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Original Article

Effectiveness of a monitored home isolation program for COVID-19 infection during the second wave of the pandemic

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ABSTRACT

Background: The rapidity of spread of COVID-19 infection during the second wave of the pandemic placed tremendous stress on healthcare resources. This study evaluated the effectiveness of a monitored home isolation (HI) program.

Methods: In this descriptive longitudinal study, symptomatic patients were screened in the HI clinic and eligible patients were followed up at home using tele-consultation, until recovery or hospitalization. HI failure was defined as need for hospitalization. Factors associated with HI failure were assessed using logistic regression analysis and expressed as odds ratio (OR) with 95% confidence interval (CI).

Results: During April and May 2021, 1957 RT-PCR confirmed patients (984 male) with mean (SD) age 40 (13.5) years were enrolled; 93.3% (n = 1825) were successfully managed at home. Of the 132 patients (6.7%) who failed HI, 57 (43.2%) required oxygen therapy and 23 needed intensive care admissions. Overall mortality was 0.4% (7/1957). On adjusted analysis, factors associated with HI failure were age ≥60 years (OR 2.24; 95%CI 1.26–3.99), male gender (OR 2.26; 95%CI 1.44

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−3.57), subjective reporting of breathing difficulty (OR 3.64; 95%CI 2.08–6.37), history of cough (OR 2.08; 95%CI 1.37–3.17), and higher heart rate (OR 1.04; 95%CI 1.02–1.05). Although patient status (non-healthcare workers), no prior vaccination and ≥2 comorbidities were associated with HI failure on unadjusted analysis, these were non-significant on adjusted analysis.

Conclusion: Monitored HI program can be used successfully during a pandemic wave to judicially use scare hospital resources. Older male patients presenting with breathlessness or cough may warrant closer monitoring.

Introduction

The rapidity of spread of corona virus disease, 2019 (COVID-19) during the two waves of the pandemic in India placed an enormous stress on the available healthcare resources. Quarantine of suspects and isolation of confirmed COVID-19 patients are measures undertaken across the world to mitigate the spread of the contagion. The concept of home isolation (HI) or institutional isolation (non-hospital setting), for asymptomatic or mildly symptomatic patients, has been advocated.[1] The Ministry of Health and Family Welfare (MoHFW), Government of India (GoI), released guidelines for HI of pre-symptomatic and mildly symptomatic patients in April 2020 with a further revision in July 2020.[2,3] Based on these guidelines, many institutions drafted protocols for selection and follow-up of patients under their HI program.

An important development in 2021 was the emergency authorization use of two vaccines, Oxford-AstraZeneca's Chad0x1 (Covishield) and Bharat biotech's BBV152 (Covaxin).[4] In the first few months, vaccination was prioritized for frontline workers and high-risk groups (>60 years and >45 years with comorbidities) with the objective of mitigating the severity of illness amongst the most vulnerable. However, by April 2021, the second wave of the pandemic in India resulted in the overburdening of most public and private hospitals. The health system struggled due to a demand–supply mismatch of hospital beds and oxygen. Hence, several institutions, including ours, refined HI programs to manage milder patients at home and in some rare cases even provided medical care and oxygen therapy through portable oxygen concentrators at home for the moderately ill patient till a bed could be organized.

In this context, we hypothesized that a carefully managed HI program with close monitoring through tele-consultation would reduce the burden on the health system by reducing the number of patients who would be hospitalized. This study evaluated the success of the monitored HI program and assessed for factors that were associated with HI failure.

Materials and methods

Participants

This descriptive longitudinal study was conducted in a large tertiary care referral hospital in South India during April and May 2021. All symptomatic patients presenting to the hospital and confirmed to have COVID-19 infection using reverse transcriptase polymerase chain reaction (RT-PCR) were screened for eligibility to be enrolled into the HI program.

