

Home care models dedicated to COVID-19 patients: the experience of a Local Health District of Veneto Region (Italy)

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Parole chiave: COVID-19; cure domiciliari; ospedalizzazione a domicilio; cure integrate a domicilio

Abstract

Background. During COVID-19 pandemic, health professionals have been working in an extreme uncertainty context. Affected patients needed to be cared at home as long as possible to avoid virus spreading and hospital resources saturation. The Veneto Regional Administration (North-east of Italy) released Regional guidelines about it. The Western Healthcare District of the Local Health Authority of the city of Vicenza (180,000 inhabitants) implemented a healthcare pathway following them. Aim of the study is to describe the results and outcomes of such implementation.

Methods. In the implemented health care pathway, a new service called “Special Unit of continuity of care” (USCA) with physicians and nurses has been dedicated to the prise en charge at home of patients suffering from Sars-CoV-2. They were referred to the USCA by general practitioners or by hospital specialists, and managed through a daily clinical monitoring by regular home visits and phone calls, specialist consultations and therapy management. In order to prevent hospital admission, an oxygen concentrator when possible has been employed and managed at home by the members of the USCA when the oxygen saturation was below 93%. An observational retrospective study has been conducted using anonymized data from different databases: the USCA activity database (from 12/01/20 to 21/31/21), the hospital and Emergency Department discharge databases, and the “healthcare co-payments exemptions database”. The latter database refers to the people excluded - because of their chronicity - from the co-payment of a list of medical exams and services. Descriptive and multivariate logistic regression analyses have been implemented.

Results. 1,419 patients suffering from Sars-CoV-2 have been cared and managed by the USCA in the considered period of time (mean 11.4 days), of whom 787 (55.5%) with at least one chronic condition (described in the above quoted “healthcare co-payments exemption database”) and 261 provided with oxygen concentrator. 275 (19.4%) needed a hospital admission, 39 (2.8%) in intensive unit; 53 died during hospitalization (3.8%). Out of the 261 patients utilizing oxygen concentrator, 103 have been admitted to

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Legenda: ED = Emergency Department; GP = General Practitioner; HCD = Healthcare co-payment exemptions database; HCD = Healthcare District; HCP = Healthcare Professional; HDR = Hospital Discharge Record; HS = Hospital Specialist; ICU = Intensive Care Unit; IQR = Interquartile Range; LHA = Local Health Authority; NHS = National Healthcare Service; OR = Odds Ratio; SAS = Statistical Analysis System; SD = Standard Deviation; USCA = Special Units of Continuity of Care

hospital (39.5%), 7.3% in intensive unit and 8.0% died. In implemented multivariate analyses, the use of oxygen concentrator, proxy measure of the severity of the condition, is the major determinant for the risk of hospital admission (adj OR: 3.2, CI 2.3-4.3) and of dying within 30 days (adj OR: 2.8 CI 1.5-5.1). Among the 261 patients provided with oxygen concentrator, 158 (60.5%) have been managed at home without any admission to emergency department and/or hospitalization.

Conclusions. In an uncertain context such as COVID-19 pandemic, the already-implemented home care model has been modified by integrating the USCA physicians and nurses and specialist care networks to prevent hospitalization and the sense of isolation and abandonment of people as much as possible. Almost 1,500 patients suffering from COVID-19 have been cared for at home over 13 months by such new service with complex and multidisciplinary activities. The risk of hospitalization and death appears determined by the severity of the pathology with high and significant OR 60% of patients with oxygen concentrators who, despite an initial high hypoxaturation were not hospitalized, represent, partly, the group of patients who would have been requiring hospital care in the absence of a home care pathway in a standard situation.

Introduction

20th February 2020 was the day when the first Italian case of Covid-19 was reported in the Lombardy Region. An integrated National Surveillance System has been created after that, monitoring the increase of the cases in the different areas of the country and the risk of saturation of hospital wards, and - above all - of the intensive care units.

The Italian National Healthcare Service (NHS) is based on a network of 20 Regional Services, where the central government defines the minimum healthcare provisions of services to be guaranteed to all citizens and financed through the general taxation. Meanwhile, the Regional Governments are responsible for the organization and delivery of healthcare to the citizens and can provide additional health services on their own funds. Basic decentralized medicine is organized on a primary care basis in Local Health Authorities (LHAs) which are, in turn, divided into healthcare districts (HCDs) on which, in addition to other services, even the general practitioners (GPs) functionally depend.

