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Hospital at home treatment with remdesivir for patients with COVID-19: real-life experience

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ABSTRACT

Objectives: Access and appropriateness of therapeutics for COVID-19 vary because of access or regulatory barriers, the severity of the disease, and for some therapies, the stage of the pandemic and circulating variants. Remdesivir has shown benefits in clinical recovery and is the treatment of choice for selected patients, both hospitalized and nonhospitalized, in main international guidelines. The use of remdesivir in alternatives to conventional hospitalization such as hospital at home (HaH) units remains incompletely explored. In this study, we aim to describe the real-life experience of outpatient remdesivir infusion for COVID-19 in a HaH unit.

Methods: We selected all the consecutive patients receiving remdesivir from a prospective cohort of 507 COVID-19 patients admitted at a HaH unit. Admission criteria included COVID-19 with a fraction of inspired oxygen requirement under 0.35 and respiratory rate under 22 rpm. Patients were daily assessed in person by a nurse and a physician.

Results: A total of 236 patients admitted at the HaH unit received remdesivir, 172 of whom were treated at home. Only 2% presented any adverse event related to the infusion, all of them mild. HaH saved 1416 day-beds, with only 5% of the patients requiring transfer back to the hospital.

Conclusion: Remdesivir infusion in HaH units seems to be a safe and efficient alternative to conventional hospitalization for treating patients with nonsevere COVID-19.

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Background

The COVID-19 pandemic has posed a serious challenge to health systems around the world. Alternatives to conventional hospitalization have been proposed in order to avoid hospital collapse and prioritize those requiring a higher intensity of care [1]. Strategies aiming to minimize conventional hospital admission include out-hospital management in repurposed hospital at home (HaH) units [2,3] or in *ad hoc* monitoring programs [4], with great heterogeneity in the admission criteria for the different programs in different settings, some of them oriented to early detection of complications in patients with mild COVID-19 [4,5] while others aim to fully substitute hospital admission in patients with nonsevere COVID-19 [6]. These last strategies, aiming to provide acute, hospital-level care at home, should therefore ensure a clinical quality and safety standard, comparable to conventional hospitalization, including the administration of gold-standard treatments for COVID-19.

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Since the onset of the pandemic, several pharmacological treatments have been assayed with unequal results. Remdesivir, is an intravenous (IV) antiviral that has shown benefits in reducing the length of stay in patients with low flow oxygen requirements [7], while a recent multicentric observational cohort study has shown a reduction in mortality at 14 and 28 days in patients receiving remdesivir [8]. Early this year, a randomized clinical trial showed that the use of early remdesivir treatment (in the first 7 days since symptoms onset) in symptomatic nonhospitalized patients with at least one risk factor for severe COVID-19 development resulted in an 87% lower risk of hospitalization or death vs placebo [9]. Given this evidence, remdesivir is used worldwide as a standard of care treatment for patients with COVID-19 requiring hospital admission and in some selected nonhospitalized patients in order to prevent disease progression [10].

In the present study, we aim to describe a real-life experience in the use of remdesivir in the out-hospital setting, specifically in a HaH unit, for patients with nonsevere COVID-19.

Methodology

Hospital Clínic of Barcelona is a 750-bed public, tertiary teaching hospital which serves 560,000 people in the metropolitan area of Barcelona. The Hospital Clínic's HaH unit started providing hospital-level, specialized, health care at patients' homes in 1996. Nowadays has a maximum capacity of 60 patients, with approximately 1800 patients treated per year. Since March 2020, the Hospital Clínic HaH unit has been adapted for also managing and treating patients with COVID-19 at home as well as patients with COVID-19 infection. Criteria for patients with COVID-19 transfer to HaH included: home conditions allowing patient isolation from cohabitants; respiratory rate <22 rpm and oxygen saturation >95% with a fraction of inspired oxygen (FiO2) <0.35 [6]. Intervention during HaH admission included daily medical and nurse visit, around-the-clock call center, usual tests at home (blood tests, cultures, electrocardiogram, and ultrasound), and oral and IV treatment. An emergent circuit for transfer back to the hospital was organized, for further tests (e.g., chest X-ray), emergent assessment at the emergency department (ED) or planned conventional hospitalization if required. For the purpose of this study, we included every patient with COVID-19 admitted in HaH from July 2020 to June 2022.