Criteria for home isolation

Mandatory criteria for the recruitment to the HI program included heart rate (HR) < 110/min, systolic blood pressure (SBP) > 100 mm Hg, respiratory rate (RR) < 24/min and pulse oximetry SpO2 >94%. Other important pre-requisites for enrolment in the HI program were the availability of caretakers to provide food and a separate room with attached bathroom for the patient. Patients enrolled in the program were dispensed a "Home isolation kit," which contained basic items such as a pulse oximeter, thermometer, sanitizer, and masks. They were taught the use of these monitors and educated on the measurement of their vital signs. All patients were monitored through tele-consultation twice a day by a designated healthcare worker (HCW) for 10 days or until hospitalization.[2,3]

Data and outcomes

Patient data were collected from the hospital electronic database and the monitoring records of the HI program and included demographic data, patient status (HCW, dependant of staff, medical, nursing or allied health student or patient), vaccination status (no vaccination, partial or full vaccination), comorbidities, symptoms, and vital signs at the time of screening as well as outcomes. Patients who received at least one dose of vaccination prior to the onset of symptoms were considered to have 'partial vaccination', while those who completed two doses of vaccine at least 2 weeks prior to the onset of symptoms were considered to be fully vaccinated. The primary outcome of the study was HI failure, defined as the need for hospitalization. HI success was defined as the successful completion of HI without the need for hospitalization. Secondary outcomes included need for oxygen therapy, intensive care unit (ICU) admission, and hospital mortality.

Statistical analysis

Summary data were presented as mean (standard deviation, SD) for continuous variables with normal distribution and categorical variables as numbers and percentages. The characteristics of HI (success and failure) of patients were compared using a t-test for continuous data and categorical data were compared using chi-square/Fisher's exact test as appropriate. Important factors associated with HI failure were explored using logistic regression analysis and expressed as odds ratio (OR) with 95% confidence intervals (CI). Nagelkerke R^2 statistics and Hosmer and Leme-show chi-square statistics were used as goodness-of-fit statistics. Statistical significance was defined as $P < 0.05$. All analyses were performed using Statistical Package for Social Sciences for Windows (SPSS) v25.

Ethical considerations

This study was approved by the Institutional Review Board and Ethics committee of the institution (IRB No.14083, 30th June 2021). We used unique identifiers and password-protected data entry software to maintain patient confidentiality. Informed consent was given by all participants.

Results

During April and May 2021, 3624 RT-PCR confirmed COVID-19 patients were screened in the HI clinic. Patients requiring immediate admission (n = 620) and those not eligible or not willing for HI (n = 1017) were excluded (Fig. 1). Although 1987 patients were recruited for HI, 30 patients were lost to follow-up despite repeated attempts to contact them. Hence, the final HI cohort comprised of 1957 patients that included 753 (38.5%) HCWs and 1204 (61.5%) patients.

In the 1957 patients (984 male) with mean (SD) age 40 (13.5) years, the main presenting symptoms were fever (38.4%), cough (27.4%), and myalgia (22.9%). A majority of patients (1825, 93.3%) were successfully managed at home while 6.7% required hospitalization (n = 132). The demographic and clinical variables are presented in Table 1, categorized as HI success and HI failure. Diabetes was the most common co-morbidity (16.6%). At least one comorbidity was present in 572 (29.2%) patients; 192 patients (9.8%) had two or more comorbidities. Only 18% of the study population (n = 353) were full vaccinated with HCWs comprising the majority (n = 312, 88.3%); 63% had not received any vaccination.

There was a significant difference in patient characteristics between HI success and failure (Table 1) for age, gender, patient status (HCW vs. patient), vaccination (fully vaccinated vs. no vaccination), comorbidities, symptoms (fever, cough, breathing difficulty), and vital signs (HR, RR). Although the differences in HR and RR were statistically significant, they were not clinically significant. Among the 132 who failed HI, 57 patients (43.2%) required oxygen therapy, 23 (17.4%) and needed ICU admission. Overall mortality in the HI cohort was 0.4% (7/1957).

Given that HCWs might be prioritized for hospitalization during a pandemic, sub-group analysis of demographic and clinical variables was undertaken among patients who were not HCWs (Table 2). In this subgroup of 1204 patients, the difference in patient characteristics between HI success and failure continued to be evident for age, gender, comorbidities, symptoms, and vital signs, wherein those who failed HI were older males with comorbidities who were symptomatic. Vaccination status was not different between HI success and HI failure (Table 2). In this subset of patients, 53 patients (49.5%) required oxygen therapy, 22 (20.6%) needed ICU admission, and 7 patients (6.5%) died.