Healthcare professionals (HCPs), during the COVID-19 pandemic, had to operate in a context of uncertainty: the overwhelming surge of patients simultaneously seeking medical care caused Intensive Care Units (ICUs) overcrowding and hospital beds' saturation. Pre-existing pathways for homecare management had to be used and adapted, aiming to reduce as much as possible the access to ICUs and hospitals, while maintaining the quality of care provided (1). Homecare provision for non-severe cases and/or those discharged from the hospitals turned out to be a pivotal action of the regional public health response. It was based on the well-developed health-social care services that were diffusely delivered at home by the HCDs, even before the outbreak of

COVID-19 (2).

The Italian central government instructed all Regional governments to create special medical units called Special Units of Continuity of Care (USCAs) for managing COVID-19 patients in the community and monitoring those in home-isolation, supporting the GPs (2), with the purpose of reducing the burden on hospitals and ICUs. USCAs, where operative, had a pivotal role in home-based care provision, through telephone consultations, home visits and support to local GPs. The Veneto Region (north-east of Italy, with nearly 5 million inhabitants) activated the USCAs by the end of March 2020, issuing regional guidelines (3, 4).

This paper aims to describe the implementation and the clinical outcomes of care pathways for home-care management of patients suffering from COVID-19 through the USCAs, who may otherwise have required inpatient hospital care, in the Western HCD (about 180,000 residents) of the LHA "8 Berica" in Vicenza, Veneto Region, north-east of Italy (5).

Materials and Methods

Study design

A retrospective medical record review of all COVID-19 patients who received medical care from the USCAs in the Western HCD of the LHA 8 "Berica", from 01/12/2020 to 31/12/2021, has been conducted.

Home care pathway for patients suffering from COVID-19

Patients with confirmed or suspected COVID-19, who needed monitoring and/or therapy, were referred to the USCA by their GPs, by the Emergency Department (ED) physicians or by Hospital Specialists

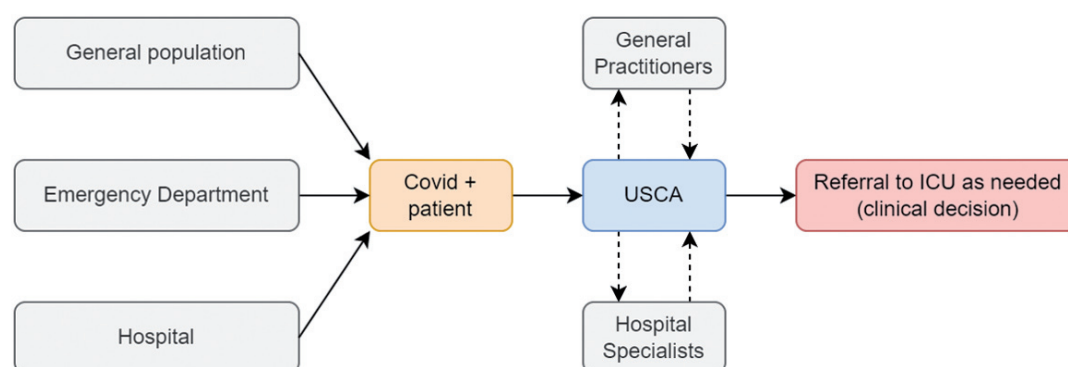


Fig. 1 - Referral pathway of patients suffering from COVID-19 to the USCA to be managed at home, Western HCD of LHA “8 Berica”, Vicenza, Veneto Region (Italy)

(HSS), through email or direct telephone call at a dedicated mobile number, which was active 12 hours per day, 7 days per week (Figure 1).

Criteria for referral to USCA was mainly left on physicians' clinical decisions, considering patient's risk factors and clinical presentation. USCA physicians have been trained through remote courses by HSs (infectious diseases, lung and emergency department specialists) who became their referral specialists for cases cared at home.