National and local pharmacological treatment protocols were followed. Since May 2020 remdesivir was included as the standard of care for patients. Following national protocols, the indication for remdesivir was initially for patients with ≤7 days since symptoms onset, pneumonia and with respiratory failure (air room saturation <93% or partial pressure of oxygen/FiO2 >300 mmHg). Since September 2020, the indication was widened to patients with ≤8 days of symptoms. In January 2022 because of newly published evidence [9], remdesivir was also indicated in patients at high-risk of progression with ≤7 days of symptoms as a 3-day course of treatment [11]. Remdesivir dosage was 200 mg daily on the 1st day followed by 100 mg daily for 2-4 more days. Remdesivir at home was infused by a registered nurse through a peripheral venous catheter for over 45 mins.

Statistical analysis

Summary statistics of quantitative characteristics were presented with median and interquartile range (IQR) and compared between groups with Student's *t*-test. Qualitative variables were described with absolute frequency and percentage and compared between groups with chi-squared exact test. Descriptive analysis was performed using SPSS for Windows, version 23.0 (SPSS Inc. Chicago. Illinois. USA). All tests were two-tailed with a confidence level set at 95%.

Results

During the 2 years of the study, a total of 3192 patients were admitted to the HaH Unit of Hospital Clínic Barcelona. Of the 3192 patients, 15.9% (n = 507) were diagnosed with COVID-19, which represents 10.7% of the total patients with COVID-19 admitted in to the Hospital Clínic in the same period.

Of the total patients with COVID-19 admitted to the HaH unit, 69.9% (n = 354) were previously admitted to the Hospital Clínic COVID-19 ward and transferred at some point to the HaH unit. Overall, 23.1% (n = 117) of the patients were admitted to the HaH unit from the ED and 7.1% (n = 36) were admitted directly to the HaH unit from their homes after a general practitioner or specialist referral (Fig. 1).

A total of 46.7% (n = 236) of the HaH patients with COVID-19 received remdesivir at any point of the disease course, composing our present study cohort. From this cohort, 27.2% (n = 64) received the full treatment at the hospital before HaH admission (hospital-based treatment group), 22.2% (n = 52) received the full course of remdesivir at home (home-based treatment group), and 50.6% (n = 120) starting the treatment at the hospital and finishing at least one dose at home (mixed treatment group). In this last group, the median time from hospital admission to HaH transfer was 3 days (IQR 2-3), and patients received a median of 2 (IQR 1-3) doses of remdesivir before HaH transfer, while patients receiving full treatment at hospital ward were transferred to HaH at a median of 7 days (IQR 4-11) after hospital admission (P <0.001) (Table 1).

Regarding baseline characteristics for the 236 patients receiving remdesivir, globally 64.1% (n = 152) were men, with a median age of 63 years old (IQR 51.5-72). 45.6% (n = 108) had a history of hypertension, while 10.5% (n = 25) were active smokers, and 25.3% (n = 60) were past smokers. The median Charlson index score was 2 (IQR 1-4), with a 10.8% presenting a Charlson index score of over 6 points. 28.3% (n = 67) were immunocompromised, mainly drug-related (Table 1).

When comparing the clinical characteristics among the three groups (hospital-based treatment, HaH-based treatment, and mixed treatment) we observe that patient gender in the HaH-based treatment group is more balanced (54% of men vs 73% and 64% in the hospital-based and mixed groups, P = 0.028), with a higher Charlson index score (3 vs 1 and 2, P <0.001 and P= 0.181 respectively), and with a higher proportion of immunocompromised patients (65.4% in the home-based vs 3.1% in the hospital-based and 27.5% in the mixed group respectively, P <0.001).