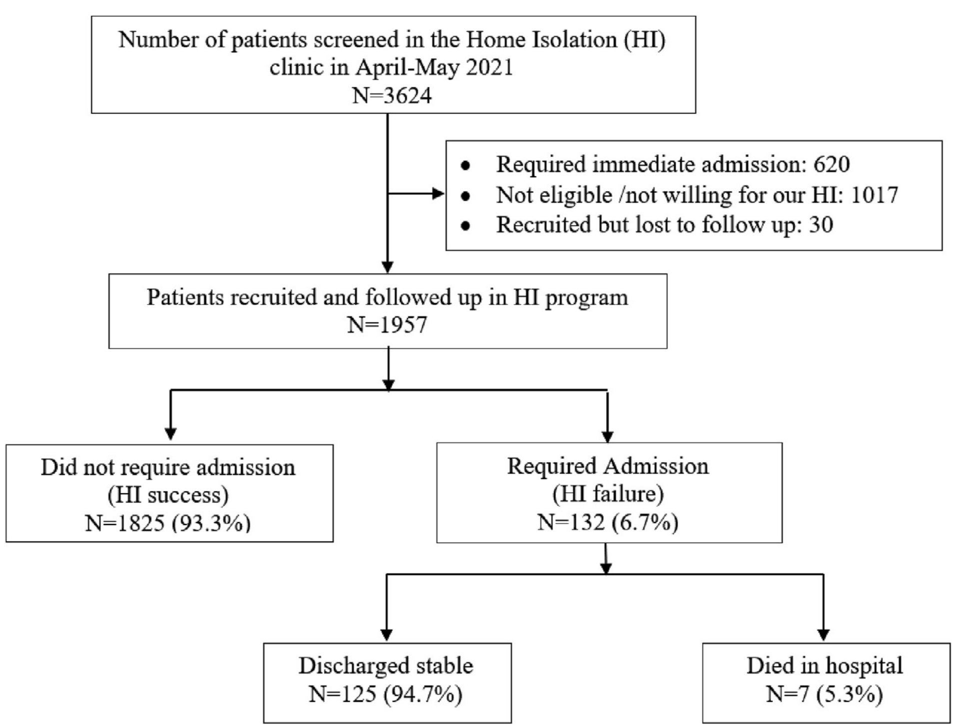

Fig. 1 – STROBE diagram shows enrolment of patients presenting to the HI clinic, success rate, and outcome of patients requiring hospital admission.

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Table 1 – Demographic and clinical variables associated with HI failure.

Variable	Overall (n = 1957)	HI success (n = 1825)	HI failure (n = 132)	p-value	Test statistics (chi-square)
Age					
≥60 years	190 (9.7)	166 (9.1)	24 (18.2)	0.001	11.59
<60 years	1767 (90.3)	1659 (90.9)	108 (81.8)		
Gender					
Male	984 (50.3)	896 (49.1)	88 (66.7)	<0.001	15.20
Female	973 (49.7)	929 (50.9)	44 (33.3)		
Patient status[a]					
Healthcare workers	753 (38.5)	728 (39.9)	25 (18.9)	<0.001	22.82
Patients/dependents	1204 (61.5)	1097 (60.1)	107 (81.1)		
Comorbidities					
Any comorbidity	572 (29.2)	501 (27.5)	71 (53.8)	<0.001	41.27
Comorbidity (≥2)	192 (9.8)	166 (9.1)	26 (19.7)	<0.001	15.63
Diabetes mellitus	325 (16.6)	279 (15.3)	46 (34.8)	<0.001	33.97
Hypertension	296 (15.1)	259 (14.2)	37 (28.0)	<0.001	18.36
Ischemic heart disease	58 (3.0)	48 (2.6)	10 (7.6)	0.001	10.46
Vaccination status[b]					
No vaccination	1233 (63.0)	1134 (62.1)	99 (75.0)	<0.001	14.49
Partial vaccination	371 (19.0)	346 (19.0)	25 (18.9)		
Full vaccination	353 (18.0)	345 (18.9)	8 (6.1)		
Clinical parameters at presentation					
Fever	748 (38.4)	661 (36.4)	87 (65.9)	<0.001	45.31
Breathing difficulty	119 (6.1)	90 (5.0)	29 (22.0)	<0.001	62.05
Cough	533 (27.4)	472 (26.0)	61 (46.2)	<0.001	25.32
Myalgia	445 (22.9)	419 (23.1)	26 (19.7)	0.37	0.81
Vital signs at presentation, mean (SD)					**t-test statistics**
Heart rate (beats/min)	90.0 (12.3)	89.6 (12.0)	95.6 (14.9)	<0.001	−4.07
Systolic blood pressure (mm Hg)	117.7 (8.0)	117.8 (7.5)	116.6 (10.5)	0.24	1.18
Respiratory rate (per min)	20.5 (2.6)	20.4 (2.6)	22.4 (2.8)	<0.001	−7.84
Outcomes					
Requirement for oxygen therapy	57 (2.9)	–	57 (43.2)	–	–
Need for ICU admission	23 (1.2)	–	23 (17.4)	–	–
Hospital mortality	7 (0.4)	–	7 (5.3)	–	–

All values are expressed as number (n) and percentage unless indicated.
HI, home isolation; ICU, intensive care unit.
[a] Healthcare workers and medical, nursing, and allied health students were taken together; dependents indicate relatives of healthcare workers.
[b] Partial vaccination indicates that patient received at least one dose of vaccination prior to the onset of symptoms; fully vaccinated indicates completion of two doses of vaccine at least 2 weeks prior to the onset of symptoms.