Physicians of USCA units monitored patients through daily medical at-home evaluations (included, but not limited to, vital assessment: SpO₂, heart and respiratory rates, blood pressure, body temperature), regular phone calls, management of therapy and frequent consulting with above-mentioned specialists, even remotely.

Patients with oxygen saturation levels below 93% were at high risk to be admitted to hospitals. Due to overcrowding of ED rooms and hospital wards, a home management approach, when possible, became necessary and had been implemented. If eligible, some of these patients were provided with an oxygen concentrator, with a maximum oxygen flow rate of 5 L/min. USCA physicians, supported by two pneumologists even by remote consultation, instructed the patients and/or their caregivers on how to use the device and monitored the utilization and the effectiveness both through home visits and remotely.

Sources of data

All diseased residents of the Western HCD of the LHA “8 Berica” who received USCA medical care

had been identified through the USCA electronic archive which collected patients' demographic data and clinical data such as the start and end dates of USCA medical care, the date of assignment of the oxygen concentrator, the saturation levels at rest and under exertion.

Only records in the USCA electronic archive referred to residents suffering from Covid-19 were included in the study and linked with the hospital discharge records (HDRs) and with the healthcare co-payments exemptions database (HCED).

HDRs contain data on all inpatient episodes and were used to analyze hospital admissions and 30-day in hospital mortality.

The HCED was used to assess the presence of chronic conditions. It includes information on all individuals with a diagnosis performed by a medical specialist with specific conditions for which the NHS provides specific inpatient and outpatient free of charge services (i.e.: chronic obstructive pulmonary disease, diabetes, hypertension, cancer).

The study was conducted using anonymized records of data routinely collected by the healthcare services. All regional healthcare records undergo a standardized anonymization process that assigns a unique anonymous code to each individual, allowing record linkage between electronic healthcare records without any possibility of back retrieving the subject's identity. All data in the LHA registries are recorded with the patient's consent and can be used as aggregate data for scientific studies without further authorization. This study complies with the Declaration of Helsinki and the Italian Decree n.196/2003 on personal data protection.

Statistical analysis

Univariate and bivariate analyses were performed to summarize data with respect to the patient demographic characteristics. Continuous variables were reported with descriptive statistics [mean, S.D., median and interquartile range (IQR)]. For categorical variables, frequencies and percentages were calculated. The difference between groups was examined by Student's t-test or Mann-Whitney test for continuous variables, Pearson's χ^2 or Fisher's exact test for categorical variables, as appropriate. A P-value <0.05 was considered statistically significant.

We plotted Kaplan-Meier curves for hospitalization; curves were compared using the log-rank test. Follow-up started at the date of USCA taking charge until date of the first hospitalization or death or end of follow-up (30 days from the start of taking charge).

The OR 30-day hospital admissions and 30-day in-hospital mortality were estimated using logistic regression in both univariate and multivariate models, adjusting for age, sex, presence of chronic diseases, assignment of oxygen concentrator.

All statistical analyses were conducted using SAS (Statistical Analysis System) software V.9.4 (SAS Institute, Cary, North Carolina, USA).

Results

Overall, in the considered time period, 1,419 patients who tested positive for COVID-19 were provided home-care by USCA physicians, for an average period of 11.4 days (std. dev.: 7.1) with a maximum of 69 days, through daily phone calls, at-home visits and management of therapy.

Patients were 714 males and 705 females; the mean age was 59.7 years (std. dev.: 18.9); 787 of them (55.5%) had already a registered chronic disease (Table 1).

Among the 1,419 patients, 275 (19.4%) required admission to hospital and 39 (2.8%) were referred to ICU, due to clinical instability and/or worsening of the symptoms; 53 (3.8%) died during hospitalization (Figure 2).