Patients in the HaH-based treatment were admitted earlier in the course of the disease, with a median time from symptoms onset to admission of 3 days (IQR 1-4) vs 5.5 days in the hospital-based group (P = 0.006) and 6 days in the mixed group (P= 0.005). Also, treatment with remdesivir was started earlier, with median days from symptoms onset to treatment of 3 days (IQR 2-5), while in the hospital-based group the treatment was delayed until 5.5 (3-7) days (P <0.001), and until 6 (4-8) days in the mixed group (P <0.001).

Radiological confirmed pneumonia was present in 70% (n = 165) of the cases. 95% (n = 61) of the patients receiving hospital-based treatment and 73% (n = 87) of the mixed group patients had pneumonia in the X-ray while only 33% (n = 17) of the patients receiving fully HaH-based treatment presented pneumonia confirmed by X-ray, although it should be considered that only 56% (n = 29) of the patients receiving HaH-based treatment had an X-ray taken. Regarding oxygen supplementation, 94% (n = 60) of the patients receiving hospital-based care required

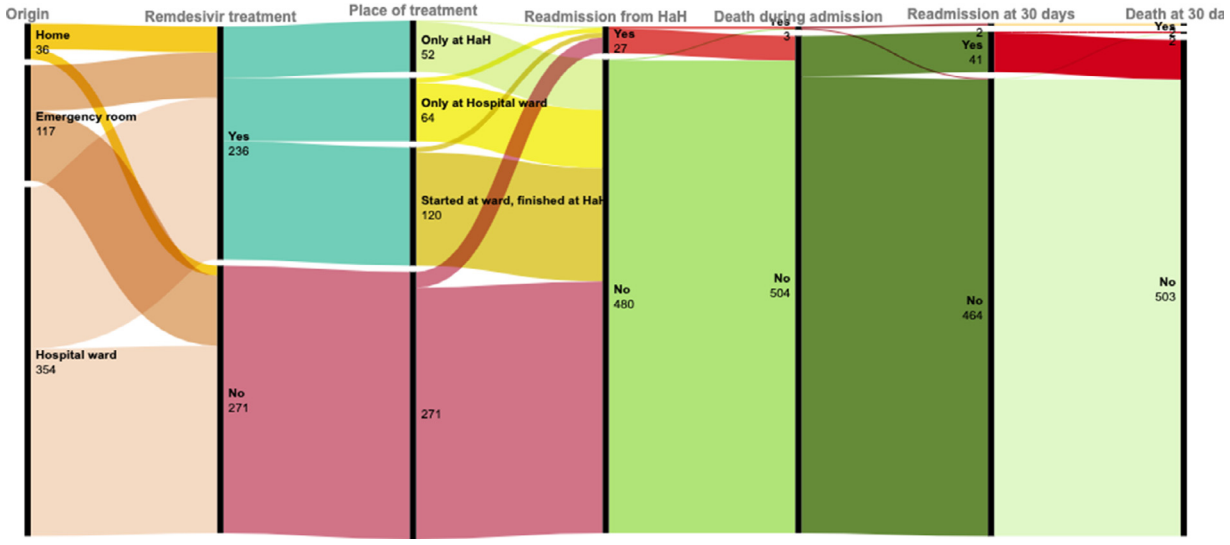

Fig. 1. Alluvial graphic showing patient allocation at each step of the process.
HaH, Hospital-at-Home.

Table 1
Clinical characteristics and outcomes of patients receiving full remdesivir treatment at home vs at hospital vs mixed home-hospital treatment.