When the key outcomes were compared between HCWs (n = 753) and patients (n = 1204), HCWs were at significantly lower risk of HI failure compared with patients (25/753 vs. 107/1204, P < 0.001). Similarly, the need for oxygen therapy (4/753 vs. 53/1204) and ICU admission (1/753 vs. 22/1204) were significantly higher (P < 0.001) for patients than for HCWs. The mortality was also significantly (P = 0.05) higher among patients (7/1204) than among HCW (0/753).

Table 3 details the unadjusted and adjusted analysis of factors associated with HI failure. On unadjusted analysis, age ≥60 years, male gender, comorbidities, patient status, vaccination status, fever, subjective reporting of breathlessness, history of cough, and vital signs (HR, RR) were associated with HI failure. For the adjusted analysis, of the symptoms that were assessed, only cough and subjective reporting of breathing difficulty were incorporated in the model since fever was considered to be a more non-specific symptom, and myalgia was non-significant on unadjusted analysis. Among vital signs, since SBP and respiratory thresholds for HI were kept at the normal physiological range as >100 mm Hg and <24/min and since the clinical differences were small, they were not included; HR was included in this analysis since the threshold for this parameter was kept beyond the physiological range as <110/min in the HI program. On adjusted analysis (Table 3), factors associated with HI failure included age ≥60 years (OR2.24; 95%CI 1.26–3.99), male gender (OR 2.26; 95%CI 1.44–3.57), presence of breathing difficulty (OR 3.64; 95%CI 2.08–6.37), history of cough (OR 2.08; 95%CI 1.37–3.17), and HR at the time of screening (OR 1.04; 95%CI 1.02–1.05).

Discussion

This study demonstrated the effectiveness of the HI program as a means to monitor and manage mild COVID-19 patients at home during the second wave of the pandemic. The HI program was designed by a team of experts from infectious diseases and the administration and implemented in the HI clinic of the hospital. The key finding was that in the cohort of 1957

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Table 2 – Demographic and clinical variables associated with HI failure among patients who were not healthcare workers.

Variable	Overall (n = 1204)	HI success (n = 1097)	HI failure (n = 107)	p-value
Age				
≥60 years	188 (15.6)	164 (14.9)	24 (22.4)	0.04
<60 years	1016 (84.4)	933 (85.1)	83 (77.6)	
Gender				
Male	709 (58.9)	635 (57.9)	74 (69.2)	0.02
Female	495 (41.1)	462 (42.1)	33 (30.8)	
Comorbidities				
Any comorbidity	389 (32.3)	330 (30.1)	59 (55.1)	<0.001
Comorbidity (≥2)	153 (12.7)	130 (11.9)	23 (21.5)	0.005
Diabetes mellitus	245 (20.4)	201 (18.3)	44 (41.1)	<0.001
Hypertension	215 (17.9)	182 (16.6)	33 (30.8)	<0.001
Ischemic heart disease	49 (4.1)	40 (3.6)	9 (8.4)	0.021
Vaccination status[a]				
No vaccination	972 (80.7)	882 (80.4)	90 (84.1)	0.35
Partial vaccination	191 (15.9)	175 (16.0)	16 (15.0)	
Full vaccination	41 (3.4)	40 (3.6)	1 (0.9)	
Clinical parameters at presentation				
Fever	503 (42.0)	432 (39.6)	71 (33.4)	<0.001
Breathing difficulty	93 (7.8)	68 (6.2)	25 (23.4)	<0.001
Cough	368 (30.7)	316 (28.9)	52 (48.6)	<0.001
Myalgia	263 (22.0)	245 (22.5)	18 (16.8)	0.18
Vital signs at presentation, mean (SD)				
Heart rate (beats/min)	90.4 (12.6)	90 (12.3)	94.8 (15.3)	0.006
Systolic blood pressure (mm Hg)	118.0 (8.8)	118.1 (8.4)	117.3 (10.6)	0.76
Respiratory rate (per min)	20.4 (1.5)	20.2 (1.2)	22.5 (2.9)	<0.001
Outcomes				
Requirement for oxygen therapy	53 (4.4)	–	53 (49.5)	–
Need for ICU admission	22 (1.8)	–	22 (20.6)	–
Hospital mortality	7 (0.6)	–	7 (6.5)	–