261 out of 1,419 (18.4%) were found with low levels of oxygen saturation ($SpO_2 < 93\%$), needing oxygen supplementation, and were provided with an oxygen concentrator and monitored at home by USCA. Among them, 158 (60.5%) have been managed completely at home without any admission to the emergency department and/or to hospital wards. We consider these patients to be the most vulnerable, with

Table 1 - Baseline characteristics of 1,419 patients with USCA home-care, by assignment of oxygen concentrator

	With portable oxygen concentrator		Without portable oxygen concentrator		Total		p-value
	n=261		n=1,158		n=1,419		
	N	%	N	%	N	%	
Gender							
Male	124	47.51	590	50.95	714	50.32	0.3693
Female	137	52.49	568	49.05	705	49.68	
Age							<.0001
mean (SD)	67.1	(13.8)	58.0	(19.5)	59.7	(18.9)	
00-39	8	3.07	187	16.15	195	13.74	
40-49	22	8.43	184	15.89	206	14.52	
50-59	47	18.01	223	19.3	270	19.03	
60-69	62	23.75	197	17.01	259	18.25	
70-79	69	26.44	202	17.44	271	19.1	
80+	53	20.31	165	14.25	218	15.36	
Chronic conditions							
Yes	175	67.05	612	52.85	787	55.46	<.0001
No	86	32.95	546	47.15	632	44.54	
Duration of home care by USCA							
mean (SD)	13.6	(9.0)	10.9	(6.5)	11.4	(7.1)	<.0001

SD: standard deviation

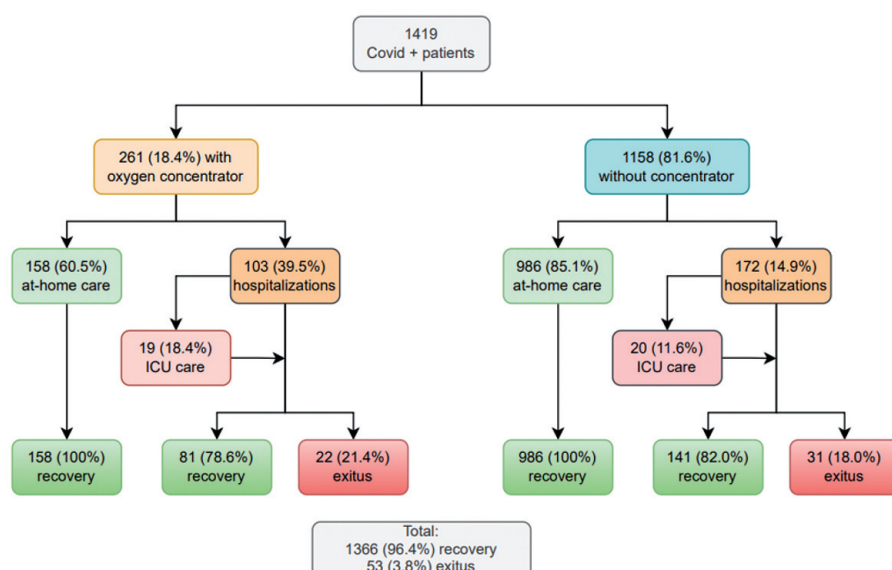


Fig. 2 - Outcomes of patients affected by COVID-19 managed at home by the USCA, Western HCD of LHA “8 Berica”, Vicenza, Veneto Region (Italy).