	Global (n = 236)	Hospital-based treatment group (n = 64)	Home-based treatment group (n = 52)	Mixed treatment group (n = 120)	*P*-value
Age years old, median (IQR)	63 (51.5-72)	59 (51-70)	66.5 (51-74.5)	64 (51.3-74)	0.260
Male sex, n (%)	153 (64.6)	47 (73.4)	28 (53.8)	77 (64.2)	0.028
Active smoker, n (%)	25 (10.1)	5 (7.8)	4 (7.7)	16 (13.3)	0.488
Past smoker, n (%)	60 (25.3)	13 (20.3)	15 (28.8)	31 (25.8)	0.556
Hypertension, n (%)	108 (45.6)	26 (40.6)	34 (65.4)	48 (40)	0.006
Immunosuppression, n (%)	114 (48.1)	2 (3.1)	32 (65.4)	33 (27.5)	<0.001
Charlson index score, median (IQR)	2 (1-4)	1 (1-3)	3 (2-4.75)	2 (1-4)	0.012
Intensive care unit prior to HaH transfer, n (%)	27 (11.4)	25 (39)	-	2 (1.7)	<0.001
Days from symptoms onset to admission, median (IQR)	5 (3-7)	5.5 (3-7)[a]	3 (1-4) [a]	6 (3-8) [a]	
Days from symptoms onset to remdesivir initiation, median (IQR)	5 (3-8)	6 (4-8) [a]	3 (2-5) [a]	6 (4-8) [a]	
Remdesivir side-effect, n (%)	5 (2.1)	1 (1.6)	2 (3.9)	2 (1.7)	0.612
Remdesivir discontinuation, n (%)	1 (0.4)	1 (0.8)	0 (0)	0 (0)	0.078
Length of global stay, median (IQR)	10 (7-13)	14 (10.3-18.75) [a]	6 (5-10) [a]	9 (7-11)	
Length of in hospital stay, median (IQR)	3 (1-6)	7 (5-11) [a]	0 (0-1) [a]	3 (2-3) [a]	
Length of HaH stay, median (IQR)	6 (5-8)	6 (4.3-8)	6 (4.3-7.8)	6 (5-8)	
Oxygen supplementation requirements, n (%)	150 (63.8)	60 (93.8)	16 (30.7)	75 (63)	<0.001
X-ray performed, n (%)	203 (86)	64 (100)	29 (55.7)	110 (91.7)	<0.001
Pneumonia total cohort, n (%)	165 (69.9)	61 (95.3)	17 (32.7)	87 (72.5)	<0.001
Pneumonia among those with chest X-ray, n (%)	165 (81.3)	61 (95.3)	17 (58.6)	87 (79.1)	0.023
Transfer back to hospital from HaH, n (%)	10 (4.3)	4 (6.3)	1 (1.9)	5 (4.2)	0.008
Intensive care unit admission after HaH transfer	4 (1.7)	2 (3.1)	0 (0)	2 (1.7)	0.060
Death during admission, n (%)	1 (0.4)	1 (1.6)	0 (0)	0 (0)	0.261
30-day readmission, n (%)	20 (8.5)	5 (7.9)	5 (9.6)	10 (8.3)	0.945
30-day death, n (%)	1 (0.4)	0 (0)	0 (0)	1 (0.8)	0.618

[a] p<0.05 when comparing HaH-based group with the other two groups separately.HaH, Hospital at Home; IQR, interquartile range.

oxygen supplementation at any point (including HaH), while only 31% (n = 16) of the patients receiving HaH-based care required oxygen at home. 39% (n = 25) of the patients receiving hospital-based care and only 1.7% (n = 2) of the mixed groups required intensive care unit (ICU) admission before HaH transfer.

Remdesivir infusion was, in general, well tolerated. Only 2% (n = 5) of patients were reported to present a possible adverse event during or after the infusion, without differences between groups. Side effects were mild (one of them reported feeling light-headed, one presented sweating and cough, one presented with emesis, and the other two presented hypotension solved with postural measures). In one of the patients receiving hospital-based care, remdesivir was discontinued because of recurrent vomiting. As this is not a placebo-controlled trial, side-effect causality cannot be distinguished between remdesivir vs the underlying COVID-19, as any potential excess of any event observed above that expected cannot be determined without a control.