Table excludes healthcare workers and staff; all values are expressed as number (n) and percentage unless indicated.
HI, home isolation; ICU, intensive care unit.
[a] Partial vaccination indicates that patient received at least one dose of vaccination prior to the onset of symptoms; fully vaccinated indicates completion of two doses of vaccine at least 2 weeks prior to the onset of symptoms.

patients, 93.3% were successfully managed at home. Among those who failed HI (6.7%), 43.2% required oxygen therapy and 17.4% needed ICU admission. The overall mortality in the HI cohort was 0.4% (7/1957). On adjusted analysis, factors associated with HI failure were age ≥60 years, male gender, subjective reporting of breathing difficulty, history of cough and higher HR. The success of the program lay in the close monitoring of patients through tele-consultation and the option given to patients to report to the emergency department (ED) in the case of any concerning symptoms.

Several studies have reported the success rate of HI or remote patients monitoring programs. In a study from Saudi Arabia that enrolled 5368 patients in 2020, 5% required hospitalization.[5] However, this study used the presence of comorbidities as an indicator for hospital admission at the discretion of the monitoring team. Further in this study, 41% of the patients were asymptomatic.[5] A large study (n = 3701) on 'remote patient monitoring program' in the United States in 2020 reported a very low hospitalization rate of 0.32%.[6] A low hospitalization rate of 1.9% was also observed in a 'virtual health care program' in Australia that enrolled 162 patients.[7] In a very small study of 41 patients from Turkey during the early pandemic in 2020, 9.8% needed hospitalization.[8] A multisite study from United Kingdom on remote patient monitoring program of 1737 confirmed or suspected COVID-19 patients showed an escalation of care to admission rate of 10% and a mortality rate of 1.1%.[9] O'Keefe et al using a telemedicine risk assessment tool to estimate the risk of hospitalization on 496 outpatients assigned to three tiers based on age ≥60 years, gender and comorbidities as covariates reported an adjusted hazard ratio for hospitalization of 3.74 for tier 2 and 10.87 for tier 3 using tier 1 as reference.[10] The success rate of our HI program was consonant with other studies despite the inclusion of older patients and those with comorbidities. It must also be pointed out that all these studies were done during the 1st wave of the pandemic in 2020 when the less virulent strains of COVID were prevalent. Our study was done during the second wave of the pandemic in India in April and May 2021, when the delta variant was postulated to be the main strain responsible for COVID infections.

In our HI program, although we pre-specified thresholds for vital signs and the requirement of an isolation room and supply of daily essentials, we did not specify an age cutoff or absence of comorbidity for eligibility for HI. The analysis suggested that older age and male gender were at higher risk for HI failure. This is consonant with our understanding that older age and male gender are at higher risk for complications, ICU requirement and mortality.[11–14] There are reports that suggest that the presence of comorbidities is associated with worse outcome in the hospital setting.[14,15] The effect of comorbidities

Table 3 – Unadjusted and adjusted analysis of factors associated with home isolation failure.

Factors	Unadjusted analysis			Adjusted analysis		
	OR	95% CI	p-value	OR	95% CI	p-value
Age (≥60 years)	2.21	1.39–3.55	0.001	2.24	1.26–3.99	0.006
Gender, male	2.07	1.43–3.02	<0.001	2.26	1.44–3.57	<0.001
Status of patient[a]						
Healthcare workers	1.00					
Patients/dependents	2.84	1.82–4.43	<0.001	1.18	0.67–2.12	0.56
Comorbidities						
Any comorbidity	3.08	2.15–4.40	<0.001	–	–	–
Comorbidity (≥2)	2.45	1.55–3.87	<0.001	1.57	0.88–2.79	0.13
Diabetes mellitus	2.96	2.03–4.33	<0.001	–	–	–
Hypertension	2.36	1.58–3.52	<0.001	–	–	–
Ischemic heart disease	3.03	1.50–6.14	0.002	–	–	–
Vaccination status[b]						
No vaccination	1.00					
Partial vaccination	0.83	0.53–1.30	0.42	1.01	0.60–1.71	0.97
Full vaccination	0.27	0.13–0.55	<0.001	0.56	0.24–1.30	0.18
Clinical symptoms						
Fever	3.38	2.33–4.90	<0.001	–	–	–
Breathing difficulty	5.40	3.40–8.58	<0.001	3.64	2.08–6.37	<0.001
Cough	2.45	1.71–3.50	<0.001	2.08	1.37–3.17	0.001
Myalgia	0.82	0.53–1.27	0.37	–	–	–
Vital signs at presentation						
Heart rate	1.04	1.03–1.06	<0.001	1.04	1.02–1.05	<0.001
Systolic blood pressure	0.98	0.96–1.01	0.14	–	–	–
Respiratory rate	1.32	1.20–1.46	<0.001	–	–	–

