), we regularly follow-up CMC patients, particularly children on long-term, invasive (IMV) or non-invasive (NIV), ventilation. These patients are subjected to periodic follow-up visits for respiratory assessment and multidisciplinary evaluation. Children suffering from chronic diseases and with medical complexity have lost the possibility to go to the hospital during the COVID-19 pandemic. Families often renounced coming to the hospital for scheduled evaluations due to the fear of contagion.

To minimize the interruption of crucial clinical services, our unit started a follow-up policy using telemedicine tools aimed at assessing the needs of patients on long-term mechanical ventilation assisted at home. These tools consisted of teleconsultation (TC) and telemonitoring (TM). TC allows the clinician to interact remotely with patients and families through a video-call. TM allows the clinician to control health parameters remotely. Notably, our Unit followed a subgroup of ventilated patients that could be monitored remotely by means of recently developed web platforms. These systems allow the clinician to easily access ventilation data, and to intervene if required. To date, only a few ventilators are equipped with TM systems, but manufacturers are working to provide new platforms.⁸

The aim of this article is to describe retrospectively our experience with telemedicine in children with chronic respiratory diseases on long-term mechanical ventilation during the COVID-19 pandemic.

2 | MATERIAL AND METHODS

In our analysis, we included the pediatric population (<18 years of age) on long-term ventilation (NIV or IMV from at least three months) for which controls were planned during the pandemic period and postponed to a later date. Patients included in our analysis were on the waiting list for a planned admission during the lockdown period, between March 2020 and May 2020. All the families, in our analysis, had postponed the planned admission for their children, due to the difficulty of movement to and from different regions during the lockdown period, as well as for fear of contagion in the hospital. We excluded patients who were unable to perform remote visits (absence of technologies at home, absence of internet connection, language barriers) and patients who did not provide informed consent for telemedicine.

Data of 21 patients followed by the Respiratory Unit of the Bambino Gesù Children's Hospital were collected during a 3 months' time, between March 2020 and May 2020 (national lockdown period). Ours is a tertiary hospital and we follow-up children on ventilation from different parts of Italy. Notably, the telehealth reimbursement policy in our region was partially active at the time of the study; healthcare providers have activated TM in patients of the TM group with partial National Health Service (NHS) reimbursement even before the pandemic, while, TCs were refunded by NHS since the start of the pandemic.

All the patients had performed TC during the pandemic period. In our analysis, we divided the patients into two different groups, with and without TM. For each group, we mainly analyzed the possible changes to the usual therapeutic plan due to our remote intervention.

2.1 | Teleconsultation

TC is a remote interaction between the doctor and the patient or the family, usually through a video-call. The clinician has the possibility to make diagnoses and/or prescriptions of drugs and treatments. During TC, a health worker, close to the patient, can assist the clinician. The Internet connection must allow the clinician to see and interact with the patient and this must take place in real or deferred time.

TC was performed weekly by the senior nurse and our unit's physician. Visits were performed in the presence of the parents; the presence of a healthcare worker was not required instead. We used a platform for telemedicine provided by our region which is specific for video-call. This platform provides all the privacy standards to guarantee the anonymous processing of data. During TCs, the following items were investigated:

- Patient's general clinical status,
- Problems related to ventilation,
- Problems with domiciliary assistance during the pandemic,
- Problems with ventilator technical assistance during the pandemic, and
- Problems with provisions of consumables during the pandemic.

2.2 | Ventilators and TM

All patients needed ventilatory support with a total number of nine different models used by our cohort: Astral 100, Astral 150, Lumis 150, and Elisee 150, manufactured by ResMed; Trilogy and Garbin, manufactured by Philips Respironics; Vemo 150, manufactured by EOVE; Vivo 60, manufactured by Breas; Puritan Bennet 560, manufactured by Covidien; Monnal t50, manufactured by AirLiquide. Of these devices, only a few can be equipped with TM: Astral 100, Astral 150, Lumis 150 (*AirView* web platform); Trilogy, Garbin (*Linde HealthView* web platform); and Vemo (*e-Servicing* by EOVE web platform). Twelve patients of our cohort had the ventilator equipped with TM.