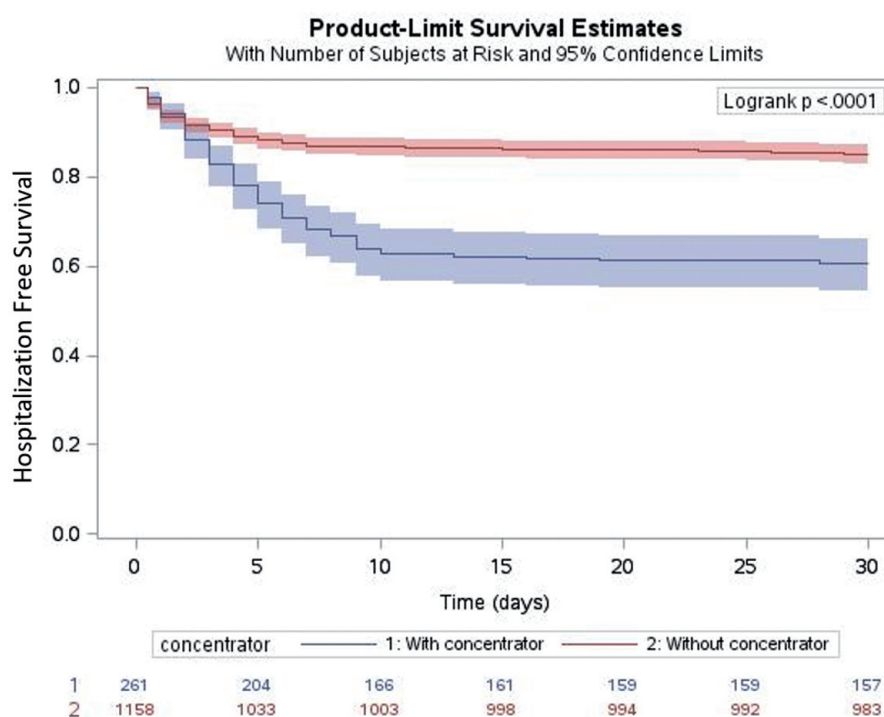


Fig. 3 - Kaplan–Meier 30-day hospitalization estimates by presence of concentrator

a high risk of complications due to their desaturation: part of these group of patients, under different circumstances, would have been cared in a hospital setting at first.

Figure 3 represents a Kaplan-Meier hospitalization-free survival curve according to presence of concentrator.

Patients with concentrator, as expected, show significant higher risk to be admitted to hospital ($p < .0001$), in particular the risk is higher in the first 10 days, after that the risk remain stable. At 5 days after the start of USCA home-care the hospitalization free survival was 74% for patients with concentrator and 88% for patients without concentrator, while at

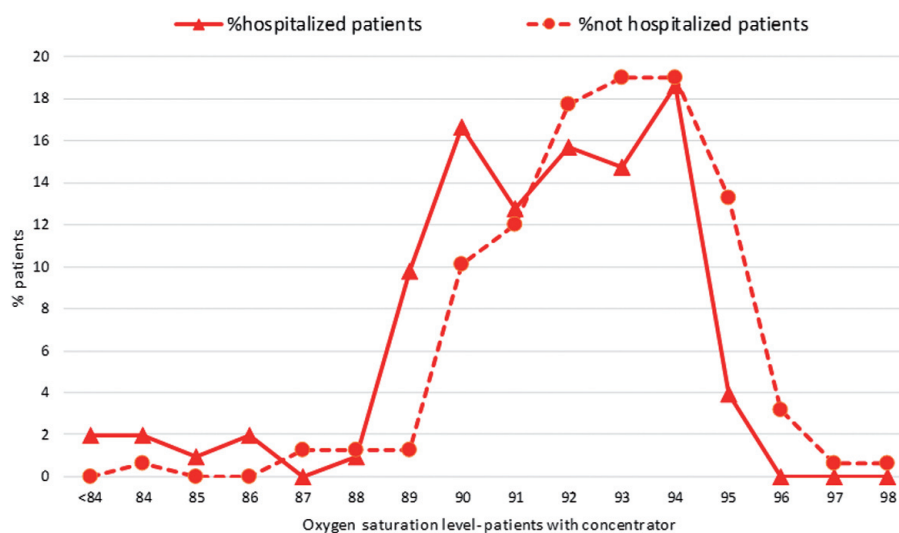


Fig. 4 - At-rest oxygen saturation level of patients suffering from COVID-19 managed by USCA at first home visit by them, differentiating the ones who have been hospitalized from the ones who have not.

10 days it was 63% vs 87%.

Figure 4 shows the at-rest oxygen saturation level of patients at home at the very first home visit by USCA possibly leading to *prise en charge* by them, differentiating the ones who have been hospitalised from the ones who have not.

Among the 261 patients who were provided with the oxygen concentrator, 3.8% had a saturation level lower than 88, 47.7% between 88 and 92 and the remaining 48.5% above 92. As expected, the percentage of hospitalization at 30 days is higher among those with saturation lower than 88 (70%) and decreases as saturation levels increase (respectively

46% and 30%).

Over the 30-day follow-up, 103 patients (39.5%) with concentrator needed an admission to hospital, 19 (7.3%) were referred to ICU and 21 (8.0%) died during hospitalization.

Multivariate logistic regression showed that patients with an oxygen concentrator (reserved to patients with $SpO_2 < 93\%$), had 3 times greater odds of 30-day hospitalization adjusted for pathology, age and sex, (adj OR: 3.2; CI 2.3 - 4.3), see Table 2, and of 30-day in-hospital mortality (adj OR: 2.8; CI 1.5 – 5.1) in Table 3.