As for the outcomes, 4% (n = 10) of the patients required to transfer back to the hospital ward after HaH admission, of which four patients were from the hospital-based group (representing 6% of the group), five patients were in the mixed group (4%) and only one patient (1.9%) from the home-based group (*P*-value = 0.008). Of the 10 patients transferred back to the hospital, four (1.7%) required ICU admission. Only one patient (0.4%) died during admission, belonging to the hospital-based group. The global median length of stay (combining hospital and HaH) was 10 days (IQR 7-13), being 6 days (IQR 5-10) in the HaH-based group vs 14 days (10-19) in the hospital-based (*P* <0.001) and 9 days (IQR 7-11) in the mixed group (*P*-value = 0.082). HaH, admission length was comparable for the three groups, 6 days (IQR 4-8) in the

HaH-based group vs 6 days (IQR 4-8) in the hospital-based (*P*-value = 0.205) and 6 days (5-8) in the mixed treatment group (*P*-value = 0.865).

Readmission at 30 days post-discharge was necessary for 20 patients (8.5%), with similar rates among groups (7.9% in the hospital-based, 8.3% in the mixed group, and 9.6% in the home-based group). One patient in the mixed group (0.8%) died in the 30 days post-discharge.

Discussion

Remdesivir efficacy and use in treating hospitalized patients with COVID-19 are supported by some strong evidence showing potential benefit in shortening the hospital stay and reducing all-cause mortality, particularly when started promptly, in hospitalized patients requiring conventional oxygen supplementation with or without corticosteroids and its use is recommended by the principal international guidelines [10,12]. In nonhospitalized patients, treatment with remdesivir is indicated only in those patients at risk for disease progression. For those without limiting drug-drug interactions, oral treatment with ritonavir-boosted nirmatrelvir is also considered an equally valid alternative in the subsetting of patients not requiring hospitalization, with data showing similar efficacy to that of remdesivir [13]. Bebtelovimab, a SARS-CoV-2 receptor-binding domain-specific antibody, has shown *in vitro* action against all circulating variants, but pre-print evidence [14] has not yet been peer-reviewed and therefore is reserved as a second line in nonhospitalized patients [15]. Finally, molnupinavir is an oral antiviral mutagen with activity against SARS-CoV-2, but with a lower clinical efficacy in preventing adverse events in clinical trials compared to remdesivir or ritonavir-boosted nirmatrelvir [16]. Because remdesivir requires IV infusion in 3 to 5 days, both in hospitalized and nonhospitalized patients, it is necessary to promote the standardization of alternatives to conventional hospitalization, assuring safety and clinical quality in the outpatient setting, such as HaH units.

The deployment of alternatives to conventional hospitalization to manage COVID-19 has flourished during the past 2 years, including the adaptation of HaH units to also manage patients with COVID-19 as one of the most popular due to the pre-existence of those units, and their experience in other acute, severe conditions. These units should therefore be able to provide a comparable standard of care and treatments as in conventional hospitalization, including IV treatments such as remdesivir.

In this work, we present a cohort of 236 patients receiving remdesivir admitted in a HaH unit. These patients are divided into three groups according to the allocation at the moment of remdesivir administration (hospital-based treatment, home-based treatment, and mixed treatment for those receiving at least one dose at the hospital and/or at least one dose at home).

Patients receiving remdesivir in our cohort were middle-aged with low comorbidities, being noticeable that the Charlson index score and the proportion of patients who were immunocompromised in the home-based group are higher than the other two groups (median Charlson of 3 vs 1 and 2, and 65% of immunocompromised vs 27% and 3% respectively). This fact is explained by the launch of an early treatment strategy in immunocompromised patients directly from their homes from January 2022 forward (data published elsewhere [11]). This fact also might partially explain the lower medians in days from symptoms onset to admission and remdesivir treatment in the home-based group, showing that a well-planned HaH program can be even more agile than a brick-and-mortar hospital in treating patients with COVID-19, particularly when oversaturated during COVID-19 waves.