By accessing these online platforms, the clinician can review the ventilation parameters and examine the trends of domiciliary therapy. Data provided by the platforms include adherence to ventilation (days of use and hours of therapy), air leaks, pressure, and flow waveforms (among others). In addition to that, *AirView* and *EOVE* platforms allow the reading of oxygen parameters, with the connection of a pulse-oximeter by the patient's family. *AirView* alone provides additional information such as the Apnea-Hypopnea Index (AHI) and the Oxygen Desaturation Index (ODI) and allows remote changes in the ventilator setting.

2.3 | Ethics

The study was conducted in agreement with the Italian regulation and received the appropriate ethical approval from our Ethical Committee (Protocol No.: 2147/2020). Informed consent was obtained from all patients participating in the study. All patients were informed about the possibility of a waiver of consent at any time.

3 | RESULTS

Twenty-eight children were included in our analysis. We excluded seven patients who were unable to perform remote visits: five patients out of 28 (17%) were unable to perform TC due to the absence of adequate technology at home (low internet signal or absence of internet connection). One patient was excluded because the family rescinded the informed consent to telemedicine during the study. One patient was excluded due to the language barrier. A total number of 21 patients were followed via TC during the COVID-19 pandemic. The mean age (SD) was 9.15 (± 4.59) years old, 14 patients

(67%) were male. Several chronic diseases affected our children: Down syndrome (2, 10%), neuromuscular diseases (5, 23%), obesity (1, 5%), parenchyma diseases (1, 5%), metabolic diseases (2, 10%), Prader-Willi syndrome (1, 5%), and central nervous system diseases (9, 42%). Regarding the type of ventilation, 13 patients (62%) were on NIV, while eight patients (38%) were on IMV. Only four patients (representing 19% of the total sample) were on a 24 h ventilation regime. Table 1 summarizes patients' characteristics considering the two subgroups of children, with (12 patients) and without TM (nine patients). Patients belonging to the TM group were mainly on pressure support ventilation-spontaneous timed (PSV-ST; 11 patients); one patient was assisted with intelligent volume assured pressure support (iVAPS). Patients on TM showed adequate daily adherence during the three months of observation (median adherence on 90 days: 86% (interquartile range [IQR], 57–98%)). Due to the small number of patients on different platforms, we did not report gathered data available only on specific software (i.e., air leaks, AHI and ODI).

The average amount of time spent with the patient during TC was 23.0 min (IQR, 18.24–25.8 min). We spent an average time of 36 min (IQR, 29.34–46.32 min) to review TM data.

Technology equipment and domiciliary assistance details for each patient are shown in Table 2. All the patients needed at least one medical device and had the requirement of home assistance by one or more physicians, nurses, and physiotherapists. Specifically, in terms of patient's home assistance, 13 patients out of 21 had physiotherapy assistance, seven patients had nursing care, and seven patients had home monthly physician assessment.

Details of patient's difficulties and our unit's interventions are listed in Table 3, again highlighting the differences between

TABLE 1 Patient's characteristics

	TM patients	non-TM patients
Age, mean (SD)	12.59 (± 5.49)	10.71 (± 7.12)
Sex, n (%)		
Male	5 (62.5%)	9 (69.2%)
Female	3 (37.5%)	4 (30.8%)
Diagnosis, n (%)		
Down	1 (12.5%)	1 (7.7%)
Obesity	1 (12.5%)	0 (0.0%)
Parenchyma	1 (12.5%)	0 (0.0%)
Metabolic	2 (25.0%)	0 (0.0%)
NM	0 (0.0%)	5 (38.4%)
PWS	0 (0.0%)	1 (7.7%)
SNC	3 (37.5%)	6 (46.2%)
Ventilation mode, n (%)		
NIV	7 (87.5%)	6 (46.2%)
IMV	1 (12.5%)	7 (53.8%)

TABLE 2 Patients' technology and assistance

	Number of patients
Technology	
Pulse-oximeter	12
Suction	10
Enteral pump	7
Oxygen	4
Cough machine	1
Assistance	
Physician	7
Nurse	7
Physiotherapist	13

patients with and without TM. On a total number of 31 TCs, our unit detected a suboptimal ventilatory therapy in six cases (19%), five TM patients, and one non-TM patient. The reported issues concerned episodes of headaches and morning sleepiness, secretions, considerable desaturations, patient-device asynchrony, and poor adherence. After the TCs, our unit changed ventilation parameters (no ventilation mode was changed) and/or interfaces, successfully improving the patients' conditions but for one child. It is important to note that parameter changes were possible only for TM patients, by using the web platforms. Specifically, we changed pressures in all the patients of the TM group (increasing IPAP and/or EPAP), we changed inspiratory and expiratory

triggers in one patient, and we changed triggers and increased back-up respiratory rate in another patient.