Table 2 – Logistic regression analysis of 30-day hospital admission

	30 day-Hospital admission (n=275)				
	n (%)	Crude OR (95%CI)	p-value	Adjusted OR (95%CI)	p-value
Gender			0.0126		0.0002
Male	157 (22.0%)	1.40 (1.08;1.83)		1.74 (1.3;2.32)	
Female	118 (16.7%)	<i>Rif.</i>		<i>Rif.</i>	
Age		1.04 (1.03;1.05)	<0.0001	1.04 (1.03;1.05)	<0.0001
Chronic conditions			<0.0001		0.4392
Yes	195 (24.8%)	2.27 (1.71;3.02)		1.14 (0.82;1.59)	
No	80 (12.7%)	<i>Rif.</i>		<i>Rif.</i>	
Oxygen concentrator			<0.0001		<0.0001
Yes	103 (39.5%)	3.74 (2.78;5.03)		3.16 (2.32;4.30)	
No	172 (14.9%)	<i>Rif.</i>		<i>Rif.</i>	

Table 3 – Logistic regression analysis of 30-day in-hospital mortality

	30 day-Hospital admission				
	n(%)	Crude OR (95% CI)	p-value	Adjusted OR (95%CI)	p-value
Gender			0.3521		0.0261
Male	30 (4.2%)	1.3 (0.75;2.26)		1.96 (1.08;3.56)	
Female	23 (3.3%)	<i>Rif.</i>		<i>Rif.</i>	
Age mean (SD)	59.7 (18.9)	1.1 (1.07;1.12)	<0.0001	1.1 (1.07;1.13)	<0.0001
Chronic conditions			0.0001		0.7398
Yes	44 (5.6%)	4.1 (1.99;8.46)		1.14 (0.52;2.5)	
No	9 (1.4%)	<i>Rif.</i>		<i>Rif.</i>	
Oxygen concentrator			<0.0001		0.0008
Yes	22 (8.4%)	3.35 (1.9;5.88)		2.78 (1.53;5.05)	
No	31 (2.7%)	<i>Rif.</i>		<i>Rif.</i>	

Discussion and conclusion

Thanks to the cooperation of professionals of different expertise (infectious diseases, lung and ED specialists and USCA), over a period of 13 months, nearly 1,500 patients suffering from COVID-19 have been constantly monitored through daily phone calls, home-visits and careful management of complex pharmacological therapy, aiming to support both the patients and the healthcare system sustainability, avoiding at the same time both the overcrowding of EDs, and the saturation of hospital wards.

The risk of hospitalization and of death correlates, as expected (6), with the clinical severity of the disease, represented by the proxy “use of oxygen concentrator”, with high and significant OR, even adjusted for pre-existing pathology and age, risk factors for severe COVID-19 disease (7).

At the same time, out of the 261 patients who were provided with oxygen concentrator because of low saturation levels, 158 (60.5%) have been managed completely at home without any admission to ED and/or hospital wards. This group of patients, in a standard situation, would have likely been hospitalized or referred to the ED, as being considered high-risk at first (8).

In a situation of uncertainty and hospital saturation, such as during the COVID-19 pandemic, health care provided at home has shown effectiveness in taking care of patients, avoiding hospital care when possible and, eventually, mitigating the feeling of isolation and abandonment. Previous studies have shown that similar protocols are well accepted (9), with high patient satisfaction (10), and first analysis seems to indicate cost-effectiveness (10-12) and effectiveness with lower rates of hospitalization and mortality (13, 14).

As other studies reported (15), when home visiting is managed with the integration of specialists' healthcare network, as our model, hospitalization could be reduced. It is reasonable to expect that integrated solutions, even outside COVID-19 experience, with collaboration among different healthcare workers, even remotely, should result in an overall reduction in hospitalization rate (16). This is even more important focusing on the Italian demographic distribution, with 23,5% of the people being 65 or older, even more at risk than the general population, as shown by the Italian mortality rates from COVID-19 (17, 18).