OR, odds ratio; CI, confidence interval.

[a] Healthcare workers and medical, nursing, and allied health students were taken together; dependents indicate relatives of healthcare workers.

[b] Partial vaccination indicates that patient received at least one dose of vaccination prior to the onset of symptoms; fully vaccinated indicates completion of two doses of vaccine at least 2 weeks prior to the onset of symptoms; for the adjusted analysis, only cough and subjective reporting of breathing difficulty were incorporated since fever is more non-specific; vital signs, only heart rate was incorporated into the model since the heart rate cutoff was kept as 110 for admission, whereas the other two parameters systolic blood pressure and respiratory rate thresholds for home isolation were kept at the normal physiological range as >100 mm Hg and 24/min.

on HI failure was not evident on adjusted analysis in the current study (OR 1.57; 95%CI 0.88–2.79). The adequacy of control of comorbidities (diabetes, hypertension) was not formally assessed in the current study. It is possible that this may influence HI success and this aspect warrants further study.

It was expected that prior vaccination would be associated with HI success, given that studies have shown that prior vaccination reduces the need for hospitalization, oxygen and ICU admission.[16–18] Although on unadjusted analysis, vaccination was associated with HI success (OR 0.27; 95%CI 0.13–0.55), the protective effect of vaccination was not evident on adjusted analysis (OR 0.56; 95%CI 0.24–1.30, P = 0.18). There was widespread vaccine hesitancy prior to the second wave of the pandemic and only 18% of the patients enrolled in the HI program had received two doses of vaccination. Among the subset of non HCWs (Table 2), only 3.4% had received full vaccination. These and the relatively smaller numbers may have contributed to the lack of significance.

The presence of certain symptoms and signs may predict HI failure. Our criteria for enrolment into the HI program was pragmatic with physiological thresholds for vital signs for RR (<24/min), SBP (<100 mmHg) and HR (<110/min). Though patients who failed HI did not have significant tachycardia, tachypnea, or hypoxia at the time of HI enrolment, our data shows that the reporting of respiratory symptoms warrants extra caution and closer monitoring during the HI period. A higher HR may also warrant closer monitoring during HI.

It is unclear if institutional isolation with direct supervision is superior to HI in the management of mild illness. There are proponents of institutional isolation who argue that this is a better measure to mitigate the spread of COVID-19 than HI.[19–21] In general, China adopted institutional monitored programs, whereas many Western countries adopted the HI model.[19,20] The advantages of institutional isolation are better control of spread and closer monitoring of symptoms and signs. The trade-off are increased cost, need for resources and greater psychological stress for the patient. The advantages of HI are its low cost and better ambience, but it comes with the increased risk of transmission to family members and the chance of missing clinical deterioration. Analysis of these strategies have shown HI to be associated with better quality of life, psychological support of family during the period of isolation, and cost savings over institutional quarantine. However, the choice of the strategy needs to be context specific with an understanding of the trade-offs.[22,23]

In India, during the first wave of the pandemic in 2020, many states advocated and implemented institutional isolation instead of HI. Although this measure, along with other containment strategies, including mass public education on COVID appropriate behaviour helped mitigate the first wave, it drained the resources of many states and hospitals. By the end of the first wave, most states began advocating and implementing HI as opposed to institutional isolation. In this context, our study adds to the body of evidence that HI could be successfully deployed in a developing country in the efficient and successful management of mild COVID-19 cases.

Conclusion

Monitored HI program can be used successfully during the COVID-19 pandemic wave to judicially use scare hospital resources. Older, male patients presenting with breathlessness or cough may warrant closer monitoring.

Disclosure of competing interest

The authors have none to declare.

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