In six (19%) cases, we observed that the domiciliary assistance was not being fully provided (four TM patients and two non-TM patients). The reported issues include interruption of physiotherapists and technical assistances, suspension of consumables supply, expired prescriptions, and failure of data transmission to the web platform. By interceding with the Health Authorities and the Home Care Providers, and with the remote assistance by our physiotherapists, we were able to successfully intervene and solve all the patients' reported problems.

We did not identify any critical or life-threatening event during our study; none of the patients required an urgent admission due to the worsening of clinical conditions.

4 | DISCUSSION

Our report has depicted how our department handled patients with medical complexity on long-term ventilation during the COVID-19 pandemic.

COVID-19 has manifested the need to avoid in-person visits to reduce the spreading of the disease. Limitations to movements and reduction of in-hospital access due to COVID-19 has required alternative solutions for the assistance of families and patients. Indeed, our unit follows patients with special needs, high dependence on technology equipment, and multiple comorbidities. Notario et al. have already explored the value of telehealth visits for CMC using a specific telehealth device. In their experience, both caregivers and

TABLE 3 Detected problems and interventions by our unit during the national lockdown period (March to May 2020)

Patient category	Type of problem	Problem details	Intervention	Outcome
TM patients	Ventilation problems (n = 5)	Sleepiness in the morning	Changed ventilation parameters	Slight improvement of sleepiness
		Presence of secretions	Recommended use of aerosol	No improvement
		Morning headache	Changes of interface and ventilation parameters	Fewer headaches
		Asynchrony with ventilator	Changed ventilation parameters	No asynchrony
		Frequent desaturations	Changed ventilation parameters	Reduction of desaturations
	Domiciliary assistance problems (n = 4)	Consumables not supplied	Intercession with Local Health Authority	Consumables regularly supplied
		Suspended physiotherapy	Remote assistance by hospital's physiotherapist	Physiotherapy performed by the family after training
		Interrupted data transmission to online server (x2)	Intercession with technical assistance	Data transmission restored
Non-TM patients	Ventilation problems (n = 1)	Scarcely tolerated ventilation	Changed interface	Improvement of therapy compliance
	Domiciliary assistance problem (n = 2)	Technical assistance not provided	Intercession with Local Health Authority	Assistance regularly provided
Prescriptions expired		Renewal of prescriptions	Renewal of prescriptions	

clinicians were comfortable with the device and found it useful for data gathering. Moreover, those patients with access to telemedicine had fewer hospital days and reduced cost rates.² Other studies showed that the adaptation to NIV at home using TM (transmission of data from a home ventilator, night pulse-oximetry, night capnography along with telephone support) was as effective as setting up the NIV in a hospital. In addition, home NIV healthcare costs were lower than in hospitals.^{9,10}

To our knowledge, our study is the first that explored the use of remote ventilatory parameters changes in Pediatrics. Recently, Duiverman et al. reported that home initiation of chronic NIV in stable hypercapnic COPD patients, with the use of telemedicine, is non-inferior to in-hospital initiation. They performed changes during NIV adaptation remotely without relevant side effects.¹⁰ In our study, we practiced changes only to children on long-term stable ventilation, avoiding main mode changes. Specifically, we changed pressure, triggers, and back-up respiratory rate when required. More studies are needed to explore the safety and cost-efficacy of remote management of home ventilation.

We presented 21 children on long-term ventilation (NIV or IMV) that had their planned admission during the pandemic and that postponed it due to lockdown. Usually, we perform admissions every 6 months to reassess the ventilatory setting; in our study, we performed weekly TCs according to the admission planning; we repeated TC when required, according to the possible presence of problems to reassess. We described patients' difficulties and our interventions, particularly focusing on mechanical ventilation, which is the main aim of hospital admission of those patients. Notably, as TM gave us access to ventilator features, we changed the respiratory parameters in four cases and the interface for one child. Moreover, the remote access to ventilatory data gave us the possibility to evaluate adherence to ventilator use and eventual problems related to ventilation (such as excessive air leaks) or poor efficacy of ventilation (high ODI and/or AHI). Such information may allow the clinician to evaluate the patient on ventilation without the need for the presence of the patient and ventilator. Information about trends of ventilation at home was useful to support the clinician in assessing the course of therapy. We found that, during the pandemic, this tool allowed us to follow-up children with chronic diseases and minor problems with ventilation without any significant issues. However, due to the scarce number of patients and to the retrospective nature of the study, we are unable to affirm that TM can increase the sensitivity of the clinician in finding problems related to ventilation. More studies are needed to explore patient's outcomes and the reliability of data transmitted by home ventilators.