Patients in the hospital-based group presented a more severe COVID-19 initially, with a higher proportion of bilateral pneumonia, oxygen requirements, and ICU admission rate. Furthermore, patients in the mixed treatment group were more similar in clinical characteristics to the home-based group, and transfer to HaH was 3 days sooner as the median than the hospital-based group. This may indicate that some of the patients in the mixed group might have benefited from direct admission to HaH from the ED or general practitioner, highlighting the importance of good communication between the different levels of attention and of establishing clear protocols for HaH admission criteria.

Only five patients, representing 2% of the cohort, were reported to present any possible adverse event during or after remdesivir infusion, all of them being mild except one patient in whom remdesivir was interrupted. This real-life data complements the safety information reported in the PINETREE trial, in which 16.5% of the patients received remdesivir at least one dose at home. In PINETREE, a 3.4% excess of adverse events were attributed to remdesivir (25/283, 8.8% in placebo compared to 34/279, 12.2% on remdesivir) [9]. Together, this supports the safe use of remdesivir in the outpatient setting, although the limitations of the present study, without a placebo comparator, precludes the determination of whether side effects were truly related to remdesivir treatment vs underlying COVID-19. Regarding outcomes, only 4.3% of the patients required to transfer back to the hospital, which can be considered a fairly low percentage if compared to other cohorts. In the Permanent Kaiser Southern California preliminary report, with 13,055 patients monitored at home, a 10% rate of readmissions is reported, although in this program patients were self-monitored, and the objective was to detect early complications rather than provide a full hospital admission substitution [4]. In other similar programs in our country, transfer back to hospital rates are between 6% and 22% [3,17]. Only one patient in our cohort died during the admission, after a hospital transfer back from HaH. Finally, it is notable that patients in the hospital-based treatment group and the mixed treatment group experienced a median 6-day reduction in their overall hospital stay, which was spent in HaH instead of occupying a hospital bed, entailing a saving of approximately 1416 bed-days in the hospital.

This work has some limitations. First, we report observational data, and therefore extrapolation and reproducibility might be limited. Secondly, heterogeneity in patients with COVID-19 along the different waves may complicate the extension of the results to other centers. Despite these shortcomings, this report is among the first to analyze the real-life experience of infusing remdesivir in the home setting, in the context of a pre-established, experienced HaH program. This proof of concept might be of interest especially to decision-makers, emphasizing the potential decentralization of COVID-19 care from hospitals. Also, these results may encourage the expansion of HaH programs, aiming to improve efficiency and patients' comfort, while reducing hospital overload during COVID-19 peaks, as well as costs and nosocomial infections.

In conclusion, our work shows that it is feasible to infuse remdesivir at home, with the same quality and safety standards as in the hospital setting. HaH units might be of significant importance in coping with high incidence peaks of the pandemic, by decongesting hospitals and facilitating the allocation of more severe patients in a conventional hospital bed. Our work shows that HaH units can safely provide the international guideline consensus standard of care to patients with COVID-19 in a patient-centered environment such as a home. Patients with COVID-19 fulfilling criteria for HaH admission (home conditions allowing patient isolation; respiratory rate <22 rpm and oxygen saturation >95% with FiO2 <0.35) should be therefore treated at home. In the future, the expansion in the use of oral antivirals may ease the early treatment of high-risk patients, although HaH units may still play a role in supplying the treatment and monitoring the evolution of patients.

Declarations of competing interest

The authors have no competing interests to declare.

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Ethics approval and consent to participate

The Ethical Board of Hospital Clínic evaluated and approved the collection of data (HCB.2020.0443). A waiver for informed consent was granted because of the state of the pandemic emergency.

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Author contributions

DN and IP conceived the study and led the protocol design. DN wrote the first draft of the manuscript. AM, CS, and NL lead the protocol implementation. BI, LM, EC, AB, and EC contributed tothe study design and/or implementation. MC, CC, AR, and AU, NG conducted the data analysis. MB, VR, JA, NS, and DN had full access to all data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. All authors read and approved the final manuscript.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author upon reasonable request.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ijid.2022.12.011.

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