In our experience the USCA has been a flexible option, capable of integrating with other healthcare professionals, both in the hospital and in the local communities, while mitigating patients' feeling of isolation and abandonment. This organisational model has allowed the management of nearly 1,500 patients, in a context of limited human resources and distress within the healthcare system and hopefully avoiding the seek of ED care and/or hospitalization of a subgroup of them, in particular for 158 patients provided with a special device to sustain lung functioning.

Our next aim is to analyze further our data to evaluate the economic impact of our model as alternative to conventional hospitalization during a pandemic.

Acknowledgments: The authors thank all nurses and physicians who have been working during the recent COVID-19 pandemic as USCA in the Western HCD of the LHA “8 Berica” in Vicenza, who tried as much as possible to cure and care patients at home.

Riassunto

I modelli di presa in carico domiciliare per le persone affette da COVID-19: l'esperienza di un Distretto socio-sanitario Veneto

Introduzione. Durante la pandemia da COVID-19, i professionisti sanitari hanno operato in un contesto di estrema incertezza. Si è reso necessario mantenere il più possibile i pazienti a domicilio per evitare il diffondersi del virus e la saturazione delle risorse ospedaliere: la Regione Veneto ha definito delle Linee Guida regionali in merito. Il distretto ovest dell'ULSS 8 Berica (180.000 residenti) ha implementato un percorso assistenziale per contestualizzarle nel territorio. Obiettivi dello studio sono la descrizione dell'applicazione e degli esiti di tale percorso assistenziale.

Metodi. Il percorso assistenziale definisce che le Unità Speciali di Continuità assistenziale (USCA) si prendano carico proattivamente dei pazienti affetti da COVID-19, segnalati dai medici territoriali o ospedalieri, su loro giudizio clinico, con monitoraggio quotidiano tramite visite domiciliari e contatti telefonici regolari, confronto con gli specialisti e gestione della terapia. Per evitare il ricovero, con saturazione di ossigeno inferiore a 93%, veniva consegnato e gestito un concentratore di ossigeno a domicilio. Tramite i dati anonimizzati del sistema informativo territoriale che descrive l'attività delle USCA dal 01/12/20 al 31/12/21, del flusso della Scheda di Dimissione Ospedaliera, del Pronto soccorso e delle esenzioni. Sono state effettuate analisi descrittive e multivariate di regressione logistica per analizzare l'attività svolta e gli esiti.

Risultati. Nel periodo considerato sono stati presi in carico a domicilio 1.419 pazienti affetti da COVID-19 (media di 11,4 giorni), dei quali 787 (55,5%) con almeno un'esenzione per patologia e 261 con concentratore di ossigeno. Per 275 (19,4%) si è reso necessario un ricovero ospedaliero, per il 2,8% (39) in terapia intensiva; 53 sono deceduti durante il ricovero (3,8%). Dei 261 pazienti in ossigenoterapia, 103 sono stati ricoverati (39,5%), il 7,3% in terapia intensiva e l'8,0% è deceduto. Nelle analisi multivariate l'uso di concentratore, proxy della gravità di patologia, è il maggiore determinante il rischio di ricovero (adj OR: 3,2, CI 2,3-4,3) e di decesso entro 30 giorni (adj OR: 2,8 CI 1,5-5,1). Dei 261 pazienti che hanno utilizzato un concentratore di ossigeno a casa, 158 (60,5%) sono stati assistiti completamente presso il loro domicilio senza ricorrere al Pronto Soccorso e/o a ospedalizzazioni.

Conclusioni. In una situazione di incertezza si è mutuato l'attuale modello di cure domiciliari integrandolo con la partecipazione di medici delle USCA e l'integrazione con le reti assistenziali specialistiche per evitare per quanto possibile l'ospedalizzazione e il senso di isolamento e abbandono delle persone. Quasi 1.500 pazienti affetti da SARS-CoV-2 sono stati presi in carico a domicilio nell'arco di 13 mesi con attività complesse e multidisciplinari. Il rischio di ricovero e di decesso appare legato alla gravità di patologia (con OR elevati). Il 60% dei pazienti con concentratore che, malgrado un'iniziale iposaturazione elevata, non sono stati ricoverati rappresentano, in parte, il gruppo di pazienti che in una situazione standard avrebbe necessitato di cure ospedaliere in mancanza di un percorso di presa in carico domiciliare.

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