Other studies have shown the advantages of telemedicine in children on long term ventilation.^{11–13} Trucco et al. reported that TM was effective in ventilated neuromuscular patients in improving home management, especially concerning respiratory exacerbations. They used transmitted clinical data, SpO₂ and transcutaneous CO₂ monitoring, spirometry, and ventilator data obtained with a pneumotachograph. Differently, we obtained our data using only patients' own ventilators, thus simplifying the need for equipment and assistance.¹³

Muñoz-Bonet et al. reported their 10 years' experience with telemedicine in ventilator-dependent children with tracheotomy. They found that telemedicine facilitated an earlier discharge and a good long-term follow-up for patients with severe chronic conditions. In addition to that, they found a reduction in parents' stress and, finally, a good acceptance by the families.¹⁴ Due to the brief follow-up period during the pandemic, we did not analyze families' satisfaction for the service and the reduction of hospital admissions, nor did we perform a full cost-analysis study. Definitely, this field requires long-term follow-up prospective studies.

To our knowledge, this is the first study that focuses on the use of TC in children on long-term ventilation. A total of 12 problems were detected during scheduled TCs. Only one problem was not solved by our remote intervention. In our small sample, during such a demanding period, our experience was that TC allowed us to detect different problems. With regard to domiciliary assistance problems related to the discontinuous service during the lockdown, we were able to intervene and solve all the issues. On the other hand, as stated above, with TM we were able to successfully deal with ventilator problems four times out of five. Notably, we did not compare the TC group with a control group followed only with a telephone call. Due to the very difficult period for families with children with disabilities, we preferred the use of an instrument as similar as possible to an in-person visit. More studies are needed to evaluate the accuracy of TC compared to other forms of remote communication to detect problems.

The adoption of telemedicine is challenged by the difficulty for some families to access a good internet connection. In our sample, five patients out of 28 patients (17%) were excluded because it was impossible to perform an adequate TC. This issue, the so-called "digital divide," was particularly noticeable during the pandemic period and needs to be carefully considered. Indeed, barriers to access to required technologies for telehealth could compromise equal access to health services. Therefore, the pandemic has manifested the urgent need to expand access to technologies to reduce the digital divide gap. Although our sample is small, the high number (17%) of patients excluded due to the lack of access to a good internet connection is a clear example of the importance to consider technology inclusion, especially for patients with chronic diseases.

There are other limitations in our study. We had a short follow-up time due to the focus on the pandemic period. Our patients were affected by different conditions and the distribution of ventilation modes is suboptimal (i.e. only one TM patient was on IMV). Moreover, as stated above, by excluding patients with families unable to perform remote visits, we did not consider underprivileged families, resulting in a clear socioeconomic bias.

5 | CONCLUSIONS

Our results highlight that the use of telemedicine in CMC ventilated patients is a feasible tool to avoid in-person visits during pandemics. We found encouraging results in using TM combined with TCs to

solve minor ventilation problems. More studies are needed to explore the effective reliability of home-ventilator TM, eventual cost-effective benefits, and long-term outcomes.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Alessandro Onofri has designed the study, collected patient data, performed the statistical analysis and the interpretation of data, and wrote the first draft of the paper. Martino Pavone, Elisabetta Verrillo, and Serena Caggiano collected patient data, were involved in the statistical analysis and the interpretation of data, contributed to the first draft of the paper. Simone De Santis has designed the study, collected patient data, performed the statistical analysis, contributed to the first draft of the paper. Nicola Ullmann collected patient data, and contributed to the interpretation of data. Renato Cutrera contributed to the design of the study, the statistical analysis and the interpretation of data, and in writing the first draft of the paper. All authors have read and approved the final manuscript.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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